表 2.7.4-98.　　重篤な有害事象を発現した被験者一覧（M15-656 試験）

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53449) TRT: Placebo + Azacitidine								
47703#	Age:7[redacted] Sex:Male Race:WHITE Weight:58.5 kg							
	TRT	1 TO 176	18	18	R: RAISED CREATININE LEVEL S: Investigations P: 血中クレアチニン増加 L: Creatinine increased	E: 23 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO MEDICATIONS TAKEN DURING THIS PERIOD V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53449) TRT: Placebo + Azacitidine							
47703#	Age:7[redacted] Sex:Male Race:WHITE Weight:58.5 kg						
	(Cont.) TRT	1 TO 176	176	176	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 176 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGEDHOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: LEUKOCYTOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53449) TRT: Placebo + Azacitidine								
47703#	Age:7[redacted] Sex:Male Race:WHITE Weight:58.5 kg							
	(Cont.) TRT	1 TO 176	176	176	R: LEUCOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 178 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE KIDNEY INJURY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53297) TRT: Placebo + Azacitidine								
47501#	Age:7[redacted] Sex:Male Race:WHITE Weight:107.6 kg							
		POST 19 TO 21	1	19	R: ACUTE MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Acute myocardial infarction	E: 19 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNKNOWN CARDIOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53297) TRT: Placebo + Azacitidine							
47501#	Age:7[redacted] Sex:Male Race:WHITE Weight:107.6 kg						
	(Cont.)	POST 19 TO 21	1	19	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 20 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: EVENT RELATED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53297) TRT: Venetoclax 400 mg QD + Azacitidine								
47502	Age:7[redacted] Sex:Female Race:WHITE Weight:72.0 kg							
	TRT	1 TO	1	1	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 6 O: No L: 6 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53297) TRT: Venetoclax 400 mg QD + Azacitidine								
47502	Age:7[redacted] Sex:Female Race:WHITE Weight:72.0 kg							
	(Cont.) TRT	1 TO	5	5	R: MELENA S: Gastrointestinal disorders P: メレナ L: Melena	E: 22 O: No L: 18 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANEXAMIC ACID, TRANSFUSION, PROTONIC PUMP INHIBITOR C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: LOW PLATELET COUNT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53297) TRT: Venetoclax 400 mg QD + Azacitidine								
47502	Age:7[redacted] Sex:Female Race:WHITE Weight:72.0 kg							
		(Cont.) TRT	1 TO	393	393	R: ACUTE MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Acute myocardial infarction	E: 399 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: SPONTANEOUS MYOCARDIAL INFARCTION WITH NO OTHER EVIDENT CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42821) TRT: Placebo + Azacitidine								
65701#	Age:8[redacted] Sex:Female Race:WHITE Weight:63.0 kg							
		POST	45 TO 47	1	45	R: HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 45 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42821) TRT: Venetoclax 400 mg QD + Azacitidine								
65704#	Age:7[redacted] Sex:Male Race:WHITE Weight:67.0 kg							
		POST	403 TO 405	1	403	R: HEMORRHAGIC GASTRITIS S: Gastrointestinal disorders P: 出血性胃炎 L: Hemorrhagic gastritis	E: 403 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NONSPECIFIC INFLAMMATION OF THE GASTRIC MUCOSA V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42821) TRT: Venetoclax 400 mg QD + Azacitidine								
65705# Age:6[redacted] Sex:Female Race:WHITE Weight:76.0 kg								
	TRT	1 TO 714	702	702	R: POST-INJECTION INFILTRATE WITH HEMORRHAGIC VASCULITIS ON THE INNER SURFACE OF THE LEFT FOREARM S: Vascular disorders P: 出血性血管炎 L: Hemorrhagic vasculitis	E: 715 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRESENCE OF A PERIPHERAL CATHETER ON THE LEFT FOREARM VEIN FOR TRANSFUSIONS PERFORMING DURING THE 25TH CYCLE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42821) TRT: Venetoclax 400 mg QD + Azacitidine							
65705#	Age:6[redacted] Sex:Female Race:WHITE Weight:76.0 kg						
(Cont.)	TRT	1 TO 714	702	702	R: POST-INJECTION INFILTRATE WITH HEMORRHAGIC VASCULITIS ON THE INNER SURFACE OF THE LEFT FOREARM S: General disorders and administration site conditions P: 注射部位漏出 L: Injection site infiltration	E: 715 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRESENCE OF A PERIPHERAL CATHETER ON THE LEFT FOREARM VEIN FOR TRANSFUSIONS PERFORMING DURING THE 25TH CYCLE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42821) TRT: Venetoclax 400 mg QD + Azacitidine								
65706#	Age:7[redacted] Sex:Male Race:WHITE Weight:50.0 kg							
	TRT	1 TO 9	9	9	R: MYOCARDIAL INFARCTION S: Cardiac disorders P: 心筋梗塞 L: Myocardial infarction	E: 9 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING O: EXERTIONAL ANGINA, MYOCARDIAL INFARCTION IN MEDICAL HISTORY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine								
10301#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.6 kg							
	TRT	1 TO 131	4	4	R: BILATERAL LOWER LEG EDEMA S: General disorders and administration site conditions P: 末梢性浮腫 L: Lower leg edema	E: 18 O: No L: 15 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLUID RETENTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine							
10301# Age:7[redacted] Sex:Male Race:WHITE Weight:81.6 kg							
(Cont.)	TRT	1 TO 131	30	30	R: FALL S: Injury, poisoning and procedural complications P: 転倒 L: Fall	E: 41 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: IMAGING C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FATIGUE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine							
10301# Age:7[redacted] Sex:Male Race:WHITE Weight:81.6 kg							
(Cont.) TRT		1 TO 131	30	30	R: INCREASED WHITE BLOOD CELL COUNT S: Investigations P: 白血球数増加 L: White blood cell count increased	E: 41 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine							
10301#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.6 kg						
	(Cont.)	TRT 1 TO 131	117	117	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 132 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DOSE REDUCED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine							
10301#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.6 kg						
(Cont.)		TRT 1 TO 131	117	117	R: RIGHT SIDED HEART FAILURE S: Cardiac disorders P: 右室不全 L: Right heart failure	E: 131 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAD A HISTORY OF RIGHT-SIDED HEART FAILURE AND CARDIOMEGALY IN FEB 2018, HE WAS ADMITTED WITH WORSENSING SYMPTOMS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Placebo + Azacitidine								
10306#	Age:7[redacted] Sex:Male Race:ASIAN Weight:56.7 kg							
		TRT	1 TO 75	25	25	R: CELLULITIS OF THE RIGHT LEG S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 34 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO KNOWN CAUSE, ALL BLOOD CULTURES WERE NEGATIVE, POSSIBLE UNDERLYING DISEASE OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine							
10302#	Age:7[redacted] Sex:Male Race:ASIAN Weight:71.1 kg						
		POST 83 TO 107 Day	2	84	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 85 O: No L: 2 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Other: DRUG INTERRUPTED ON FRI FEB 9 TO ALLOW FOR COUNT RECOVERY PER PROTOCOL (BONE MARROW SHOWED LESS THAN 5% BLASTS ON MOST RECENT REPORT) O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine							
10302#	Age:7[redacted] Sex:Male Race:ASIAN Weight:71.1 kg						
		(Cont.) POST 83 TO 107	2	84	R: KLEBSIELLA PNEUMONIAE INFECTION S: Infections and infestations P: クレブシエラ感染 L: Klebsiella pneumoniae infection	E: 93 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Other: DRUG WAS INTERRUPTED ON FRIDAY FEB 9TH FOR COUNT RECOVERY PER PROTOCOL (CONFIRMED LESS THAN 5% BLASTS IN BONE MARROW) O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine								
10302#	Age:7[redacted] Sex:Male Race:ASIAN Weight:71.1 kg							
		(Cont.) POST	83 TO 107	2	84	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 88 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Other: DRUG WAS INTERRUPTED ON FRIDAY FEB 9TH FOR COUNT RECOVERY PER PROTOCOL (CONFIRMED LESS THAN 5% BLASTS IN BONE MARROW) C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine								
10302#	Age:7[redacted] Sex:Male Race:ASIAN Weight:71.1 kg							
	(Cont.)	POST	83 TO 107	3	85	R: LUNG INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 105 O: No L: 21 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? ASPIRATION PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine							
10302#	Age:7[redacted] Sex:Male Race:ASIAN Weight:71.1 kg						
		(Cont.) POST 83 TO 107	19	101	R: SEPTIC SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 105 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DISEASE- ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine							
10303#	Age:7[redacted] Sex:Male Race:WHITE Weight:82.5 kg						
	TRT	1 TO 35	4	4	R: LUNG INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 12 O: No L: 9 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine								
10303#	Age:7[redacted] Sex:Male Race:WHITE Weight:82.5 kg							
	(Cont.)	TRT 1 TO 35	18	18	R: FAILURE TO COPE S: General disorders and administration site conditions P: セルフケア障害 L: Impaired self-care	E: 41 O: No L: 24 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANOREXIA, DEPRESSION, WEAKNESS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110269) TRT: Venetoclax 400 mg QD + Azacitidine							
10307# Age:7[redacted] Sex:Male Race:WHITE Weight:60.3 kg							
	TRT	1 TO 206	80	80	R: DISCITIS AT T7 AND T8 S: Infections and infestations P: 椎間板炎 L: Intervertebral discitis	E: 99 O: No L: 20 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine								
77103#	Age:7[redacted] Sex:Male Race:WHITE Weight:63.0 kg							
		TRT 1 TO 213	19	19	R: EPIGASTRIC PAIN S: Gastrointestinal disorders P: 上腹部痛 L: Epigastric pain	E: 26 O: No L: 8 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TOTAL PARENTERAL NUTRITION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CROHN'S DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				19	R: MUCOSITIS S: General disorders and administration site conditions P: 粘膜の炎症 L: Mucositis	E: 31 O: No L: 13 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine							
77103# Age:7[redacted] Sex:Male Race:WHITE Weight:63.0 kg							
(Cont.) TRT	1 TO 213	28	28	R: ANGIO INVASIVE ASPERGILLOSIS S: Infections and infestations P: アスペルギルス感染 L: Aspergillosis	E: 56 O: No L: 29 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		30	30	R: SYSTEMIC CANDIDA ALBICANS INFECTION S: Infections and infestations P: 全身性カンジダ L: Systemic candida	E: 56 O: No L: 27 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine								
77103#	Age:7[redacted] Sex:Male Race:WHITE Weight:63.0 kg							
(Cont.)	POST	214 TO 231	14	227	R: GASTRO INTESTINAL BLEEDING S: Gastrointestinal disorders P: 胃腸出血 L: Gastro intestinal bleeding	E: 230 O: No L: 4 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF ACUTE LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine							
77104#	Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg						
	TRT	1 TO 88	46	R: SYSTEMIC INFECTION S: Infections and infestations P: 全身性感染 L: Systemic infection	E: 89 O: No L: 44 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			52	R: ASPERGILLOSIS -UPPER AND LOWER LOBES OF THE LUNG S: Infections and infestations P: 気管支肺アスペルギルス症 L: Bronchopulmonary aspergillosis	E: 89 O: No L: 38 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine							
77104# Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg							
	(Cont.) TRT	1 TO 88	78	78	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 88 O: No L: 11 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine								
77105#	Age:8[redacted] Sex:Female Race:WHITE Weight:72.0 kg							
		TRT 1 TO 28	18	18	R: KLEBSIELLA PNEUMONIA BACTEREMIA S: Infections and infestations P: クレブシエラ性菌血症 L: Klebsiella bacteremia	E: 70 O: No L: 53 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine								
77105# Age:8[redacted] Sex:Female Race:WHITE Weight:72.0 kg								
(Cont.) TRT		1 TO 28	18	18	R: KLEBSIELLA PNEUMONIA BACTEREMIA S: Infections and infestations P: クレブシエラ菌性肺炎 L: Klebsiella pneumonia	E: 70 O: No L: 53 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111556) TRT: Venetoclax 400 mg QD + Azacitidine								
77105#	Age:8[redacted] Sex:Female Race:WHITE Weight:72.0 kg							
	(Cont.)	POST	29 TO 72	1	29	R: BRONCHIALPNEUMONIA S: Infections and infestations P: 肺炎 L: Bronchopneumonia	E: 71 O: No L: 43 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Placebo + Azacitidine							
90602# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
	TRT	1 TO 59	59	59	R: PROGRESSION OF PRE EXISTING CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKAEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Venetoclax 400 mg QD + Azacitidine							
90603#	Age:8[redacted] Sex:Male Race:WHITE Weight:76.2 kg						
	TRT	1 TO 210	16	16	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 39 O: No L: 24 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT ADMITTERD TO ANOTHER SITE FOR FEVERS ON THE 25 MAY 2018. FOR SEPTIC OBSERVATION AND PROPHYLAXIS ANTIBIOTICS. SITE HAS LIMITED INFORMATION BUT SUSPECT FEVERS COULD BE RELATED TO PICC LINE. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Venetoclax 400 mg QD + Azacitidine							
90603# Age:8[redacted] Sex:Male Race:WHITE Weight:76.2 kg							
(Cont.)	TRT	1 TO 210	133	133	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 138 O: No L: 6 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Venetoclax 400 mg QD + Azacitidine								
90604	Age:8[redacted]	Sex:Male	Race:WHITE	Weight:92.0 kg				
	TRT	1	TO	15	15	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 20 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Venetoclax 400 mg QD + Azacitidine							
90604 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:92.0 kg				
(Cont.) TRT	1 TO	148	148	R: TOOTH ABSCESS - WORSENING TOOTH ACHE S: Infections and infestations P: 歯膿瘍 L: Tooth abscess	E: 150 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TOOTH EXTRACTION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TOOTH ABSCESS AND TOOTH REQUIRING EXTRACTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53332) TRT: Venetoclax 400 mg QD + Azacitidine							
90604	Age:8[redacted] Sex:Male Race:WHITE Weight:92.0 kg						
(Cont.)	TRT	1 TO	148	148	R: TOOTH ABSCESS - WORSENING TOOTH ACHE S: Gastrointestinal disorders P: 歯痛 L: Tooth ache	E: 150 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TOOTH EXTRACTION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TOOTH ABSCESS AND TOOTH REQUIRING EXTRACTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Placebo + Azacitidine								
36002#	Age:8[redacted] Sex:Male Race:WHITE Weight:72.7 kg							
	TRT	1 TO 119	56	56	R: CHRONIC KIDNEY DISEASE S: Renal and urinary disorders P: 慢性腎臓病 L: Chronic kidney disease	E: 59 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY CHRONIC KIDNEY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Placebo + Azacitidine							
36002#	Age:8[redacted] Sex:Male Race:WHITE Weight:72.7 kg						
	(Cont.) TRT	1 TO 119	68	68	R: TUMER LYSIS SYNDROME S: Metabolism and nutrition disorders P: 腫瘍崩壊症候群 L: Tumor lysis syndrome	E: 75 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: Yes

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Placebo + Azacitidine							
36002#	Age:8[redacted] Sex:Male Race:WHITE Weight:72.7 kg						
(Cont.)		TRT 1 TO 119	118	118	R: PROGRESSION OF PRE-EXISTING CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	E: 120 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGEDHOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: MYELOIDE ACUTE LEUCEMIA IN PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Placebo + Azacitidine								
36004# Age:6[redacted] Sex:Female Race:WHITE Weight:58.5 kg								
		TRT 1 TO 314	3	3	R: E. COLI BACTERIEMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 8 O: No L: 6 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTIOUS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			220	220	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 226 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Placebo + Azacitidine							
36004#	Age:6[redacted] Sex:Female Race:WHITE Weight:58.5 kg						
	(Cont.)	POST 315 TO 403	27	341	R: RESPIRATORY INFECTION S: Infections and infestations P: 気道感染 L: Respiratory infection	E: 349 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOSUPPRESSION ASSOCIATED WITH THE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine								
36001	Age:6[redacted] Sex:Female Race:WHITE Weight:72.2 kg							
		TRT 1 TO	34	34	R: FEBRILLE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 49 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROLONGUED NEUTROPENIA AND COPD V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine							
36001 Age:6[redacted]	Sex:Female	Race:WHITE	Weight:72.2 kg				
(Cont.) TRT	1	TO	217	217	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 220 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS COPD. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine							
36001	Age:6[redacted] Sex:Female Race:WHITE Weight:72.2 kg						
(Cont.)	TRT	1 TO 368	368	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 378 O: No L: 11 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHRONIC OBSTRUCTIVE PULMONARY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine							
36001	Age:6[redacted] Sex:Female Race:WHITE Weight:72.2 kg						
	(Cont.)	TRT 1 TO	659	659	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 665 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine							
36003# Age:7[redacted] Sex:Male Race:WHITE Weight:53.0 kg							
	TRT	1 TO 372	20	20	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 34 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (119098) TRT: Venetoclax 400 mg QD + Azacitidine							
36003# Age:7[redacted] Sex:Male Race:WHITE Weight:53.0 kg							
(Cont.) TRT	1 TO 372	38	38	R: CELLULITIS OF THE PENIS S: Infections and infestations P: 男性外性器蜂巣炎 L: Penile cellulitis	E: 62 O: No L: 25 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PROLONGED NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Placebo + Azacitidine								
42301# Age:6[redacted] Sex:Female Race:WHITE Weight:90.0 kg								
	TRT	1 TO 399	65	65	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 67 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: RED BLOOD CELLS TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Venetoclax 400 mg QD + Azacitidine								
42303#	Age:6[redacted] Sex:Male Race:WHITE Weight:90.0 kg							
		TRT 1 TO 28	4	4	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 5 O: No L: 2 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			28	28	R: INFLUENZA VIRUS INFECTION S: Infections and infestations P: インフルエンザ L: Influenza	E: 34 O: No L: 7 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Venetoclax 400 mg QD + Azacitidine								
42304#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg							
	TRT	1 TO 463	64	64	R: ATRIAL FIBRILATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 64 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IDIOPATHIC CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Venetoclax 400 mg QD + Azacitidine								
42304#	Age:7[redacted]	Sex:Female	Race:WHITE	Weight:51.0 kg				
(Cont.)		TRT	1 TO 463	66	66	R: E. COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 75 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Venetoclax 400 mg QD + Azacitidine							
42304# Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg							
(Cont.)	TRT	1 TO 463	247	247	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 248 O: No L: 2 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83585) TRT: Venetoclax 400 mg QD + Azacitidine								
42304#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg							
		(Cont.) POST	464 TO 662	4	467	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 470 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSIVE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (41877) TRT: Venetoclax 400 mg QD + Azacitidine								
74101#	Age:8[redacted] Sex:Male Race:WHITE Weight:55.7 kg							
		TRT	1 TO 27	1	1	R: TLS S: Metabolism and nutrition disorders P: 腫瘍崩壊症候群 L: Tumor lysis syndrome	E: 7 O: No L: 7 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: Yes

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (41877) TRT: Venetoclax 400 mg QD + Azacitidine							
74101# Age:8[redacted] Sex:Male Race:WHITE Weight:55.7 kg							
(Cont.)	TRT	1 TO 27	20	20	R: KLEBSIELLA PNEUMONIAE + ENTEROCOCCUS FAECIUM S: Infections and infestations P: 腸球菌感染 L: Enterococcus faecium infection	E: 37 O: No L: 18 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPHENIA SECONDARY TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (41877) TRT: Venetoclax 400 mg QD + Azacitidine							
74101# Age:8[redacted] Sex:Male Race:WHITE Weight:55.7 kg							
(Cont.) TRT	1 TO 27	20	20	R: KLEBSIELLA PNEUMONIAE + ENTEROCOCCUS FAECIUM S: Infections and infestations P: クレブシエラ感染 L: Klebsiella pneumoniae infection	E: 37 O: No L: 18 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPHENIA SECONDARY TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52201# Age:7[redacted] Sex:Male Race:WHITE Weight:90.0 kg							
	TRT	1 TO 435	170	170	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 175 O: No L: 6 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	436 TO 456	15	450	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 455 O: No L: 6 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BONE MARROW FAILURE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52202# Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg							
	TRT	1 TO 376	313	313	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 318 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNSUPRESSION, BENIGN PROSTATIC HYPERPLASIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52202#	Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg						
	(Cont.) TRT	1 TO 376 Day 319	319	R: C-REACTIVE PROTEIN INCREASED S: Investigations P: C一反応性蛋白増加 L: C-reactive protein increased	E: 334 O: No L: 16 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNSUPPRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52202# Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg							
(Cont.)	TRT	1 TO 376	347	347	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 351 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine								
52202# Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg								
(Cont.) TRT		1 TO 376	356	356	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 362 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: PLATELET TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine								
52202#	Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg							
	(Cont.)	POST 377 TO 382	1	377	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 381 O: No L: 5 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52203#	Age:7[redacted] Sex:Female Race:WHITE Weight:77.0 kg						
	TRT	1 TO 241	14	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 22 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			227	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 251 O: No L: 25 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52203# Age:7[redacted] Sex:Female Race:WHITE Weight:77.0 kg							
(Cont.)	TRT	1 TO 241	234	234	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 251 O: No L: 18 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML, NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine								
52204 Age:8[redacted] Sex:Female Race:WHITE Weight:67.0 kg								
	TRT	1 TO	13	13	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 14 O: No L: 2 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ISCHAEMIC HEART DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52204 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:67.0 kg				
(Cont.) TRT	1 TO	574	574	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 591 O: No L: 18 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE CAUSE OF ANEMIA MAY BE AML DESPITE THAT BONE MARROW BLAST COUNT WAS 1 % ON 3 DEC 2019. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (80224) TRT: Venetoclax 400 mg QD + Azacitidine							
52205#	Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg						
		TRT 1 TO 35	30	30	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 37 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (54102) TRT: Placebo + Azacitidine								
90001	Age:7[redacted] Sex:Male Race:WHITE Weight:80.5 kg							
	TRT	1 TO	17	17	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 19 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (54102) TRT: Placebo + Azacitidine							
90001	Age:7[redacted] Sex:Male Race:WHITE Weight:80.5 kg						
	(Cont.) TRT	1 TO	200	R: CARDIAC DISORDER-ST-ELEVATION MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: ST segment elevation myocardial infarction	E: 204 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (54102) TRT: Venetoclax 400 mg QD + Azacitidine							
90002#	Age:7[redacted] Sex:Male Race:WHITE Weight:73.4 kg						
	TRT	1 TO 155	65	R: HICKMAN LINE INFECTION S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 74 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86901	Age:6[redacted] Sex:Male Race:ASIAN Weight:35.7 kg						
	TRT	1 TO	22	22	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 33 O: No L: 12 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86901	Age:6[redacted] Sex:Male Race:ASIAN Weight:35.7 kg						
(Cont.)	TRT	1 TO	57	57	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 63 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine								
86901 Age:6[redacted] Sex:Male Race:ASIAN Weight:35.7 kg								
(Cont.) TRT	1	TO	145	145	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 152 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			403	403	R: NAUSEA S: Gastrointestinal disorders P: 悪心 L: Nausea	O: No I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86902# Age:7[redacted] Sex:Male Race:ASIAN Weight:69.3 kg							
	TRT	1 TO 28	15	15	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 18 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTIOUS ENTERITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86902# Age:7[redacted] Sex:Male Race:ASIAN Weight:69.3 kg							
(Cont.) TRT	1 TO 28	15	15	R: VOMITING S: Gastrointestinal disorders P: 嘔吐 L: Vomiting	E: 18 O: No L: 4 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTIOUS ENTERITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86902#	Age:7[redacted] Sex:Male Race:ASIAN Weight:69.3 kg						
		(Cont.) POST 29 TO 42	12	40	R: DISSEMINATED INTRAVASCULAR COAGULATION S: Blood and lymphatic system disorders P: 播種性血管内凝固 L: Disseminated intravascular coagulation	E: 41 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING O: AGGRAVATION OF THE ORIGINAL DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (180513) TRT: Venetoclax 400 mg QD + Azacitidine							
86904 Age:7[redacted] Sex:Female Race:ASIAN Weight:59.8 kg							
	TRT	1 TO	286	286	R: CELLULITIS OF THE LEFT EYE S: Infections and infestations P: 眼窩蜂巣炎 L: Orbital cellulitis	E: 297 O: No L: 12 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine							
48001# Age:8[redacted] Sex:Female Race:WHITE Weight:54.0 kg							
	TRT	1 TO 142	21	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 30 O: No L: 10 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONIA RELATED TO AML DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine								
48001# Age:8[redacted] Sex:Female Race:WHITE Weight:54.0 kg								
(Cont.)	TRT	1 TO 142	101	101	R: HEMORRAGE ON RIGHT GLUTEUS ARTERY S: Vascular disorders P: 動脈出血 L: Arterial hemorrhage	E: 104 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PATIENT SHOWN HEMORRAGE ON RIGHT GLUTEUS ARTERY. DATA EVIDENCED BY XRAY IMAGES PERFOMED ON 28JUN2018. HEMORRHAGE WAS RELATED TO ANTICOAGULANT PROPHYLAXIS.NTO RELATED TO STUDY DRUGS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine							
48001#	Age:8[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
	(Cont.)	POST 143 TO 169	2	144	R: PNUEMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 168 O: No L: 25 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AE RELATED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine								
48002#	Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg							
		POST	10 TO 376	1	10	R: MULTIPLE ORGAN FAILURE S: General disorders and administration site conditions P: 多臓器機能不全症候群 L: Multiple organ failure	E: 16 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PNEUMONITS IN AML PATIENT DURING INDUCTION THERAPY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine							
48004 Age:8[redacted] Sex:Male Race:WHITE Weight:79.2 kg							
	TRT	1 TO #	322	322	R: ABSCESS TO LEFT THIGH S: Infections and infestations P: 四肢膿瘍 L: Thigh abscess	E: 348 O: No L: 27 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE CONDITION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine								
48005# Age:7[redacted] Sex:Female Race:WHITE Weight:56.6 kg								
	TRT	1 TO 84	51	51	R: STAPHYLOCOCCUS COAGULASE - PICC LINE S: Infections and infestations P: ブドウ球菌感染 L: Staphylococcal infection	E: 64 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS RELATED TO PICC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine							
48005# Age:7[redacted] Sex:Female Race:WHITE Weight:56.6 kg							
(Cont.)	TRT	1 TO 84	51	51	R: STAPHYLOCOCCUS COAGULASE - PICC LINE S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 64 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS RELATED TO PICC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Placebo + Azacitidine							
48005#	Age:7[redacted] Sex:Female Race:WHITE Weight:56.6 kg						
	(Cont.)	TRT 1 TO 84	84	84	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 116 O: No L: 33 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONITIS IN PATIENT WITH ACUTE MYELOIDE LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Venetoclax 400 mg QD + Azacitidine								
48003#	Age:7[redacted] Sex:Female Race:WHITE Weight:63.0 kg							
	TRT	1 TO 187	28	28	R: STRANGURY S: Renal and urinary disorders P: 有痛性排尿困難 L: Strangury	E: 40 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MORE LIKELY A COMPLICATION OF CONCURRENT RECTAL TENESMUS AND AGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Venetoclax 400 mg QD + Azacitidine 48003#	Age:7[redacted] Sex:Female Race:WHITE Weight:63.0 kg						
(Cont.)	TRT	1 TO 187	52	52	R: PRESYNCOPE S: Nervous system disorders P: 失神寸前の状態 L: Presyncope	E: 55 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT SHOWN LIPOTIMIA ON 20 MAY 2018 AND WAS HOSPITALIZED. DURING HOSPITALIZATION PATIENT HAD FEVER AND INFECTION WAS SUSPECTED. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Venetoclax 400 mg QD + Azacitidine 48003# Age:7[redacted] Sex:Female Race:WHITE Weight:63.0 kg								
	(Cont.) TRT	1 TO 187	186	186	R: URINARY INFECTION S: Infections and infestations P: 尿路感染 L: Urinary infection	E: 193 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA AND BLASTOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121250) TRT: Venetoclax 400 mg QD + Azacitidine							
48006# Age:8[redacted] Sex:Female Race:WHITE Weight:54.0 kg							
	TRT	1 TO 175	13	R: HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	E: 41 O: No L: 29 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HEART FAILURE IN PATIENT WITH PNEUMONITIS AND ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Placebo + Azacitidine							
13703#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg						
		TRT 1 TO 128	49	49	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 52 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: ADMITTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine								
13701#	Age:4[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:167.5 kg							
	TRT	1 TO 55	5	5	R: MELENA S: Gastrointestinal disorders P: メレナ L: Melena	E: 9 O: No L: 5 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: RBC TRANSFUSIONS, PROLONGED HOSPITALIZATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CHRONIC KIDNEY DISEASE STAGE 3 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine							
13701# Age:4[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:167.5 kg							
(Cont.)	TRT	1 TO 55	22	22	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 220 O: No L: 199 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: ADMITTED, CONMED INCREASED, ICD DEVICE INTERROGATION, ECG C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PRE-EXISTING MEDICAL CONDITION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine								
13701#	Age:4[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:167.5 kg							
		(Cont.) POST	56 TO 259	3	58	R: RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Respiratory failure	E: 61 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, INTUBATION; CONTINUOUS VENO-VENOUS HEMODIALYSIS C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CONGESTIVE HEART FAILURE; ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine								
13707#	Age:6[redacted] Sex:Male Race:WHITE Weight:111.0 kg							
		POST	220 TO 569	1	220	R: GRAM POSITIVE BACTEREMIA S: Infections and infestations P: 菌血症 L: Gram-positive bacteremia	E: 224 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IMMUNOSUPPRESSION DUE TO ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine							
13708# Age:7[redacted] Sex:Male Race:WHITE Weight:85.6 kg							
	TRT	1 TO 200 Day 31	31	R: RHINOVIRUS S: Infections and infestations P: ライノウイルス感染 L: Rhinovirus infection	E: 33 O: No L: 3 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: ADMITTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine							
13709	Age:8[redacted] Sex:Male Race:WHITE Weight:120.5 kg						
		TRT 1 TO #	470	470	R: RIGHT ANKLE WOUND W/ MRSA INFECTION S: Infections and infestations P: ブドウ球菌性創感染 L: MRSA wound infection	O: No I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (979679) TRT: Venetoclax 400 mg QD + Azacitidine							
13709	Age:8[redacted] Sex:Male Race:WHITE Weight:120.5 kg						
(Cont.) TRT		1 TO	568	568	R: RSV RESPIRATORY INFECTION S: Infections and infestations P: RSウイルス感染 L: Respiratory syncytial virus infection	E: 577 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44501# Age:7[redacted] Sex:Male Race:WHITE Weight:78.0 kg							
	TRT	1 TO 16	4	4	R: NONSPECIFIC C-REACTIVE PROTEIN INCREASE S: Investigations P: C一反応性蛋白増加 L: C-reactive protein increased	E: 5 O: No L: 2 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANTIBIOTIC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44501# Age:7[redacted] Sex:Male Race:WHITE Weight:78.0 kg							
(Cont.)	TRT	1 TO 16	10	10	R: INFLUENZA B S: Infections and infestations P: インフルエンザ L: Influenza B virus infection	E: 17 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFLUENZA B VIRUS INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44502#	Age:7[redacted] Sex:Male Race:WHITE Weight:65.2 kg						
	TRT	1 TO 48 Day 22	22	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 32 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN INFECT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44502#	Age:7[redacted] Sex:Male Race:WHITE Weight:65.2 kg						
(Cont.)		TRT 1 TO 48	38	38	R: SEPTIC CHOLECYSTITIS S: Hepatobiliary disorders P: 胆嚢炎 L: Cholecystitis	E: 49 O: No L: 12 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION A: Other: END OF TREAMTENT ON THE 19.JUN.2018 C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MASSIVE INFILTRATION OF AML IN THE EXTRACTED GALLBLADDER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44502#	Age:7[redacted] Sex:Male Race:WHITE Weight:65.2 kg						
	(Cont.)	TRT 1 TO 48	38	38	R: SEPTIC CHOLECYSTITIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 49 O: No L: 12 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION A: Other: END OF TREAMTENT ON THE 19.JUN.2018 C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MASSIVE INFILTRATION OF AML IN THE EXTRACTED GALLBLADDER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44502#	Age:7[redacted] Sex:Male Race:WHITE Weight:65.2 kg						
	(Cont.)	POST 49 TO 506	2	50 R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME, MULTI ORGAN DYSFUNCTION SYNDROME S: General disorders and administration site conditions P: 多臓器機能不全症候群 L: Multiple organ dysfunction syndrome	E: 56 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PROGRESSIVE DISEASE , HEMATOLOGICAL SCHOCK V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110536) TRT: Venetoclax 400 mg QD + Azacitidine							
44502#	Age:7[redacted] Sex:Male Race:WHITE Weight:65.2 kg						
	(Cont.)	POST 49 TO 506	2	50 R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME, MULTI ORGAN DYSFUNCTION SYNDROME S: General disorders and administration site conditions P: 全身性炎症反応症候群 L: Systemic inflammatory response syndrome	E: 56 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PROGRESSIVE DISEASE , HEMATOLOGICAL SCHOCK V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Placebo + Azacitidine							
15207# Age:6[redacted] Sex:Male Race:WHITE Weight:148.2 kg							
	TRT	1 TO 288	13	13	R: VIRAL RESPIRATORY TRACT INFECTION (CORONOVIRUS) S: Infections and infestations P: コロナウイルス感染 L: Coronavirus infection	E: 24 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ETIOLOGY PRESUMABLY DUE TO CORONAVIRUS AND PULMONARY EDEMA FROM DIASTOLIC HEART FAILURE EXACERBATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Placebo + Azacitidine							
15207# Age:6[redacted] Sex:Male Race:WHITE Weight:148.2 kg							
(Cont.) TRT		1 TO 288	171	171	R: MELENA S: Gastrointestinal disorders P: メレナ L: Melena	E: 197 O: No L: 27 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LIKELY RELATED TO AML AND THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Placebo + Azacitidine							
15214#	Age:6[redacted] Sex:Male Race:WHITE Weight:74.7 kg						
	TRT	1 TO 36 Day 22	22	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 40 O: No L: 19 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Placebo + Azacitidine							
15214# Age:6[redacted] Sex:Male Race:WHITE Weight:74.7 kg							
(Cont.)	TRT	1 TO 36	36	36	R: ACUTE RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 41 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, INTUBATION	S: Yes, LIFE THREATENING O: AML AND UNDERLYING LUNG DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15202# Age:8[redacted] Sex:Male Race:WHITE Weight:81.6 kg							
	TRT	1 TO 99	18	18	R: E COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 19 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15202# Age:8[redacted] Sex:Male Race:WHITE Weight:81.6 kg								
(Cont.)	TRT	1 TO 99	24	24	R: CELLULITIS-PERIANAL REGION S: Infections and infestations P: 肛門直腸蜂巣炎 L: Cellulitis anorectal	E: 41 O: No L: 18 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	100 TO 153	9	108	R: PERIRECTAL PAIN S: Gastrointestinal disorders P: 肛門周囲痛 L: Perianal pain	E: 110 O: No L: 3 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15202#	Age:8[redacted] Sex:Male Race:WHITE Weight:81.6 kg							
	(Cont.)	POST 100 TO 153	24	123	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 152 O: No L: 30 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15204#	Age:6[redacted] Sex:Male Race:WHITE Weight:97.1 kg							
	TRT	1 TO 225	94	94	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 100 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15205 Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg								
		TRT 1 TO	24	24	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 28 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			296	296	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 332 O: No L: 37 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15205 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:88.0 kg				
(Cont.) TRT	1 TO	742	742	R: ACUTE HYPOXIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 747 O: No L: 6 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15206 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:111.1 kg				
	TRT	1 TO	563	563	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 577 O: No L: 15 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15206 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:111.1 kg				
(Cont.) TRT	1 TO	580	580	R: EPISTAXIS S: Respiratory, thoracic and mediastinal disorders P: 鼻出血 L: Epistaxis	E: 583 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COAGULOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15206 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:111.1 kg				
(Cont.) TRT	1 TO	729	729	R: HEART FAILURE (ACUTE) S: Cardiac disorders P: 急性心不全 L: Acute heart failure	E: 733 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HEART DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15209 Age:8[redacted] Sex:Male Race:WHITE Weight:118.3 kg								
	TRT	1 TO	162	162	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 165 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15209 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:118.3 kg				
(Cont.) TRT	1 TO	176	176	R: GENERALIZED WEAKNESS S: General disorders and administration site conditions P: 無力症 L: Weakness generalized	E: 183 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DOSE REDUCED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15209 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:118.3 kg				
(Cont.) TRT	1 TO	443	443	R: CARDIAC CHEST PAIN S: Cardiac disorders P: 狭心症 L: Chest pain - cardiac	E: 444 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CT ANGIOGRAM, EKG, LEXISCAN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BRADYCARDIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15210	Age:8[redacted] Sex:Male Race:WHITE Weight:78.3 kg							
	TRT	1 TO	3	3	R: NECK PAIN S: Musculoskeletal and connective tissue disorders P: 頚部痛 L: Neck pain	E: 16 O: No L: 14 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, MRI C-SPINE & LUMBAR PUNCTURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECT NECK PAIN IS MUSCULOSKELETAL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15212#	Age:7[redacted] Sex:Female Race:WHITE Weight:75.2 kg							
	TRT	1 TO 58	5	5	R: BLOOD BILIRUBIN INCREASED S: Investigations P: 血中ビリルビン増加 L: Blood bilirubin increased	E: 9 O: No L: 5 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BILIARY OBSTRUCTION FROM BILIARY SLUDGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15212#	Age:7[redacted] Sex:Female Race:WHITE Weight:75.2 kg							
	(Cont.) TRT	1 TO 58	19	19	R: SEPSIS - STREP VERIDANS S: Infections and infestations P: レンサ球菌性敗血症 L: Streptococcal sepsis	E: 20 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15212#	Age:7[redacted] Sex:Female Race:WHITE Weight:75.2 kg							
(Cont.)	TRT	1 TO 58	34	34	R: PLEURAL EFFUSION EMPYEMA S: Infections and infestations P: 感染性胸水 L: Infectious pleural effusion	E: 61 O: No L: 28 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: CYCLE 2 DELAYED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15212#	Age:7[redacted] Sex:Female Race:WHITE Weight:75.2 kg						
	(Cont.)	POST 59 TO 79	3	61 R: STROKE S: Nervous system disorders P: 脳血管発作 L: Stroke	E: 78 O: No L: 18 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLY RELATED TO AML, INFECTION, THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine								
15213#	Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg							
	TRT	1 TO 57	20	20	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 24 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15213# Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg							
(Cont.)	TRT	1 TO 57	29	29	R: RASH (RASH COVERING MUCH OF BODY, ITCHY, RED) S: Skin and subcutaneous tissue disorders P: 紅斑性皮疹 L: Erythematous rash	E: 33 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CEFEPIME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15213#	Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg						
	(Cont.) TRT	1 TO 57	29	29	R: RASH (RASH COVERING MUCH OF BODY, ITCHY, RED) S: Skin and subcutaneous tissue disorders P: 全身性皮疹 L: Generalized rash	E: 33 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CEFEPIME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15213# Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg							
(Cont.)	TRT	1 TO 57	29	29	R: RASH (RASH COVERING MUCH OF BODY, ITCHY, RED) S: Skin and subcutaneous tissue disorders P: そう痒性皮疹 L: Itchy rash	E: 33 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CEFEPIME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53186) TRT: Venetoclax 400 mg QD + Azacitidine							
15213#	Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg						
	(Cont.) TRT	1 TO 57	57	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 88 O: No L: 32 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Placebo + Azacitidine								
10005 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:83.3 kg					
	TRT	1 TO	565	565	R: INVASIVE MALIGNANT MELANOMA MID BACK S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性黒色腫 L: Malignant melanoma	E: 603 O: No L: 39 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DEVELOPED ON SUN EXPOSED SKIN OF BACK OF THIS AGED PATIENT. CAUSE IS LIKELY EPIDEMIOLOGICAL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine								
10002#	Age:7[redacted] Sex:Female Race:WHITE Weight:65.0 kg							
		TRT	1 TO 384	114	114	R: PELVIC FRACTURE S: Injury, poisoning and procedural complications P: 骨盤骨折 L: Pelvic fracture	E: 117 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WALKING DOG, AND TRIPPED OVER THE DOG LEASH V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine							
10002# Age:7[redacted] Sex:Female Race:WHITE Weight:65.0 kg							
(Cont.)	TRT	1 TO 384	378	378	R: SOLID LEFT LOWER POLE RENAL MASS WITH VASCULARITY S: Renal and urinary disorders P: 腎腫瘤 L: Renal mass	O: Yes I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: PATIENT BEING REFERRED TO UROLOGY FOR ASSESSMENT.	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HIGH LIKELIHOOD OF VHL MUTATION FOR RENAL CELL CARCINOMA INDEPENDENT OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine							
10002#	Age:7[redacted] Sex:Female Race:WHITE Weight:65.0 kg						
	(Cont.)	POST 385 TO 463	30	414	R: LEFT LEG DVT S: Vascular disorders P: 深部静脈血栓症 L: Deep vein thrombosis leg	E: 425 O: No L: 12 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCORDING TO INVESTIGATOR,AML IS THE CAUSE OF DVT. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine							
10003 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:67.0 kg				
	TRT	1 TO	31	31	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 51 O: No L: 21 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PI,AGE, OTHER COMORBIDITIES AND AML (IMMUNODEFICIENCY) HAVE CONTRIBUTED TO PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine							
10003	Age:8[redacted] Sex:Female Race:WHITE Weight:67.0 kg						
	(Cont.)	TRT 1 TO	64	64	R: HEMOPTYSIS S: Respiratory, thoracic and mediastinal disorders P: 喀血 L: Hemoptysis	E: 71 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POSSIBLE RELATED TO PATIENT CON MED OF APIXIBAN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52758) TRT: Venetoclax 400 mg QD + Azacitidine							
10003 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:67.0 kg				
(Cont.) TRT	1 TO	66	66	R: PSEUDOANEURYSM ARISING FROM THE ANTERIOR BASAL SEGMENTAL ARTERY TO THE LEFT LOWER LOBE S: Injury, poisoning and procedural complications P: 血管偽動脈瘤 L: Pseudoaneurysm	E: 71 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PER INVESTIGATOR, THIS AE IS DUE TO EXTENSIVE CARDIOVASCULAR HISTORY OF THE PATIENT. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121371) TRT: Venetoclax 400 mg QD + Azacitidine								
85001#	Age:7[redacted] Sex:Male Race:ASIAN Weight:61.8 kg							
	TRT	1 TO 217	3	3	R: LEUKOPENIA S: Blood and lymphatic system disorders P: 白血球減少症 L: Leukopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			72	72	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 82 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121371) TRT: Venetoclax 400 mg QD + Azacitidine							
85001#	Age:7[redacted] Sex:Male Race:ASIAN Weight:61.8 kg						
	(Cont.) TRT	1 TO 217	158	158	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 177 O: No L: 20 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121371) TRT: Venetoclax 400 mg QD + Azacitidine								
85003#	Age:7[redacted] Sex:Male Race:ASIAN Weight:60.2 kg							
		TRT 1 TO 147	68	68	R: LEUKOPENIA S: Blood and lymphatic system disorders P: 白血球減少症 L: Leukopenia	E: 99 O: No L: 32 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				68	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 99 O: No L: 32 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Placebo + Azacitidine								
42405# Age:6[redacted] Sex:Female Race:WHITE Weight:47.0 kg								
	TRT	1 TO 49	6	6	R: ALTERATION OF THE GENERAL STATE S: General disorders and administration site conditions P: 全身健康状態低下 L: Reduced general condition	E: 30 O: No L: 25 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Placebo + Azacitidine								
42405# Age:6[redacted] Sex:Female Race:WHITE Weight:47.0 kg								
(Cont.)	TRT	1 TO 49	45	45	R: BRONCHOPNEUMONIA S: Infections and infestations P: 肺炎 L: Bronchopneumonia	E: 51 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Placebo + Azacitidine								
42406#	Age:7[redacted] Sex:Female Race:WHITE Weight:73.0 kg							
		TRT	1 TO 294	26	26	R: PNEUMONIA PICHIA CACTOPHILIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 127 O: No L: 102 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DOSE REDUCED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Placebo + Azacitidine								
42411#	Age:6[redacted] Sex:Male Race:WHITE Weight:93.1 kg							
	TRT	1 TO 140	135	135	R: INFECTION BLOOD ACINETOBACTER BAUMANII S: Infections and infestations P: アシネトバクター性菌血症 L: Acinetobacter bacteremia	E: 149 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	141 TO 150	7	147	R: CARDIAC DECOMPENSATION S: Cardiac disorders P: 心不全 L: Decompensation cardiac	E: 149 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Placebo + Azacitidine								
42414#	Age:7[redacted] Sex:Male Race:WHITE Weight:71.0 kg							
	TRT	1 TO 16	14	14	R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME S: General disorders and administration site conditions P: 全身性炎症反応症候群 L: Systemic inflammatory response syndrome	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42401#	Age:6[redacted] Sex:Male Race:WHITE Weight:85.0 kg						
	TRT	1 TO 196	5	5	R: PNEUMONITIS S: Respiratory, thoracic and mediastinal disorders P: 肺臓炎 L: Pneumonitis	E: 97 O: No L: 93 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42401# Age:6[redacted] Sex:Male Race:WHITE Weight:85.0 kg							
	(Cont.)	TRT 1 TO 196	120	120	R: PULMONARY INFECTIOUS SYNDROME S: Infections and infestations P: 肺感染 L: Lung infection	E: 131 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: APLASIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42401#	Age:6[redacted] Sex:Male Race:WHITE Weight:85.0 kg							
	(Cont.)	TRT 1 TO 196	186	186	R: NONSPECIFIC FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 192 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42401#	Age:6[redacted] Sex:Male Race:WHITE Weight:85.0 kg						
		(Cont.) POST 197 TO 395	1	197	R: SUBDURAL HEMATOMA S: Injury, poisoning and procedural complications P: 硬膜下血腫 L: Subdural hematoma	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42402#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.0 kg							
	TRT	1 TO 141	3	3	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 36 O: No L: 34 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO APLASIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42402#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.0 kg						
	(Cont.)	TRT 1 TO 141	75	75	R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME S: General disorders and administration site conditions P: 全身性炎症反応症候群 L: Systemic inflammatory response syndrome	E: 77 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42402#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.0 kg							
	(Cont.) TRT	1 TO 141	91	91	R: PNEUMOCYSTIS JIROVECII S: Infections and infestations P: ニューモシスチス・イロベチイ感染 L: Pneumocystis jirovecii infection	O: Yes I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			132	132	R: PNEUMOPATHY S: Respiratory, thoracic and mediastinal disorders P: 肺障害 L: Pneumopathy	O: Yes I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRIL NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42403#	Age:7[redacted] Sex:Female Race:WHITE Weight:52.0 kg							
		TRT 1 TO 28	3	3	R: VIRAL BRONCHIC INFECTION S: Infections and infestations P: ウイルス性気管支炎 L: Bronchitis viral	E: 12 O: No L: 10 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			17	17	R: PANCYTOPENIA S: Blood and lymphatic system disorders P: 汎血球減少症 L: Pancytopenia	E: 36 O: No L: 20 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: PLATELET AND RBC TRANSFUSIONS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42403#	Age:7[redacted] Sex:Female Race:WHITE Weight:52.0 kg						
	(Cont.)	POST 29 TO 222	9	37	R: CEREBRAL VASCULAR ACCIDENT S: Nervous system disorders P: 脳血管発作 L: Cerebrovascular accident	E: 49 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AGE AND ANTECEDENT OF HYPERTENSION ARE INVOLVED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42407 Age:6[redacted]	Sex:Female	Race:WHITE	Weight:58.0 kg				
	TRT	1 TO	222	222	R: RIGHT INFLAMMATORY AXILLARY ABSCESS S: Infections and infestations P: 皮下組織膿瘍 L: Axillary abscess	E: 227 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AXILLARY ABSCESS ARE LINKED TO HER ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine 42407 Age:6[redacted] Sex:Female Race:WHITE Weight:58.0 kg							
	(Cont.) TRT	1 TO	636	R: PNEUMONITIS S: Respiratory, thoracic and mediastinal disorders P: 肺臓炎 L: Pneumonitis	E: 647 O: No L: 12 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			710	R: PNEUMONITIS S: Respiratory, thoracic and mediastinal disorders P: 肺臓炎 L: Pneumonitis	E: 723 O: No L: 14 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42408#	Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg							
	TRT	1 TO 522	15	15	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 19 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42408# Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg								
(Cont.)	TRT	1 TO 522	43	43	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 46 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42408#	Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg							
	(Cont.)	TRT 1 TO 522	94	94	R: DENTAL INFLAMMATION S: Infections and infestations P: 歯髄炎 L: Tooth inflammation	E: 100 O: No L: 7 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELATED DENTAL INFLAMMATION (AE 3) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42408# Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg							
(Cont.)	TRT	1 TO 522	168	168	R: CYTOLYTIC AND CHOLESTATIC HEPATITIS S: Hepatobiliary disorders P: 肝炎 L: Cytolytic hepatitis	E: 274 O: No L: 107 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine 42408# Age:7[redacted] Sex:Male Race:WHITE Weight:88.0 kg							
(Cont.)	TRT	1 TO 522	168	168	R: CYTOLYTIC AND CHOLESTATIC HEPATITIS S: Hepatobiliary disorders P: 胆汁うっ滞性肝炎 L: Cholestatic hepatitis	E: 274 O: No L: 107 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42410#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg						
	TRT	1 TO 71	6	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 114 O: No L: 109 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE PULMONARY INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42410#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg							
(Cont.)	TRT	1 TO 71	19	19	R: ALTERATION OF THE GENERAL CONDITION S: Investigations P: 全身健康状態異常 L: General physical condition abnormal	E: 34 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42410#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg							
(Cont.)	TRT	1 TO 71	70	70	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 115 O: No L: 46 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFLAMATORY FORM OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg								
	TRT	1 TO 280	2	2	R: ALTERATION OF THE GENERAL STATE S: General disorders and administration site conditions P: 全身健康状態低下 L: Reduced general condition	E: 57 O: No L: 56 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 280	12	12	R: CEREBRAL VASCULAR ACCIDENT WITH HEMIPARESIS S: Nervous system disorders P: 脳血管発作 L: Cerebrovascular accident	E: 24 O: No L: 13 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ISCHEMIC ORIGIN WITH NO IDENTIFIED CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 280	12	12	R: CEREBRAL VASCULAR ACCIDENT WITH HEMIPARESIS S: Nervous system disorders P: 不全片麻痺 L: Hemiparesis	E: 24 O: No L: 13 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ISCHEMIC ORIGIN WITH NO IDENTIFIED CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
	(Cont.) TRT	1 TO 280	69	69	R: ANAL FISTULA S: Gastrointestinal disorders P: 痔瘻 L: Anal fistula	E: 234 O: No L: 166 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 280	86	86	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 98 O: No L: 13 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 280	112	112	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 127 O: No L: 16 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 280	148	148	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 163 O: No L: 16 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412#	Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg						
(Cont.)	TRT	1 TO 280	193	193	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 198 O: No L: 6 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412#	Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg						
(Cont.)		TRT 1 TO 280	234	234	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 235 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DOSE REDUCED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42412# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
	(Cont.)	TRT 1 TO 280	280	280	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 283 O: No L: 4 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine								
42413#	Age:8[redacted] Sex:Male Race:WHITE Weight:76.0 kg							
	TRT	1 TO 141	2	2	R: CHRONIC RENAL DISEASE S: Renal and urinary disorders P: 慢性腎臓病 L: Chronic kidney disease	E: 24 O: No L: 23 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42413#	Age:8[redacted] Sex:Male Race:WHITE Weight:76.0 kg						
	(Cont.)	TRT 1 TO 141	9	9	R: PNEUMOCYSTIS AND ASPERGILLUS INFECTION S: Infections and infestations P: アスペルギルス感染 L: Aspergillus infection	E: 146 O: No L: 138 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42413# Age:8[redacted] Sex:Male Race:WHITE Weight:76.0 kg							
	(Cont.) TRT	1 TO 141	9	9	R: PNEUMOCYSTIS AND ASPERGILLUS INFECTION S: Infections and infestations P: ニューモシスチス・イロベチイ感染 L: Pneumocystis jirovecii infection	E: 146 O: No L: 138 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (83588) TRT: Venetoclax 400 mg QD + Azacitidine							
42413# Age:8[redacted] Sex:Male Race:WHITE Weight:76.0 kg							
(Cont.) TRT	1 TO 141	141	141	R: SEPTIC SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 145 O: No L: 5 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52791) TRT: Venetoclax 400 mg QD + Azacitidine							
13101#	Age:7[redacted] Sex:Male Race:WHITE Weight:56.6 kg						
	TRT	1 TO 553	58	58	R: INFLUENZA S: Infections and infestations P: インフルエンザ L: Influenza	E: 61 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE FLU V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52791) TRT: Venetoclax 400 mg QD + Azacitidine							
13102#	Age:8[redacted] Sex:Female Race:WHITE Weight:86.6 kg						
	TRT	1 TO 229 Day	1	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 27 O: No L: 27 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HUMAN RHINOVIRUS/ENTEROVIRUS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52791) TRT: Venetoclax 400 mg QD + Azacitidine							
13102# Age:8[redacted] Sex:Female Race:WHITE Weight:86.6 kg							
(Cont.) TRT	1 TO 229	104	104	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 113 O: No L: 10 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOBLASTIC LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (52791) TRT: Venetoclax 400 mg QD + Azacitidine							
13102# Age:8[redacted] Sex:Female Race:WHITE Weight:86.6 kg							
(Cont.)	POST	230 TO 257	10	239	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 252 O: No L: 14 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112045) TRT: Venetoclax 400 mg QD + Azacitidine							
55102#	Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg						
	TRT	1 TO 49 Day 22	22	R: HYPONATREMIA S: Metabolism and nutrition disorders P: 低ナトリウム血症 L: Hyponatremia	E: 42 O: No L: 21 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, INFUSION SUBSTITUTION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW INTAKE OF SODIUM V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112045) TRT: Venetoclax 400 mg QD + Azacitidine							
55102# Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg							
(Cont.) TRT	1	1 TO 49	29	29	R: SOFT TISSUE INFECTION ON LEGS BILAT. S: Infections and infestations P: 軟部組織感染 L: Soft tissue infection	E: 40 O: No L: 12 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SOFT TISSUE INFECTION IN TERRAIN OF OEDEMA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112045) TRT: Venetoclax 400 mg QD + Azacitidine								
55103#	Age:7[redacted] Sex:Male Race:WHITE Weight:75.0 kg							
		POST 126 TO 155	16	141	R: SYNCOPE S: Nervous system disorders P: 失神 L: Syncope	E: 141 O: No L: 1 Day I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SYNCOPE DUE TO ANEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Placebo + Azacitidine								
74602#	Age:8[redacted] Sex:Female Race:WHITE Weight:68.0 kg							
		POST	417 TO 497	5	421	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 450 O: No L: 30 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION DEVELOPED AROUND PICC LINE INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine								
74601# Age:8[redacted] Sex:Female Race:WHITE Weight:77.6 kg								
	TRT	1 TO 214	33	33	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 34 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74601# Age:8[redacted] Sex:Female Race:WHITE Weight:77.6 kg							
(Cont.)	TRT	1 TO 214	213	213	R: OSTEOMYELITIS L1-L4 S: Infections and infestations P: 骨髄炎 L: Spinal osteomyelitis	E: 256 O: No L: 44 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74601#	Age:8[redacted] Sex:Female Race:WHITE Weight:77.6 kg						
	(Cont.)	POST 215 TO 257	24	238	R: CONFUSION, HEADACHE S: Psychiatric disorders P: 錯乱状態 L: Confusion	E: 256 O: No L: 19 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION AML-EXTRAMEDULLARY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74601#	Age:8[redacted] Sex:Female Race:WHITE Weight:77.6 kg						
		(Cont.) POST 215 TO 257	24	238	R: CONFUSION, HEADACHE S: Nervous system disorders P: 頭痛 L: Headache	E: 256 O: No L: 19 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION AML-EXTRAMEDULLARY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74603#	Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg						
	TRT	1 TO 244	19	R: FEBRILE NEUTROPENIA (SINGLE GROWTH OF STAPH HOMINIS) S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 37 O: No L: 19 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74603# Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg							
(Cont.)	TRT	1 TO 244	19	19	R: FEBRILE NEUTROPENIA (SINGLE GROWTH OF STAPH HOMINIS) S: Investigations P: ブドウ球菌検査陽性 L: Staphylococcus test positive	E: 37 O: No L: 19 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine								
74603#	Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg							
(Cont.)	TRT	1 TO 244	49	49	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 77 O: No L: 29 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine								
74603#	Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg							
(Cont.)		TRT	1 TO 244	64	64	R: ILEUS S: Gastrointestinal disorders P: イレウス L: Ileus	E: 72 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74603#	Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg						
	(Cont.) TRT	1 TO 244	119	119	R: STAPHYLOCOCCUS HOMINIS BACTEREMIA S: Infections and infestations P: ブドウ球菌性菌血症 L: Staphylococcal bacteremia	E: 125 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine								
74603#	Age:7[redacted] Sex:Female Race:WHITE Weight:95.0 kg							
	(Cont.)	POST	245 TO 255	8	252	R: LEUKOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 254 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74604 Age:6[redacted]	Sex:Male	Race:WHITE	Weight:62.0 kg				
	TRT	1 TO	262	262	R: STAPH EPIDERMIDIS BACTERMIA S: Infections and infestations P: ブドウ球菌感染 L: Staphylococcus epidermidis infection	E: 275 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74604 Age:6[redacted]	Sex:Male	Race:WHITE	Weight:62.0 kg				
(Cont.) TRT	1 TO	515	515	R: EMPHYSEMA S: Respiratory, thoracic and mediastinal disorders P: 肺気腫 L: Emphysema	O: No I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128249) TRT: Venetoclax 400 mg QD + Azacitidine							
74604	Age:6[redacted] Sex:Male Race:WHITE Weight:62.0 kg						
(Cont.)	TRT	1 TO	578	578	R: COPD EXACERBATION S: Respiratory, thoracic and mediastinal disorders P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 592 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AE# 14 EMPHYSEMA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53187) TRT: Placebo + Azacitidine							
13902# Age:7[redacted] Sex:Female Race:WHITE Weight:97.5 kg							
	TRT	1 TO 151	91	91	R: CELLULITIS, LEFT LOWER EXTREMITY S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 111 O: No L: 21 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53187) TRT: Placebo + Azacitidine							
13902#	Age:7[redacted] Sex:Female Race:WHITE Weight:97.5 kg						
	(Cont.)	TRT 1 TO 151	151	151	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 174 O: No L: 24 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PHYSICIAN, POSSIBLY RELATED TO DISEASE. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53187) TRT: Placebo + Azacitidine									
13902#	Age:7[redacted] Sex:Female Race:WHITE Weight:97.5 kg								
		(Cont.) POST	152 TO 207	29	180	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 189 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, PROCEDURE #11-13; RIGHT KNEE ASPIRATION, X-RAY CHEST, X-RAY RIGHT KNEE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53187) TRT: Venetoclax 400 mg QD + Azacitidine							
13901# Age:7[redacted] Sex:Male Race:WHITE Weight:78.4 kg							
	TRT	1 TO 300	22	22	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 31 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90901	Age:7[redacted] Sex:Male Race:WHITE Weight:78.3 kg							
	TRT	1 TO	13	13	R: FEBRILE NEUTROPAENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 19 O: No L: 7 Days I: No	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, CHEST X-RAY, BLOOD TESTS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPAENIA DUE TO NEWLY DIAGNOSED AML V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg				
(Cont.) TRT	1 TO	20	20	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 31 O: No L: 12 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, CHEST X-RAY AND OPG X-RAY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg				
(Cont.) TRT	1 TO	172	172	R: FEBRILE NEUTROPAENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 174 O: No L: 3 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg				
(Cont.) TRT	1 TO	178	178	R: PARAINFUENZA VIRUS 1 S: Infections and infestations P: パラインフルエンザウイルス感染 L: Parainfluenzae virus infection	E: 206 O: No L: 29 Days I: No	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPAENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg				
(Cont.) TRT	1 TO	206	206	R: STAPHYLOCOCCUS EPIDERMIDIS BACTEREMIA S: Infections and infestations P: ブドウ球菌性菌血症 L: Staphylococcal bacteraemia	E: 215 O: No L: 10 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg					
(Cont.) TRT	1	TO	214	214	R: R) ARM BASILIC VEIN THROMBUS S: Vascular disorders P: 四肢静脈血栓症 L: Venous thrombosis limb	E: 243 O: No L: 30 Days I: No	D: No G: Grade 2 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			240	240	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 243 O: No L: 4 Days I: No	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN ETIOLOGY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90901 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:78.3 kg				
(Cont.) TRT	1 TO	414	414	R: SUPERVENTRICULAR TACHYCARDIA S: Cardiac disorders P: 上室性頻脈 L: Supraventricular tachycardia	E: 415 O: No L: 2 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90903#	Age:8[redacted] Sex:Male Race:WHITE Weight:73.9 kg							
	TRT	1 TO 27	2	2	R: FEBRILE NEUTROPAENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 12 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ?R) THUMB INFLAMMATION OR ?GUT SOURCE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90903# Age:8[redacted] Sex:Male Race:WHITE Weight:73.9 kg							
(Cont.) TRT	1 TO 27	22	22	R: ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 23 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: 2 UNITS RED CELLS TRANSFUSED AS AN INPATIENT OVERNIGHT	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		25	25	R: FEBRILE NEUTROPAENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 53 O: No L: 29 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg						
	TRT	1 TO 411	4	4	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 12 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPAENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
(Cont.)		TRT 1 TO 411	20	20	R: SIGMOID DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Sigmoid diverticulitis	E: 26 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg						
	(Cont.)	TRT 1 TO 411	89	89	R: SIGMOID DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Sigmoid diverticulitis	E: 93 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY - SIGMOID POLYPS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
	(Cont.)	TRT	1 TO 411	106	106	R: PSEUDOMONAS AERUGINOSA BACTEREMIA S: Infections and infestations P: シュードモナス性菌血症 L: Pseudomonal bacteremia	E: 116 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DOSE REDUCED O: TRANSFUSIONS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg						
(Cont.)	TRT	1 TO 411	273	273	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 283 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine							
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg						
	(Cont.)	TRT 1 TO 411	388	388	R: NON ST ELEVATION MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Non ST segment elevation myocardial infarction	E: 395 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPAENIA AND PMHX HYPERTENSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
(Cont.)		TRT	1 TO 411	389	389	R: INFECTIVE DERMATITIS S: Infections and infestations P: 感染性皮膚炎 L: Dermatitis infected	E: 395 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128619) TRT: Venetoclax 400 mg QD + Azacitidine								
90904#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
	(Cont.)	POST	412 TO 593	26	437	R: CARDIAC ISCHAEMIA S: Cardiac disorders P: 心筋虚血 L: Cardiac ischaemia	E: 438 O: No L: 2 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GRADE 3 ANAEMIA - ONGOING INTERMITTENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Placebo + Azacitidine								
34401#	Age:7[redacted] Sex:Female Race:WHITE Weight:63.3 kg							
	TRT	1 TO 144	33	33	R: HYPERTROPHIED ANAL PAPILLA S: Gastrointestinal disorders P: 肛門肥大乳頭 L: Hypertrophic anal papilla	E: 38 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Placebo + Azacitidine							
34401# Age:7[redacted] Sex:Female Race:WHITE Weight:63.3 kg							
(Cont.)	TRT	1 TO 144	71	71	R: PULMONARY ASPERGILLOSIS S: Infections and infestations P: 気管支肺アスペルギルス症 L: Pulmonary aspergillosis	E: 81 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Placebo + Azacitidine								
34401# Age:7[redacted] Sex:Female Race:WHITE Weight:63.3 kg								
(Cont.)		TRT	1 TO 144	122	122	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 129 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Placebo + Azacitidine							
34401#	Age:7[redacted] Sex:Female Race:WHITE Weight:63.3 kg						
	(Cont.)	POST 145 TO 725	1	145	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 198 O: No L: 54 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Placebo + Azacitidine							
34401#	Age:7[redacted] Sex:Female Race:WHITE Weight:63.3 kg						
	(Cont.)	POST 145 TO 725	17	161 R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 171 O: No L: 11 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Venetoclax 400 mg QD + Azacitidine								
34403#	Age:8[redacted] Sex:Male Race:WHITE Weight:90.9 kg							
	POST	119 TO 171	14	132	R: NEUTROPENIC SEPSIS S: Infections and infestations P: 好中球減少性敗血症 L: Neutropenic sepsis	E: 143 O: No L: 12 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112070) TRT: Venetoclax 400 mg QD + Azacitidine								
34404#	Age:7[redacted] Sex:Female Race:WHITE Weight:60.4 kg							
		TRT	1 TO 53	20	20	R: DISSEMINATED HERPES SIMPLEX TYPE 1 INFECTION OF ORALE MUCOSA S: Infections and infestations P: 単純ヘルペス L: Herpes simplex type I	E: 35 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BECAUSE OF NEUTROPENIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14102# Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg								
		TRT	1 TO 253	68	68	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 80 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine							
14102# Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg							
(Cont.)	TRT	1 TO 253	68	68	R: ORAL MUCOSITITS S: Gastrointestinal disorders P: 口内炎 L: Mucositis oral	E: 80 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14102#	Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg							
		(Cont.) TRT	1 TO 253	148	148	R: PSEUDOMONAS AERUGINOSA BACTEREMIA S: Infections and infestations P: シュードモナス性菌血症 L: Pseudomonal bacteremia	E: 162 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMPROMISED IMMUNE SYSTEM RELATED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine							
14102# Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg							
	(Cont.) TRT	1 TO 253	253	253	R: PANCYTOPENIA S: Blood and lymphatic system disorders P: 汎血球減少症 L: Pancytopenia	E: 271 O: No L: 19 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14102#	Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg							
		(Cont.) POST	254 TO 286	21	274	R: EPISTAXIS S: Respiratory, thoracic and mediastinal disorders P: 鼻出血 L: Epistaxis	E: 278 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine							
14102# Age:6[redacted] Sex:Male Race:WHITE Weight:116.6 kg							
(Cont.)	POST	254 TO 286	27	280	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 284 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED STATE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14104#	Age:5[redacted] Sex:Male Race:WHITE Weight:83.9 kg							
		TRT	1 TO 427	11	11	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 20 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AZACITADINE AS INDICATED ON THIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14104# Age:5[redacted] Sex:Male Race:WHITE Weight:83.9 kg								
(Cont.) TRT		1 TO 427	306	306	R: BACTEREMIA S: Infections and infestations P: 菌血症 L: Bacteremia	E: 313 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INDWELLING IV CATHETER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine							
14106#	Age:7[redacted] Sex:Male Race:WHITE Weight:88.9 kg						
	TRT	1 TO 602	15	15	R: VOLUME DEPLETION S: Metabolism and nutrition disorders P: 血液量減少症 L: Volume depletion	E: 17 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: COMPROMISED IMMUNE SYSTEM R/T AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14106#	Age:7[redacted] Sex:Male Race:WHITE Weight:88.9 kg							
		(Cont.) POST TREATMENT	603 TO 640	4	606	R: STREPTOCOCCUS PNEUMONIAE/SALIVARIS BACTEREMIA S: Infections and infestations P: レンサ球菌性菌血症 L: Streptococcal bacteremia	E: 617 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMPROMISED IMMUNE SYSTEM R/T AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103450) TRT: Venetoclax 400 mg QD + Azacitidine								
14108#	Age:7[redacted] Sex:Male Race:WHITE Weight:102.9 kg							
		POST 134 TO 173	29	162	R: VOLUME DEPLETION S: Metabolism and nutrition disorders P: 血液量減少症 L: Volume depletion	E: 172 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GEMTUZUMAB (MYLOTARG) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine							
40101#	Age:8[redacted] Sex:Female Race:WHITE Weight:48.5 kg						
	TRT	1 TO 56	10	10	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 22 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS A NEUTROPENIA ALREADY IN MH AND IS THEREFORE VULNERABLE TO INFECTIONS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine								
40101# Age:8[redacted] Sex:Female Race:WHITE Weight:48.5 kg								
(Cont.) TRT		1 TO 56	25	25	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 32 O: No L: 8 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS NEUTROPENIA IN HIS MH. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine								
40103#	Age:9[redacted] Sex:Female Race:WHITE Weight:57.0 kg							
	TRT	1 TO 361	78	78	R: GASTROINTESTINAL BLEEDING S: Gastrointestinal disorders P: 胃腸出血 L: Gastrointestinal bleeding	E: 84 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, GASTROSCOPY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PLAVIX IS SUSPECTED TO HAVE CAUSED ANGIODYSPLASIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine								
40103# Age:9[redacted] Sex:Female Race:WHITE Weight:57.0 kg								
(Cont.)	TRT	1 TO 361	105	105	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 107 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, BLOOD TRANSFUSION ADMINISTERED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine							
40103#	Age:9[redacted] Sex:Female Race:WHITE Weight:57.0 kg						
(Cont.)	TRT	1 TO 361	361	361	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 386 O: No L: 26 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION O: PLATELETS TRANSFUED	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine								
40103#	Age:9[redacted] Sex:Female Race:WHITE Weight:57.0 kg							
		(Cont.) POST	362 TO 387	13	374	R: SUBDURAL HEMATOMA S: Injury, poisoning and procedural complications P: 硬膜下血腫 L: Subdural hematoma	E: 385 O: No L: 12 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRE-EXISTING THROMBOPENIA GRADE 4 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Placebo + Azacitidine								
40104#	Age:7[redacted] Sex:Female Race:WHITE Weight:134.0 kg							
		TRT	1 TO 7	6	R: STROKE S: Nervous system disorders P: 脳血管発作 L: Stroke	E: 28 O: No L: 23 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: ATRIAL FIBRILLATION, INSUFFICIENT ANTI-COAGULATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Venetoclax 400 mg QD + Azacitidine							
40102# Age:8[redacted] Sex:Female Race:WHITE Weight:69.0 kg							
	TRT	1 TO 91	52	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 57 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: PLATELETS TRANSFUSED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOPENIA INTERMITTEND DUE TO UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114203) TRT: Venetoclax 400 mg QD + Azacitidine							
40102#	Age:8[redacted] Sex:Female Race:WHITE Weight:69.0 kg						
		(Cont.) POST 92 TO 203	1	92	R: STAPHYLOCOCCUS SEPSIS S: Infections and infestations P: ブドウ球菌性敗血症 L: Staphylococcal sepsis	E: 108 O: No L: 17 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INCREASED SUSCEPTIBILITY TO INFECTION DUE TO UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE	R:Reported Term / S:System Organ Class / P:MedDRA 21.0 Preferred Term / L:Lower Level Term	E:Rx Day Ended / O:Ongoing as of Rx Day / L:Length / I:Intermittent?	D:DLT Event / G:NCI Toxicity / R:Relationship to Venetoclax/Placebo / Z:Relationship to AZA / A:Actions Taken / O:Other Actions Taken / C:Concomitant or Additional Treatment Given	S:Serious AE? / O:Other Cause of Event / V:Abbvie Opinion of Venetoclax/Placebo Causality / A:Abbvie Opinion of Azacitidine Causality / R:AE Related to TLS
INV: [redacted] (114203) TRT: Venetoclax 400 mg QD + Azacitidine							
40102#	Age:8[redacted] Sex:Female Race:WHITE Weight:69.0 kg						
(Cont.)	POST	92 TO 203	17	R: ERYTHROBLAST LEUKEMIA S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 赤白血病 L: Erythroleukaemia	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AS AML MIGHT HAVE BEEN INHIBITED DUE TO AZACITIDINE AND VENETOCLAX/PLACEBO THERAPY, HIDDEN ERYTHROBLAST LEUKEMIA PROBABLY BROKE OUT. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110129) TRT: Venetoclax 400 mg QD + Azacitidine							
47401# Age:8[redacted] Sex:Male Race:WHITE Weight:63.0 kg							
	TRT	1 TO 264	69	69	R: ASTHENIA S: General disorders and administration site conditions P: 無力症 L: Asthenia	E: 166 O: No L: 98 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18201	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
		TRT 1 TO	1	1	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 8 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18201	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
(Cont.)	TRT	1 TO	22	22	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 23 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:59.0 kg				
(Cont.) TRT	1 TO	22	22	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 161 O: No L: 140 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201 Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
(Cont.) TRT	1 TO	23	23	R: INVASIVE FUNGAL INFECTION S: Infections and infestations P: 全身性真菌症 L: Systemic mycosis	E: 110 O: No L: 88 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201 Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
(Cont.)	TRT	1 TO	84	84	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 97 O: No L: 14 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, HOSPITALIZATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg						
	(Cont.) TRT	1 TO	123	123	R: EPISTAXIS S: Respiratory, thoracic and mediastinal disorders P: 鼻出血 L: Epistaxis	E: 127 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, HOSPITALIZTION AND TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PARANASAL FUNGAL INFECTION RESOLVED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18201	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
	(Cont.) TRT	1 TO	195	195	R: EPISTAXIS S: Respiratory, thoracic and mediastinal disorders P: 鼻出血 L: Epistaxis	E: 196 O: No L: 2 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, HOSPITALIZATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PARANASAL FUNGAL INFECTION RESOLVED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18201 Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg								
	(Cont.) TRT	1 TO	412	412	R: CHOLELITHIASIS S: Hepatobiliary disorders P: 胆石症 L: Cholelithiasis	E: 414 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CHOLELITHIASIS IS A DIAGNOSIS THAT WAS OBSERVED IN MEDICAL HISTORY. THE THE ETIOLOGY OF CHOLELITHIASIS WAS NOT DETERMINED. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:59.0 kg				
(Cont.) TRT	1 TO	412	412	R: RIGHT INGUINAL HERNIA S: Gastrointestinal disorders P: 鼠径ヘルニア L: Right inguinal hernia	E: 414 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: FRAGILITY OF THE ABDOMINAL WALL WITHOUT DEFINITE CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18201 Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg								
(Cont.) TRT		1 TO	637	637	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 666 O: No L: 30 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				637	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 651 O: No L: 15 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine							
18201	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg						
	(Cont.) TRT	1 TO	640	640	R: DELIRIUM S: Psychiatric disorders P: 譫妄 L: Delirium	E: 641 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (177357) TRT: Venetoclax 400 mg QD + Azacitidine								
18202#	Age:8[redacted] Sex:Male Race:WHITE Weight:60.4 kg							
	TRT	1 TO 3	3	3	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 8 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, NEPHROLOGY DOCTORS CONTACTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEPHROTOXICITY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110131) TRT: Venetoclax 400 mg QD + Azacitidine								
47101 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:74.0 kg					
	TRT	1 TO	551	551	R: BRONCHO INFECTION S: Infections and infestations P: 気管支炎 L: Bronchial infection	E: 569 O: No L: 19 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PANCYTOPENIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110131) TRT: Venetoclax 400 mg QD + Azacitidine							
47101 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:74.0 kg				
(Cont.) TRT	1 TO	551	551	R: PANCYTOPENIA S: Blood and lymphatic system disorders P: 汎血球減少症 L: Pancytopenia	O: No I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: TRANSFUSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROBABLE PROGRESSION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110036) TRT: Placebo + Azacitidine								
52501# Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg								
	TRT	1 TO 138	13	13	R: INFLAMMED HEMORRHOIDS S: Gastrointestinal disorders P: 痔核 L: Hemorrhoids	E: 24 O: No L: 12 Days I: Yes	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110036) TRT: Venetoclax 400 mg QD + Azacitidine							
52502#	Age:7[redacted] Sex:Female Race:WHITE Weight:58.0 kg						
	TRT	1 TO 282	22	R: SYMPTOMATIC ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 26 O: No L: 5 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			75	R: E-COLI BAKTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 89 O: No L: 15 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110036) TRT: Venetoclax 400 mg QD + Azacitidine							
52502# Age:7[redacted] Sex:Female Race:WHITE Weight:58.0 kg							
		(Cont.) TRT 1 TO 282	170	170	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 180 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			229	229	R: E-COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 241 O: No L: 13 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110036) TRT: Venetoclax 400 mg QD + Azacitidine								
52502#	Age:7[redacted] Sex:Female Race:WHITE Weight:58.0 kg							
		(Cont.) TRT	1 TO 282	253	253	R: ASPERGILLUS UPPER AIRWAY INFECTION S: Infections and infestations P: アスペルギルス感染 L: Aspergillus infection	E: 268 O: No L: 16 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBILITY OF PERITONITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine								
38604#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
	TRT	1 TO 355	19	19	R: BRONCHOPNEUMONIA S: Infections and infestations P: 肺炎 L: Bronchopneumonia	E: 35 O: No L: 17 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROBABLY DUE TO HER LONG NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine								
38604#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
		(Cont.) POST	356 TO 482	9	364	R: BACTEREMIA S: Infections and infestations P: 菌血症 L: Bacteremia	E: 375 O: No L: 12 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ABDOMINAL INFECTION FOCUS POSSIBLE FINALLY WAS PULMONARY FOCUS AND BACTEREMIA (GRAM-POSITIVE COCCI) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine								
38604#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
		(Cont.) POST	356 TO 482	27	382	R: BACTEREMIA S: Infections and infestations P: 菌血症 L: Bacteremia	E: 388 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BLOOD CULTURES POSITIVE GRAM NEGATIVE BACILI V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine								
38605#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.6 kg							
	TRT	1 TO 62	7	7	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 11 O: No L: 5 Days I: Yes	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROBABLE RESPIRATORY FOCUS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine							
38605# Age:7[redacted] Sex:Male Race:WHITE Weight:72.6 kg							
	(Cont.) TRT	1 TO 62	35	35	R: RIGHT PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 62 O: No L: 28 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine							
38605#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.6 kg						
	(Cont.)	TRT 1 TO 62	61	61	R: GENERAL DISCOMFORT S: General disorders and administration site conditions P: 不快感 L: General discomfort	E: 65 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF BILATERAL BRONCHOPNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine							
38605# Age:7[redacted] Sex:Male Race:WHITE Weight:72.6 kg							
(Cont.)	TRT	1 TO 62	61	61	R: FEBRILE SYNDROME S: General disorders and administration site conditions P: 発熱 L: Febrile reaction	E: 65 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF BILATERAL BRONCHOPNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110903) TRT: Venetoclax 400 mg QD + Azacitidine							
38605#	Age:7[redacted] Sex:Male Race:WHITE Weight:72.6 kg						
	(Cont.)	POST 63 TO 66	1	63	R: BILATERAL BRONCHOPNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral bronchopneumonia	E: 64 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF BILATERAL BROCHOPNEUMONIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40501#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
		TRT	1 TO 264	57	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 59 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40501#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg						
(Cont.)	TRT	1 TO 264	134	134	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 145 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40501# Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
	(Cont.) TRT	1 TO 264	143	143	R: SIGMOID DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Sigmoid diverticulitis	E: 150 O: No L: 8 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40501#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
(Cont.)		TRT	1 TO 264	151	151	R: SIGMOID DIVERDICULITIS S: Infections and infestations P: 憩室炎 L: Sigmoid diverticulitis	E: 177 O: No L: 27 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40501#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
(Cont.)	TRT	1 TO 264	192	192	R: BACTERIAL INFECTION WITH CITROBACTER FREUNDII OF PERIPHERALLY INSERTED CENTRAL VENOUS CATHETER S: Infections and infestations P: シトロバクター感染 L: Citrobacter freundii infection	E: 200 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: STUDY DRUG WAS ALREADY INTERRUPTED DUE TO AE SIGMOID DIVERTICULITIS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION WITH GRAMNEGATIVE CITROBACTER FREUNDII, CAUSE: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40501#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
(Cont.)	TRT	1 TO 264	192	192	R: BACTERIAL INFECTION WITH CITROBACTER FREUNDII OF PERIPHERALLY INSERTED CENTRAL VENOUS CATHETER S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 200 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: STUDY DRUG WAS ALREADY INTERRUPTED DUE TO AE SIGMOID DIVERTICULITIS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION WITH GRAMNEGATIVE CITROBACTER FREUNDII, CAUSE: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine 40501# Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg							
(Cont.)	TRT	1 TO 264	253	253	R: CONSTIPATION S: Gastrointestinal disorders P: 便秘 L: Constipation	E: 254 O: No L: 2 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STOOL DISORDER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40501# Age:7[redacted] Sex:Female Race:WHITE Weight:67.9 kg								
(Cont.)	TRT	1 TO 264	254	254	R: PARASTOMAL INFECTION LOCOREGIONAL S: Infections and infestations P: ストーマ部感染 L: Stoma site infection	E: 291 O: No L: 38 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STOMA BASEPLATE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	265 TO 833	5	269	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 282 O: No L: 14 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40502# Age:8[redacted] Sex:Male Race:WHITE Weight:78.6 kg							
	TRT	1 TO 97	51	R: EPISTAXIS S: Respiratory, thoracic and mediastinal disorders P: 鼻出血 L: Epistaxis	E: 61 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			54	R: HEMATURIA S: Renal and urinary disorders P: 血尿 L: Hematuria	E: 61 O: No L: 8 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: PLACEMENT OF PERMANENT CATHETER C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40503#	Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg							
	TRT	1 TO 166	46	46	R: SYMPTOMATIC ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 164 O: No L: 119 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40503# Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg							
(Cont.) TRT	1 TO 166	57	57	R: CONGESTIVE HEPATOPATHY S: Hepatobiliary disorders P: 肝臓うっ血 L: Hepatic congestion	E: 60 O: No L: 4 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: DELAY OF 3 DAYS O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40503# Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg							
	(Cont.) TRT	1 TO 166	136	136	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 148 O: No L: 13 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40503#	Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg							
	(Cont.) TRT	1 TO 166	142	142	R: CARDIAC DECOMPENSATION S: Cardiac disorders P: 心不全 L: Decompensation cardiac	E: 148 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40503# Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg							
	(Cont.) TRT	1 TO 166	165	165	R: SYMPTOMATIC ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 175 O: No L: 11 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	167 TO 730	10	176	R: PLEURAL EFFUSIONS S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Pleural effusion	O: Yes I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AUTOIMMUNE DISORDER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine							
40503#	Age:7[redacted] Sex:Male Race:WHITE Weight:79.9 kg						
		(Cont.) POST 167 TO 730	11	177	R: PNEUMOTHORAX S: Respiratory, thoracic and mediastinal disorders P: 気胸 L: Pneumothorax	E: 184 O: No L: 8 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PLEURIX DRAINAGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113030) TRT: Venetoclax 400 mg QD + Azacitidine								
40506 Age:7[redacted] Sex:Male Race:WHITE Weight:93.9 kg								
	TRT	1 TO	204	204	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 211 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			266	266	R: INFECTION OF UNKNOWN ORIGIN S: Infections and infestations P: 感染 L: Infection	E: 271 O: No L: 6 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072)							
TRT: Placebo + Azacitidine							
23101#	Age:7[redacted] Sex:Male Race:WHITE Weight:90.1 kg						
	TRT	1 TO 153 Day 102	102	R: RECTAL BLEEDING S: Gastrointestinal disorders P: 直腸出血 L: Rectal bleeding	E: 110 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		111	111	R: RECTAL BLEEDING S: Gastrointestinal disorders P: 直腸出血 L: Rectal bleeding	E: 117 O: No L: 7 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Placebo + Azacitidine							
23101# Age:7[redacted] Sex:Male Race:WHITE Weight:90.1 kg							
(Cont.)	TRT	1 TO 153	129	129	R: HEMATURIA S: Renal and urinary disorders P: 血尿 L: Hematuria	E: 136 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Placebo + Azacitidine							
23101#	Age:7[redacted] Sex:Male Race:WHITE Weight:90.1 kg						
	(Cont.)	TRT 1 TO 153 Day	147	147	R: ENTEROKOCKER SEPSIS S: Infections and infestations P: 腸球菌性敗血症 L: Enterococcal sepsis	E: 153 O: No L: 7 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Placebo + Azacitidine								
23101#	Age:7[redacted] Sex:Male Race:WHITE Weight:90.1 kg							
	(Cont.)	POST	154 TO 479	24	177	R: URINARY RETENTION S: Renal and urinary disorders P: 尿閉 L: Urinary retention	E: 190 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO OTHER CAUSE OF EVENT TO PROVIDE. MAYBE MORPHINE TREATMENT? V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23102# Age:8[redacted] Sex:Female Race:WHITE Weight:85.0 kg							
	TRT	1 TO 321	99	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 101 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			104	R: GINGIVAL INFECTION S: Infections and infestations P: 歯肉炎 L: Gingival infection	E: 117 O: No L: 14 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted](109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103	Age:7[redacted] Sex:Male Race:WHITE Weight:101.6 kg						
		TRT 1 TO	28	28	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 31 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, TEMPERATURE COLLECTED. NO OTHER PROCEDURES DONE. C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103	Age:7[redacted] Sex:Male Race:WHITE Weight:101.6 kg						
(Cont.)	TRT	1 TO	64	64	R: INCREASED CRP S: Investigations P: C一反応性蛋白増加 L: CRP increased	E: 66 O: No L: 3 Days I: No	G: Grade 1 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:101.6 kg				
(Cont.) TRT	1 TO	217	217	R: WORSENING OF ARTHRITIS RIGHT HIP JOINT S: Musculoskeletal and connective tissue disorders P: 関節炎 L: Arthritis aggravated	E: 227 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMORBIDITY - REUMATOID ARTHRITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103	Age:7[redacted] Sex:Male Race:WHITE Weight:101.6 kg						
(Cont.)	TRT	1 TO	288	288	R: RED, SWOLLEN, PAINFUL RIGHT FOOT AND LOWER LEG S: Skin and subcutaneous tissue disorders P: 紅斑 L: Localized erythema	E: 297 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:101.6 kg				
(Cont.)	TRT	1 TO #	288	288	R: RED, SWOLLEN, PAINFUL RIGHT FOOT AND LOWER LEG S: Musculoskeletal and connective tissue disorders P: 四肢痛 L: Pain of lower extremities	E: 297 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109072) TRT: Venetoclax 400 mg QD + Azacitidine							
23103 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:101.6 kg				
(Cont.)	TRT	1 TO	288	288	R: RED, SWOLLEN, PAINFUL RIGHT FOOT AND LOWER LEG S: General disorders and administration site conditions P: 末梢腫脹 L: Swelling of legs	E: 297 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118083) TRT: Placebo + Azacitidine							
44701#	Age:7[redacted] Sex:Male Race:WHITE Weight:88.3 kg						
		POST 102 TO 328	29	130	R: TRANSFUSION REACTION TO PLATELET TRANSFUSION S: Injury, poisoning and procedural complications P: 輸血反応 L: Transfusion reaction	E: 132 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: A PLATELET TRANSFUSION WAS GIVEN. THIS IS THE CAUSE OF A TRANSFUSION REACTION. THE PATIENT HAD NO HLA ANTIBODIES PRIOR TO THE EVENT. NOW HLA B37 ANTIBODIES COULD BE PROOFED ON 25 APR 2018. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118083) TRT: Venetoclax 400 mg QD + Azacitidine								
44702#	Age:8[redacted] Sex:Male Race:WHITE Weight:89.9 kg							
	TRT	1 TO 315	55	55	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 69 O: No L: 15 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118083) TRT: Venetoclax 400 mg QD + Azacitidine							
44702# Age:8[redacted] Sex:Male Race:WHITE Weight:89.9 kg							
(Cont.) TRT	1 TO 315	62	62	R: PNEUMONIA WITH MULTIPLE PATHOGENS S: Infections and infestations P: 肺炎 L: Pneumonia	E: 98 O: No L: 37 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, BRONCHOSCOPY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNNOSUPPRESSION AFTER CHEMOTHERAPY AND STILL PRESENT AML. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine								
44003# Age:7[redacted] Sex:Male Race:WHITE Weight:67.0 kg								
	TRT	1 TO 159	22	22	R: LEUCOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 57 O: No L: 36 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine								
44003#	Age:7[redacted] Sex:Male Race:WHITE Weight:67.0 kg							
		(Cont.) TRT	1 TO 159	57	57	R: GENERAL HEALTH DETERIORATION S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 206 O: No L: 150 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUCEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine								
44004#	Age:7[redacted] Sex:Male Race:WHITE Weight:106.0 kg							
	TRT	1 TO 70	23	23	R: SEPTICEMIA S: Infections and infestations P: 敗血症 L: Septicemia	E: 39 O: No L: 17 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE (AML) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine								
44004#	Age:7[redacted] Sex:Male Race:WHITE Weight:106.0 kg							
(Cont.)	TRT	1 TO 70	67	67	R: CIRCULATORY COLLAPSE S: Vascular disorders P: 循環虚脱 L: Circulatory collapse	E: 67 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine							
44004# Age:7[redacted] Sex:Male Race:WHITE Weight:106.0 kg							
(Cont.)	TRT	1 TO 70	67	67	R: FEVER IN NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 75 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine							
44004#	Age:7[redacted] Sex:Male Race:WHITE Weight:106.0 kg						
	(Cont.)	POST 71 TO 299	24	94	R: FEVER IN NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 100 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Other: DRUG HAS BEEN WITHDRAW BY SUBJECT 20MAY2018 C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUCEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Placebo + Azacitidine								
44005#	Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg							
		POST	29 TO 45	2	30	R: DETERIORATION OF GENERAL HEALTH CONDITION S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 44 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine							
44001#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.6 kg						
	TRT	1 TO 266 Day 169	169	R: DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Diverticulitis	E: 176 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DIVERTICULOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine							
44001#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.6 kg						
		(Cont.) POST 267 TO 318	11	277	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 285 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, HOSPITALIZATION, I.V. ANTIBIOTICS C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML RELAPSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine								
44006	Age:7[redacted] Sex:Male Race:WHITE Weight:103.1 kg							
		TRT 1 TO	22	22	R: FEVER IN NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 31 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			339	339	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 343 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine								
44007#	Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg							
		TRT 1 TO 275	24	24	R: ESCHERIA COLI SEPTICEMIA S: Infections and infestations P: 大腸菌性敗血症 L: Septicemia due to Escherichia coli (E. coli)	E: 38 O: No L: 15 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			51	51	R: WORSENING OF ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation aggravated	E: 53 O: No L: 3 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine							
44007#	Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg						
(Cont.)	TRT	1 TO 275 Day 158	158	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 158 O: No L: 1 Day I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (120499) TRT: Venetoclax 400 mg QD + Azacitidine								
44007#	Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg							
		(Cont.) POST	276 TO 326	23	298	R: ATYPICAL PNEUMONIA S: Infections and infestations P: 異型肺炎 L: Atypical pneumonia	E: 324 O: No L: 27 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUCEMIA, NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118172) TRT: Venetoclax 400 mg QD + Azacitidine								
10501#	Age:7[redacted] Sex:Male Race:WHITE Weight:82.5 kg							
		POST	34 TO 43	1	34	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 42 O: No L: 9 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116166) TRT: Placebo + Azacitidine							
40302 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:79.0 kg				
	TRT	1 TO	151	151	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 155 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPERTHYREOIDSM DUE TO MEDICATION CHANGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116166) TRT: Placebo + Azacitidine							
40302	Age:8[redacted] Sex:Female Race:WHITE Weight:79.0 kg						
	(Cont.)	TRT 1 TO	318	318	R: LUMBAGO (THORACIC SPINE) S: Musculoskeletal and connective tissue disorders P: 背部痛 L: Lumbago	E: 322 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBILE CAUSED BY PATIENT WHILE SLEEPING - DUE TO DEGENERATIVE SPINAL DISORDERS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116166) TRT: Venetoclax 400 mg QD + Azacitidine								
40301#	Age:6[redacted] Sex:Female Race:WHITE Weight:54.0 kg							
	TRT	1 TO 3	1	1	R: WORSENING PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia aggravated	E: 13 O: No L: 13 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IMMUNOSUPRRESSION DUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116166) TRT: Venetoclax 400 mg QD + Azacitidine							
40301#	Age:6[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
(Cont.)	TRT	1 TO 3	3	3	R: VENTRICULAR TACHYCARDIA S: Cardiac disorders P: 心室性頻脈 L: Ventricular tachycardia	E: 13 O: No L: 11 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION A: Other: DUE TO THE FACT THAT WE CANNOT PRECLUDE A REALTIONSHIP BETWEEN AZACITIDNE AND VENTRICULAR TACHYCARDIA, INVESTIGATOR DECIDED TO STOP STUDY DRUG TREATMENT O: Multiple: MEDICAL PROCEDURE, CARDIOVERSION	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (77449) TRT: Venetoclax 400 mg QD + Azacitidine								
80102#	Age:7[redacted] Sex:Female Race:ASIAN Weight:56.0 kg							
	TRT	1 TO 57	53	53	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 210 O: No L: 158 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (77449) TRT: Venetoclax 400 mg QD + Azacitidine								
80102#	Age:7[redacted] Sex:Female Race:ASIAN Weight:56.0 kg							
		(Cont.) POST	58 TO 732	3	60	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 66 O: No L: 7 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE USE OF VENTOLIN NEBUL(INHALATION) IS POSSIBLY CAUSE OF EVENT. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted](77449) TRT: Venetoclax 400 mg QD + Azacitidine							
80102#	Age:7[redacted] Sex:Female Race:ASIAN Weight:56.0 kg						
		(Cont.) POST 58 TO 732	4	61	R: DELIRIUM S: Psychiatric disorders P: 譫妄 L: Delirium	E: 67 O: No L: 7 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: RESTRAINTS APPLIED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DELIRIUM SEEMS TO BE CAUSED BY PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116471) TRT: Venetoclax 400 mg QD + Azacitidine							
97001# Age:8[redacted] Sex:Male Race:ASIAN Weight:71.8 kg							
	TRT	1 TO 28	8	8	R: PRE-MATURE ATRIAL CONTRACTIONS S: Cardiac disorders P: 上室性期外収縮 L: Premature atrial contraction	O: Yes I: Yes	G: Grade 1 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116471) TRT: Venetoclax 400 mg QD + Azacitidine							
97001# Age:8[redacted] Sex:Male Race:ASIAN Weight:71.8 kg							
(Cont.)	TRT	1 TO 28	25	25	R: FUNGAL PNEUMONIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	O: Yes I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116471) TRT: Venetoclax 400 mg QD + Azacitidine							
97001#	Age:8[redacted] Sex:Male Race:ASIAN Weight:71.8 kg						
	(Cont.)	POST 29 TO 61	11	39	R: ACUTE HEPATITIS S: Hepatobiliary disorders P: 急性肝炎 L: Hepatitis acute	E: 49 O: No L: 11 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: SUSPECT SHOCK AND ANTIBIOTICS RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114975) TRT: Placebo + Azacitidine								
97104#	Age:7[redacted] Sex:Female Race:ASIAN Weight:50.0 kg							
	TRT	1 TO 21	12	12	R: URINARY TRACT INFECTION(CANDIDA) S: Infections and infestations P: カンジダ尿 L: Urine candida	E: 39 O: No L: 28 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114975) TRT: Venetoclax 400 mg QD + Azacitidine								
97101# Age:7[redacted] Sex:Male Race:ASIAN Weight:65.0 kg								
	TRT	1 TO 7	6	6	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 12 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114975) TRT: Venetoclax 400 mg QD + Azacitidine							
97101#	Age:7[redacted] Sex:Male Race:ASIAN Weight:65.0 kg						
	(Cont.)	TRT 1 TO 7	6	6	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 11 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (99205) TRT: Placebo + Azacitidine							
65101# Age:6[redacted] Sex:Female Race:WHITE Weight:70.0 kg							
	TRT	1 TO 268	11	11	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 21 O: No L: 11 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (99205) TRT: Placebo + Azacitidine								
65101# Age:6[redacted] Sex:Female Race:WHITE Weight:70.0 kg								
(Cont.)	TRT	1 TO 268	143	143	R: ACUTE SUBCUTANEOUS PARAPROCTITIS S: Gastrointestinal disorders P: 直腸炎 L: Paraproctitis	E: 149 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, DISSECTION OF PARAPROCTITIS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POSSIBLE LOCAL TRAUMA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103235) TRT: Venetoclax 400 mg QD + Azacitidine								
86803#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg							
		TRT	1 TO 268	112	112	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 118 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103235) TRT: Venetoclax 400 mg QD + Azacitidine								
86803#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg							
		(Cont.) POST	269 TO 323	29	297	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	O: Yes I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (103235) TRT: Venetoclax 400 mg QD + Azacitidine							
86803#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg						
	(Cont.)	POST 269 TO 323	29	297	R: PROGRESSION OF PRE-EXISTING MALIGNANCY S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	E: 322 O: No L: 26 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111005) TRT: Placebo + Azacitidine							
34201# Age:8[redacted] Sex:Male Race:WHITE Weight:64.7 kg							
	TRT	1 TO 336	105	105	R: INFLUENZA A INFECTION S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 141 O: No L: 37 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OPPORTUNISTIC INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111005) TRT: Placebo + Azacitidine							
34202#	Age:7[redacted] Sex:Male Race:WHITE Weight:69.5 kg						
		TRT 1 TO 500	14	14	R: DEHYDRATION S: Metabolism and nutrition disorders P: 脱水 L: Dehydration	E: 17 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			42	42	R: WORSENING CONSTIPATION S: Gastrointestinal disorders P: 便秘 L: Constipation aggravated	E: 44 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111005) TRT: Placebo + Azacitidine							
34202#	Age:7[redacted] Sex:Male Race:WHITE Weight:69.5 kg						
(Cont.)	TRT	1 TO 500	86	86	R: CENTRAL VENOUS CATHETER INFECTION S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 92 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OPPORTUNISTIC INFECTION WITH S. EPIDERMIDIS AT THE CATHETER SITE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111005) TRT: Venetoclax 400 mg QD + Azacitidine							
34204 Age:6[redacted] Sex:Female Race:WHITE Weight:88.0 kg							
		TRT 1 TO #	184	184	R: LEFT LOWER LEG WOUND INFECTION S: Infections and infestations P: 創傷感染 L: Wound infection	E: 200 O: No L: 17 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MULTIPLE BACTERIAL PATHOGENS IDENTIFIED IN WOUND- AND BLOOD CULTURES. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Placebo + Azacitidine								
15502#	Age:7[redacted] Sex:Male Race:WHITE Weight:76.1 kg							
		TRT	1 TO 28	24	24	R: STAPH BACTEREMIA S: Infections and infestations P: ブドウ球菌性菌血症 L: Staphylococcal bacteremia	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine								
14601#	Age:7[redacted] Sex:Male Race:WHITE Weight:113.3 kg							
		TRT 1 TO 49	48	48	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 56 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: RELATED TO PROGRESSIVE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine							
14602# Age:7[redacted] Sex:Female Race:WHITE Weight:77.1 kg							
	TRT	1 TO 56	15	15	R: INCARCERATED HERNIA S: General disorders and administration site conditions P: 嵌頓ヘルニア L: Incarcerated hernia	E: 66 O: No L: 52 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, EMERGENCY SURGERY TO REDUCE HERNIA AND POSSIBLE RESECTION OF BOWEL C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: WEAKNESS/HERNIA WITH POOR MESH IN THE PAST V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine								
14602#	Age:7[redacted] Sex:Female Race:WHITE Weight:77.1 kg							
		(Cont.) POST	57 TO 67	1	57	R: RENAL FAILURE S: Renal and urinary disorders P: 腎不全 L: Renal failure	E: 65 O: No L: 9 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine							
14603# Age:7[redacted] Sex:Male Race:WHITE Weight:60.3 kg							
	TRT	1 TO 519	21	21	R: KLEBSIELLA/STREPTOCOCCUS BACTEREMIA S: Infections and infestations P: クレブシエラ性菌血症 L: Klebsiella bacteremia	E: 27 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine								
14603# Age:7[redacted] Sex:Male Race:WHITE Weight:60.3 kg								
(Cont.) TRT		1 TO 519	21	21	R: KLEBSIELLA/STREPTOCOCCUS BACTEREMIA S: Infections and infestations P: レンサ球菌性菌血症 L: Streptococcal bacteremia	E: 27 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine							
14603# Age:7[redacted] Sex:Male Race:WHITE Weight:60.3 kg							
(Cont.)	TRT	1 TO 519	65	65	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: PLATELET AND RBC TRANSFUSIONS	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine								
14604#	Age:7[redacted] Sex:Female Race:WHITE Weight:66.4 kg							
	TRT	1 TO 182	42	42	R: MYOCARDIAL EDEMA S: Cardiac disorders P: 心筋浮腫 L: Myocardial edema	E: 50 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: HOSPITAL ADMISSION WITH CARDIAC WORK UP. STRESS TEST C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109796) TRT: Venetoclax 400 mg QD + Azacitidine							
14605# Age:7[redacted] Sex:Male Race:WHITE Weight:109.1 kg							
	TRT	1 TO 396	33	33	R: PNEUMONIA (LUNG INFECTION) S: Infections and infestations P: 肺炎 L: Pneumonia	E: 36 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (133889) TRT: Placebo + Azacitidine								
23301#	Age:8[redacted] Sex:Male Race:WHITE Weight:54.0 kg							
	TRT	1 TO 55	49	49	R: VANCOMYCIN RESISTANT ENTEROCOCCI IN BLOOD S: Infections and infestations P: 腸球菌性敗血症 L: Enterococcal sepsis	E: 68 O: No L: 20 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112456) TRT: Venetoclax 400 mg QD + Azacitidine							
20101# Age:8[redacted] Sex:Female Race:WHITE Weight:72.5 kg							
	TRT	1 TO 443	11	11	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 15 O: No L: 5 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: THE PATIENT RECEIVED TWO UNITS OF BLOOD AND ANEMIA IMPROVED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112456) TRT: Venetoclax 400 mg QD + Azacitidine							
20101# Age:8[redacted] Sex:Female Race:WHITE Weight:72.5 kg							
(Cont.) TRT	1 TO 443	59	59	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 61 O: No L: 3 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
		94	94	R: E COLI SEPTICEMIA S: Infections and infestations P: 大腸菌性敗血症 L: Septicemia due to Escherichia coli (E. coli)	E: 105 O: No L: 12 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: HYDRATION AND BROAD SPECTRUM ANTIBIOTICS WITH PENICILLIN AND GENTAMYCINE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112456) TRT: Venetoclax 400 mg QD + Azacitidine								
20101# Age:8[redacted] Sex:Female Race:WHITE Weight:72.5 kg								
	(Cont.)	POST	444 TO 510	28	471	R: FLUE TYPE A S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 479 O: No L: 9 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, X-RAY EXAMINATION OF THE LUNGS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMMUNITY AQUIRED FLUE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115036) TRT: Venetoclax 400 mg QD + Azacitidine								
93203#	Age:7[redacted] Sex:Female Race:ASIAN Weight:46.0 kg							
		POST 18 TO 27	4	21	R: ACUTE CARDIAC INSUFFICIENCY S: Cardiac disorders P: 急性心不全 L: Acute cardiac insufficiency	E: 26 O: No L: 6 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				21	R: CEREBRAL HEMORRHAGE S: Nervous system disorders P: 脳出血 L: Cerebral hemorrhage	E: 25 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115041) TRT: Venetoclax 400 mg QD + Azacitidine								
94402#	Age:7[redacted] Sex:Female Race:ASIAN Weight:50.0 kg							
		TRT	1 TO 70	4	R: PLATELET COUNT DECREASED S: Investigations P: 血小板数減少 L: Platelet count decreased	O: Yes I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: TRANSFUSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130295) TRT: Venetoclax 400 mg QD + Azacitidine								
93002#	Age:7[redacted] Sex:Male Race:ASIAN Weight:59.4 kg							
		POST 29 TO 151	24	52	R: GINGIVAL INFECTION S: Infections and infestations P: 歯肉炎 L: Gingival infection	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ASSOCIATED WITH THE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130295) TRT: Venetoclax 400 mg QD + Azacitidine								
93008#	Age:7[redacted] Sex:Male Race:ASIAN Weight:69.6 kg							
	TRT	1 TO 56	39	39	R: EPIDIDYMO-ORCHITIS S: Infections and infestations P: 精巣炎 L: Epididymo-orchitis	O: Yes I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Placebo + Azacitidine								
13303#	Age:7[redacted] Sex:Male Race:WHITE Weight:75.5 kg							
	TRT	1 TO 537	69	69	R: SYNCOPE S: Nervous system disorders P: 失神 L: Syncope	E: 71 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BASED ON THE HISTORY, COMORBIDITY, AND CARDIAC HISTORY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine							
13301#	Age:7[redacted] Sex:Male Race:WHITE Weight:73.9 kg						
		TRT 1 TO 544 Day 94	94	R: SYNCOPE, HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 96 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			94	R: SYNCOPE, HYPOTENSION S: Nervous system disorders P: 失神 L: Syncope	E: 96 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine							
13301#	Age:7[redacted] Sex:Male Race:WHITE Weight:73.9 kg						
	(Cont.)	TRT 1 TO 544	276	276	R: SINUSITIS S: Infections and infestations P: 副鼻腔炎 L: Sinusitis	E: 291 O: No L: 16 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DOSE REDUCED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine							
13305 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:74.2 kg				
	TRT	1 TO 17	17	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 69 O: No L: 53 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		65	65	R: CELLULITIS; MRSA ON RIGHT UPPER THIGH S: Infections and infestations P: ブドウ球菌性蜂巣炎 L: MRSA cellulitis	E: 85 O: No L: 21 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine								
13305	Age:8[redacted] Sex:Female Race:WHITE Weight:74.2 kg							
	(Cont.) TRT	1 TO	86	86	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 88 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			133	133	R: MYOCARDIAL INFARCTION S: Cardiac disorders P: 心筋梗塞 L: Myocardial infarction	E: 137 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CO-MORBID CONDITION AML, CAD, COPD, HTN, DIVERTICULOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine							
13305 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:74.2 kg				
	(Cont.) TRT	1 TO	186	186	R: NAIL INFECTION RING FINGER OF RIGHT HAND S: Infections and infestations P: 爪感染 L: Nail infection	E: 206 O: No L: 21 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOSUPPRESSIVE FROM NATURE OF DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine								
13305 Age:8[redacted] Sex:Female Race:WHITE Weight:74.2 kg								
(Cont.) TRT	1 TO		229	229	R: CELLULITIS OF LEFT SECOND TOE S: Infections and infestations P: 蜂巣炎 L: Cellulitis of toe	E: 255 O: No L: 27 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			425	425	R: CLOSTRIDIUM DIFFICILE COLITIS S: Infections and infestations P: クロストリジウム・ディフィシレ大腸炎 L: Clostridium difficile colitis	E: 437 O: No L: 13 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (50863) TRT: Venetoclax 400 mg QD + Azacitidine							
13305 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:74.2 kg				
(Cont.) TRT	1 TO	461	461	R: CELLULITIS (LEFT CHEST MEDIPORT) S: Infections and infestations P: 医療機器使用部位蜂巣炎 L: Medical device site cellulitis	E: 485 O: No L: 25 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42822) TRT: Placebo + Azacitidine								
55203	Age:7[redacted]	Sex:Female Race:WHITE Weight:77.1 kg						
	TRT	1 TO	3	3	R: BACTERIAL ACUTE BRONCHIAL INFECTION S: Infections and infestations P: 細菌性気管支炎 L: Bronchitis bacterial	E: 14 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42822) TRT: Placebo + Azacitidine							
55203	Age:7[redacted] Sex:Female Race:WHITE Weight:77.1 kg						
(Cont.)	TRT	1 TO	63	63	R: WORSENING URINARY TRACT INFECTION - KLEBSIELLA PNEUMONIAE S: Infections and infestations P: クレブシエラ感染 L: Klebsiella pneumoniae infection	E: 68 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: URINE SEDIMENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42822) TRT: Placebo + Azacitidine							
55203	Age:7[redacted] Sex:Female Race:WHITE Weight:77.1 kg						
(Cont.)	TRT	1 TO Day 63	63	R: WORSENING URINARY TRACT INFECTION - KLEBSIELLA PNEUMONIAE S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 68 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: URINE SEDIMENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42822) TRT: Placebo + Azacitidine							
55203	Age:7[redacted] Sex:Female Race:WHITE Weight:77.1 kg						
	(Cont.)	TRT 1 TO	677	677	R: URINARY INFECTION S: Infections and infestations P: 尿路感染 L: Urinary infection	E: 692 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CORYNEBACTERIUM UREALYTICUM V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Placebo + Azacitidine							
26101# Age:7[redacted] Sex:Male Race:WHITE Weight:93.3 kg							
		TRT 1 TO 112	112	112	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 118 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine								
26102 Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg								
	TRT	1 TO	8	8	R: CREATININE INCREASED S: Investigations P: 血中クレアチニン増加 L: Creatinine increased	E: 10 O: No L: 3 Days I: No	G: Grade 1 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine							
26102 Age:7[redacted]	Sex:Female	Race:WHITE	Weight:85.7 kg				
(Cont.)	TRT	1 TO 14	14	R: POSITIVE ESCHERICHIA COLI URINARY TRACT INFECTION S: Infections and infestations P: 大腸菌性尿路感染 L: Escherichia urinary tract infection	E: 18 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine							
26102 Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
(Cont.) TRT	1 TO	25	25	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 29 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine							
26102 Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
		(Cont.) TRT 1 TO	59	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 70 O: No L: 12 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			89	R: LUNG INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 105 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine							
26102 Age:7[redacted]	Sex:Female	Race:WHITE	Weight:85.7 kg				
(Cont.) TRT	1 TO	92	92	R: URINARY TRACT INFECTION (ESCHERICHIA COLI) S: Infections and infestations P: 大腸菌性尿路感染 L: Escherichia urinary tract infection	E: 105 O: No L: 14 Days I: Yes	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110497) TRT: Venetoclax 400 mg QD + Azacitidine							
26102 Age:7[redacted] Sex:Female Race:WHITE Weight:85.7 kg							
(Cont.)	TRT	1 TO	150	150	R: ESCHERICHIA COLI SEPTICAEMIA S: Infections and infestations P: 大腸菌性敗血症 L: Septicaemia due to Escherichia coli (E. coli)	E: 156 O: No L: 7 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (993628) TRT: Venetoclax 400 mg QD + Azacitidine								
38101 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:87.4 kg					
	TRT	1 TO	170	170	R: ISCHEMIC COLITIS S: Gastrointestinal disorders P: 虚血性大腸炎 L: Ischemic colitis	E: 175 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BASAL CONDITION (AML) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110840) TRT: Venetoclax 400 mg QD + Azacitidine								
38701# Age:8[redacted] Sex:Male Race:WHITE Weight:80.0 kg								
		POST 18 TO 33	4	21	R: ACUTE RENAL FAILURE S: Renal and urinary disorders P: 急性腎障害 L: Acute renal failure	E: 31 O: No L: 11 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE GASTROENTERITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110840) TRT: Venetoclax 400 mg QD + Azacitidine							
38701#	Age:8[redacted] Sex:Male Race:WHITE Weight:80.0 kg						
	(Cont.)	POST 18 TO 33	4	21	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 32 O: No L: 12 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ACUTE GASTROENTERITIS AND ACUTE RENAL FAILURE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110840) TRT: Venetoclax 400 mg QD + Azacitidine							
38701#	Age:8[redacted] Sex:Male Race:WHITE Weight:80.0 kg						
	(Cont.)	POST 18 TO 33	4	21	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 31 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION VIRAL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (131649) TRT: Placebo + Azacitidine							
26201#	Age:7[redacted] Sex:Male Race:WHITE Weight:64.5 kg						
	TRT	1 TO 437	1	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 37 O: No L: 37 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			83	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 172 O: No L: 90 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (131649) TRT: Placebo + Azacitidine							
26201# Age:7[redacted] Sex:Male Race:WHITE Weight:64.5 kg							
(Cont.) TRT		1 TO 437	190	190	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 338 O: No L: 149 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			197	197	R: INCREASED CRP S: Investigations P: C一反応性蛋白増加 L: CRP increased	E: 225 O: No L: 29 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Placebo + Azacitidine								
80004#	Age:6[redacted] Sex:Male Race:ASIAN Weight:80.2 kg							
	TRT	1 TO 75	51	51	R: WORSENING FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 56 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THERE WAS NO SIGN OF INFECTION. DUE TO UNDERLYING DISEASE(AML) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Placebo + Azacitidine								
80004# Age:6[redacted] Sex:Male Race:ASIAN Weight:80.2 kg								
	(Cont.) TRT	1 TO 75	62	62	R: ACUTE ISCHEMIC STROKE S: Nervous system disorders P: 虚血性脳卒中 L: Ischemic stroke	E: 95 O: No L: 34 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO DECREASED PLATELET OF UNDERLYING DISEASE(AML) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Placebo + Azacitidine							
80004#	Age:6[redacted] Sex:Male Race:ASIAN Weight:80.2 kg						
(Cont.)	TRT	1 TO 75	75	75	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 95 O: No L: 21 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BECAUSE OF UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine							
80001# Age:5[redacted] Sex:Male Race:ASIAN Weight:62.0 kg							
	TRT	1 TO 64	19	19	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 30 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MRSA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine							
80001#	Age:5[redacted] Sex:Male Race:ASIAN Weight:62.0 kg						
	(Cont.)	POST 65 TO 168	2	66	R: PNEUMONIC CONSOLIDATION S: Respiratory, thoracic and mediastinal disorders P: 肺硬化 L: Lung consolidation	E: 167 O: No L: 102 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine								
80003#	Age:7[redacted] Sex:Female Race:ASIAN Weight:46.5 kg							
		TRT	1 TO 510	136	136	R: ESCHERICHIA COLI SEPTIC SHOCK. S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 153 O: No L: 18 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO UNDERLYING DISEASE(AML), V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine								
80003#	Age:7[redacted] Sex:Female Race:ASIAN Weight:46.5 kg							
	(Cont.) TRT	1 TO 510	136	136	R: ESCHERICHIA COLI SEPTIC SHOCK. S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 153 O: No L: 18 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO UNDERLYING DISEASE(AML), V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine							
80003# Age:7[redacted] Sex:Female Race:ASIAN Weight:46.5 kg							
(Cont.) TRT	1 TO 510	198	198	R: RHINOVIRUS INFECTION S: Infections and infestations P: ライノウイルス感染 L: Rhinovirus infection	E: 204 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BECAUSE OF ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine 80003# Age:7[redacted] Sex:Female Race:ASIAN Weight:46.5 kg							
		(Cont.) TRT 1 TO 510	245	245	R: ESCHERICHIA COLI INFECTION S: Infections and infestations P: 大腸菌感染 L: Escherichia coli infection	E: 256 O: No L: 12 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ESCHERICHIA COLI WAS DETECTED IN THE SUBJECT'S BLOOD AND URINE CULTURES. NO OTHER CAUSE WAS DETECTED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111505) TRT: Venetoclax 400 mg QD + Azacitidine								
80003#	Age:7[redacted] Sex:Female Race:ASIAN Weight:46.5 kg							
(Cont.)		TRT	1 TO 510	332	332	R: BACK SPRAIN S: Injury, poisoning and procedural complications P: 靭帯捻挫 L: Back sprain	E: 338 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SHE HURT HER BACK WHEN SHE TRIED TO LIFT SOMETHING HEAVY UP. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Placebo + Azacitidine							
93604# Age:7[redacted] Sex:Male Race:ASIAN Weight:62.0 kg							
	TRT	1 TO 334	15	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: Yes I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			115	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 133 O: No L: 19 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IT MAY CAUSEOF MEDICAL HISTORY OF G4 NEUTROPENIA AND G3 LEUKOPENIA R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Placebo + Azacitidine							
93604#	Age:7[redacted] Sex:Male Race:ASIAN Weight:62.0 kg						
(Cont.)	TRT	1 TO 334	200	200	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 267 O: No L: 68 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION AT UNKNOWN SITE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Placebo + Azacitidine							
93604#	Age:7[redacted] Sex:Male Race:ASIAN Weight:62.0 kg						
(Cont.)		TRT 1 TO 334	200	200	R: SKIN INFECTION(BILATERAL MEDIAL THIGH) S: Infections and infestations P: 皮膚感染 L: Skin infection	E: 267 O: No L: 68 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Venetoclax 400 mg QD + Azacitidine							
93605 Age:7[redacted]	Sex:Female	Race:ASIAN	Weight:51.0 kg				
	TRT	1 TO	30	30	R: BLOOD TRANSFUSION REACTION S: Injury, poisoning and procedural complications P: 輸血反応 L: Transfusion reaction	E: 31 O: No L: 2 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE SUBBJECT HAD PACKED RED BLOOD CELLS TRANSFUSION IN THE NIGHT OF 08-JAN-2019 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Venetoclax 400 mg QD + Azacitidine							
93608#	Age:7[redacted] Sex:Male Race:ASIAN Weight:60.0 kg						
		POST 20 TO 41	1	20	R: CEREBRAL INFARCTION S: Nervous system disorders P: 脳梗塞 L: Cerebral infarction	E: 39 O: No L: 20 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING O: LACUNAR INFARCTION,AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Venetoclax 400 mg QD + Azacitidine							
93608#	Age:7[redacted] Sex:Male Race:ASIAN Weight:60.0 kg						
		(Cont.) POST 20 TO 41	6	25 R: HYPERNATREMIA S: Metabolism and nutrition disorders P: 高ナトリウム血症 L: Hypernatremia	E: 40 O: No L: 16 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, LIFE THREATENING O: CEREBRAL INFARCTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			8	27 R: HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 40 O: No L: 14 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING O: CEREBRAL INFARCTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115029) TRT: Venetoclax 400 mg QD + Azacitidine							
93609	Age:6[redacted] Sex:Male Race:ASIAN Weight:63.5 kg						
	TRT	1 TO	167	167	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 170 O: No L: 4 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53098) TRT: Placebo + Azacitidine							
86604	Age:7[redacted] Sex:Male Race:ASIAN Weight:57.0 kg						
	TRT	1 TO 386	386	R: DEPRESSED LEVEL OF CONSCIOUSNESS S: Nervous system disorders P: 意識レベルの低下 L: Depressed level of consciousness	O: No I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE POSSIBILITY OF TEMPORARY DECLINE IN DEPRESSED LEVEL OF CONSCIOUSNESS DUE TO DEHYDRATION IS SUSPECTED. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine								
86201#	Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg							
	TRT	1 TO 371	34	34	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 43 O: No L: 10 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			138	138	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 152 O: No L: 15 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine							
86201# Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg							
(Cont.)	TRT	1 TO 371	196	196	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 249 O: No L: 54 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine							
86201#	Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg						
(Cont.)		TRT 1 TO 371	289	289	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 297 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine							
86201# Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg							
(Cont.)	TRT	1 TO 371	321	321	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 344 O: No L: 24 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine								
86201#	Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg							
		(Cont.) TRT	1 TO 371	356	356	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	O: Yes I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine								
86201#	Age:7[redacted] Sex:Male Race:ASIAN Weight:57.7 kg							
	(Cont.)	POST	372 TO 428	11	382	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine							
86203 Age:8[redacted]	Sex:Female	Race:ASIAN	Weight:60.6 kg				
	TRT	1 TO	179	179	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 186 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53099) TRT: Venetoclax 400 mg QD + Azacitidine							
86204	Age:7[redacted] Sex:Female Race:ASIAN Weight:52.9 kg						
	TRT	1 TO	74	R: SEPSIS(STAPHYLOCOCCAL) S: Infections and infestations P: ブドウ球菌性敗血症 L: Staphylococcal sepsis	E: 85 O: No L: 12 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118823) TRT: Placebo + Azacitidine								
86002#	Age:8[redacted] Sex:Female Race:ASIAN Weight:45.1 kg							
	TRT	1 TO 16	1	1	R: ACUTE SUPPURATIVE THYROIDITIS S: Infections and infestations P: 感染性甲状腺炎 L: Infectious thyroiditis	E: 51 O: No L: 51 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION OF THE THYROID GLAND WHICH OCCURRED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118823) TRT: Placebo + Azacitidine							
86002#	Age:8[redacted] Sex:Female Race:ASIAN Weight:45.1 kg						
(Cont.)	TRT	1 TO 16	15	15	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: DIALYSIS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113476) TRT: Placebo + Azacitidine								
26003#	Age:8[redacted] Sex:Female Race:WHITE Weight:60.4 kg							
		TRT 1 TO 57	32	32	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 58 O: No L: 27 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113476) TRT: Placebo + Azacitidine								
26003# Age:8[redacted] Sex:Female Race:WHITE Weight:60.4 kg								
(Cont.) TRT		1 TO 57	37	37	R: ISCHEMIC HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	E: 70 O: No L: 34 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CORONARY ARTERY DISEASE, FEVER/INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113476) TRT: Placebo + Azacitidine							
26003#	Age:8[redacted] Sex:Female Race:WHITE Weight:60.4 kg						
	(Cont.)	POST 58 TO 72	4	61	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 70 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, LONG HOSPITALIZATION, DECREASED IMMUNITY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113476) TRT: Venetoclax 400 mg QD + Azacitidine								
26001 Age:7[redacted] Sex:Female Race:WHITE Weight:82.3 kg								
	TRT	1 TO	17	17	R: DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Diverticulitis	E: 30 O: No L: 14 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			75	75	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 79 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113476) TRT: Venetoclax 400 mg QD + Azacitidine							
26001	Age:7[redacted] Sex:Female Race:WHITE Weight:82.3 kg						
(Cont.)	TRT	1 TO 321	321	R: DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Diverticulitis	E: 330 O: No L: 10 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA,DIVERTICULITIS 2016&2017 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (133536) TRT: Venetoclax 400 mg QD + Azacitidine								
52602#	Age:8[redacted] Sex:Male Race:WHITE Weight:60.0 kg							
		TRT	1 TO 45	45	45	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 48 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONIA HAS NOT IMPROVED, THE GENERAL CONDITION OF THE PATIENT HAS DETERIORATED DUE TO PNEUMONIA. THE PATIENT DID NOT HAS LUNG CANCER.POOR GENERAL CONDITION. AND UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Placebo + Azacitidine								
38001#	Age:8[redacted] Sex:Male Race:WHITE Weight:77.5 kg							
	TRT	1 TO 63	22	22	R: PERICORONITIS S: Infections and infestations P: 歯冠周囲炎 L: Pericoronitis	E: 49 O: No L: 28 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VIRAL INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Placebo + Azacitidine								
38001#	Age:8[redacted] Sex:Male Race:WHITE Weight:77.5 kg							
(Cont.)	TRT	1 TO 63	44	44	R: ALVEOLITIS POST EXODONTIA S: Infections and infestations P: 歯槽骨炎 L: Alveolitis of jaw	E: 49 O: No L: 6 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INADEQUATE ORGANIZATION OF THE POST-EXODONTIA COCCI V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Placebo + Azacitidine							
38001# Age:8[redacted] Sex:Male Race:WHITE Weight:77.5 kg							
(Cont.)	TRT	1 TO 63	51	51	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 64 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Other: VENETOCLAX DOSE REDUCED BUT NOT FOR THE AE, BECAUSE POSACONAZOLE WAS ADMINISTRATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA SINCE THE DIAGNOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Placebo + Azacitidine							
38003#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.3 kg						
		TRT 1 TO 5	5	R: SEVERE ACUTE RESPIRATORY FAILURE, IN A PATIENT WITH PNEUMONIA RHINOVIRUS S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 16 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFLAMMATORY / INFECTIOUS PROCESS WITH SIGNS SUGGESTING POSSIBLE CARDIAC DECOMPENSATION. THE PROCESS IS INFECTIOUS: PCR RHINOVIRUS POSITIVE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Placebo + Azacitidine								
38003#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.3 kg							
	(Cont.)	TRT 1 TO 5	5	5	R: SEVERE ACUTE RESPIRATORY FAILURE, IN A PATIENT WITH PNEUMONIA RHINOVIRUS S: Infections and infestations P: ライノウイルス感染 L: Rhinovirus infection	E: 16 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFLAMMATORY / INFECTIOUS PROCESS WITH SIGNS SUGGESTING POSSIBLE CARDIAC DECOMPENSATION. THE PROCESS IS INFECTIOUS: PCR RHINOVIRUS POSITIVE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Venetoclax 400 mg QD + Azacitidine								
38002#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
		TRT	1 TO 210	48	48	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 68 O: No L: 21 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA SINCE STUDY INITIAL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Venetoclax 400 mg QD + Azacitidine								
38002#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
		(Cont.) TRT	1 TO 210	83	83	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 94 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: 0 NEUTHOPHILS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Venetoclax 400 mg QD + Azacitidine							
38002# Age:7[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
(Cont.)	TRT	1 TO 210	113	113	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 126 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: 0 NEUTHOPHILS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Venetoclax 400 mg QD + Azacitidine							
38002#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.6 kg						
	(Cont.)	TRT 1 TO 210	164	164	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 193 O: No L: 30 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110899) TRT: Venetoclax 400 mg QD + Azacitidine								
38002#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
		(Cont.) TRT	1 TO 210	202	202	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 232 O: No L: 31 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Placebo + Azacitidine							
28102#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.7 kg						
	TRT	1 TO 7 Day 3	3	R: PLEURAL EFFUSION BILATERAL S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Bilateral pleural effusion	E: 9 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Placebo + Azacitidine							
28102#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.7 kg						
(Cont.)		TRT 1 TO 7	4	4	R: UREMIA S: Renal and urinary disorders P: 高窒素血症 L: Uremia	E: 9 O: No L: 6 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: Yes

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Venetoclax 400 mg QD + Azacitidine								
28101# Age:8[redacted] Sex:Female Race:WHITE Weight:78.5 kg								
	TRT	1 TO 89	36	36	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 75 O: No L: 40 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Other: NEXT CYCLE (CYCLE 2) IS DELAYED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Venetoclax 400 mg QD + Azacitidine							
28101# Age:8[redacted] Sex:Female Race:WHITE Weight:78.5 kg							
(Cont.)	TRT	1 TO 89	36	36	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 42 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: CYCLE 2 DELAYED O: Multiple: MEDICAL PROCEDURE, X-RAY, CHEST. BLOOD AND URINE CULTURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Venetoclax 400 mg QD + Azacitidine							
28101# Age:8[redacted] Sex:Female Race:WHITE Weight:78.5 kg							
(Cont.)	TRT	1 TO 89 Day 71	71	R: WEIGHT LOSS S: Investigations P: 体重減少 L: Weight loss	E: 93 O: No L: 23 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: FOCUS ON NUTRITION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112073) TRT: Venetoclax 400 mg QD + Azacitidine							
28101# Age:8[redacted] Sex:Female Race:WHITE Weight:78.5 kg							
(Cont.) TRT	1 TO 89	89	89	R: BRAIN CT SCANS HYPERDENSE CHANGES S: Investigations P:頭部コンピュータ断層撮影異常 L: Computerised tomogram head abnormal	E: 93 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PROGRESSION OF DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53182) TRT: Placebo + Azacitidine								
15102# Age:6[redacted] Sex:Male Race:WHITE Weight:134.0 kg								
	TRT	1 TO 12	12	12	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 21 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53182) TRT: Venetoclax 400 mg QD + Azacitidine								
15101#	Age:8[redacted] Sex:Male Race:WHITE Weight:75.0 kg							
	TRT	1 TO 220	217	217	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 219 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53182) TRT: Venetoclax 400 mg QD + Azacitidine								
15103#	Age:7[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:65.6 kg							
	TRT	1 TO 29	25	25	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 26 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110491) TRT: Venetoclax 400 mg QD + Azacitidine							
23201# Age:8[redacted] Sex:Male Race:WHITE Weight:85.5 kg							
	TRT	1 TO 206	35	35	R: INFLUENSA B S: Infections and infestations P: インフルエンザ L: Influenza B virus infection	E: 41 O: No L: 7 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONTAMINATED FROM ORDINARY SOCIETY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110491) TRT: Venetoclax 400 mg QD + Azacitidine								
23201#	Age:8[redacted] Sex:Male Race:WHITE Weight:85.5 kg							
		(Cont.) POST	207 TO 240	4	210	R: E COLI SEPTEKEMIA S: Infections and infestations P: 大腸菌性敗血症 L: Septicemia due to Escherichia coli (E. coli)	E: 227 O: No L: 18 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELAPSED AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
					210	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 227 O: No L: 18 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110491) TRT: Venetoclax 400 mg QD + Azacitidine								
23201#	Age:8[redacted] Sex:Male Race:WHITE Weight:85.5 kg							
	(Cont.)	POST	207 TO 240	30	236	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 239 O: No L: 4 Days I: Yes	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELAPSED AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53275) TRT: Venetoclax 400 mg QD + Azacitidine								
15401#	Age:7[redacted] Sex:Male Race:WHITE Weight:98.3 kg							
		TRT 1 TO 255	255	255	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 269 O: No L: 15 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53275) TRT: Venetoclax 400 mg QD + Azacitidine								
15401#	Age:7[redacted] Sex:Male Race:WHITE Weight:98.3 kg							
	(Cont.) TRT	1 TO 255	255	255	R: NAUSEA S: Gastrointestinal disorders P: 悪心 L: Nausea	E: 269 O: No L: 15 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: PATIENT HOSPITALIZED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	256 TO 270	2	257	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 268 O: No L: 12 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING O: DISEASE RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53275) TRT: Venetoclax 400 mg QD + Azacitidine								
15401#	Age:7[redacted] Sex:Male Race:WHITE Weight:98.3 kg							
	(Cont.)	POST	256 TO 270	13	268	R: ENCEPHALOPATHY S: Nervous system disorders P: 脳症 L: Encephalopathy	E: 269 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING O: SEPSIS, AKI, RESPIRATORY FAILURE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53275) TRT: Venetoclax 400 mg QD + Azacitidine								
15401#	Age:7[redacted] Sex:Male Race:WHITE Weight:98.3 kg							
	(Cont.)	POST 256 TO 270	13	268	R: RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Respiratory failure	E: 269 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, INTUBATION	S: Yes, LIFE THREATENING O: SEPSIS, UNDERLYING AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Placebo + Azacitidine							
40702# Age:7[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	TRT	1 TO 49 Day 25	25	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 40 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Placebo + Azacitidine								
40702#	Age:7[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
(Cont.)		TRT 1 TO 49	40	40	R: SEPTICAEMIA S: Infections and infestations P: 敗血症 L: Septicaemia	E: 49 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Venetoclax 400 mg QD + Azacitidine							
40701# Age:8[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	TRT	1 TO 314	17	17	R: PNEUMONIA PERIHILAR RIGHT S: Infections and infestations P: 肺炎 L: Pneumonia	E: 28 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUCAEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Venetoclax 400 mg QD + Azacitidine							
40701# Age:8[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	(Cont.) TRT	1 TO 314	104	104	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 114 O: No L: 11 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DOSE REDUCED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Venetoclax 400 mg QD + Azacitidine							
40701#	Age:8[redacted] Sex:Male Race:WHITE Weight:77.0 kg						
	(Cont.) TRT	1 TO 314	115	115	R: CARDIAC DECOMPENSATION S: Cardiac disorders P: 心不全 L: Decompensation cardiac	E: 121 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LASIX WAS INTERRUPTED SINCE MONTHS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Venetoclax 400 mg QD + Azacitidine							
40701# Age:8[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
(Cont.) TRT	1 TO 314	188	188	R: PNEUMONIA RIGHT S: Infections and infestations P: 肺炎 L: Pneumonia	E: 204 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		312	312	R: SEPTICAEMIA S: Infections and infestations P: 敗血症 L: Septicaemia	E: 323 O: No L: 12 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (999763) TRT: Venetoclax 400 mg QD + Azacitidine							
40703# Age:7[redacted] Sex:Male Race:WHITE Weight:70.5 kg							
	TRT	1 TO 97	57	57	R: FEBRILE NEUTROPENIE S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 108 O: No L: 52 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine								
42203#	Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg							
		TRT 1 TO 13	12	12	R: ACUTE RESPIRATORY DISTRESS SYNDROM S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸窮迫症候群 L: Acute respiratory distress syndrome	E: 14 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNKNOWN ORIGIN PNEUMOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine								
42204# Age:8[redacted] Sex:Male Race:WHITE Weight:65.0 kg								
	TRT	1 TO 70	15	15	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 40 O: No L: 26 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42204# Age:8[redacted] Sex:Male Race:WHITE Weight:65.0 kg							
(Cont.)	TRT	1 TO 70	21	21	R: BILATERAL PLEURAL EFFUSION S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Bilateral pleural effusion	E: 31 O: No L: 11 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PLEURAL EFFUSION WAS LINKED TO A PICTURE OF ANASARCA SECONDARY TO UNDERNUTRITION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42204# Age:8[redacted] Sex:Male Race:WHITE Weight:65.0 kg							
(Cont.)	TRT	1 TO 70	22	22	R: IATROGENIC CONFUSIONAL SYNDROME S: Psychiatric disorders P: 錯乱状態 L: Confusional state	E: 26 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT MEDICATION: AMBISOME (START DATE 03-FEB-2018 AND END DATE 09-FEB-2018 CF "CONCOMITANT MEDICATIONS FORM". TREATMENT WAS STOPPED BECAUSE OF THIS AE. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42204# Age:8[redacted] Sex:Male Race:WHITE Weight:65.0 kg							
(Cont.) TRT	1 TO 70	32	32	R: RIGHT PLEURAL EFFUSION S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Pleural effusion	E: 78 O: No L: 47 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PLEURAL EFFUSION WAS LINKED TO A PICTURE OF ANASARCA SECONDARY TO UNDERNUTRITION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42204# Age:8[redacted] Sex:Male Race:WHITE Weight:65.0 kg							
(Cont.) TRT	1 TO 70	36	36	R: WORSENING OF GENERAL CONDITION S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 77 O: No L: 42 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: OLD AGE AND DECLINING NEURAL FUNCTIONS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42206# Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
	TRT	1 TO 262	26	26 R: MUCOSITIS WITH VESICULAR ULCERATION OF THE PALATE S: General disorders and administration site conditions P: 粘膜の炎症 L: Mucositis	E: 31 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				26 R: MUCOSITIS WITH VESICULAR ULCERATION OF THE PALATE S: Gastrointestinal disorders P: 口蓋潰瘍 L: Palatal ulcer	E: 31 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42206# Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
(Cont.) TRT	1 TO 262	27	27	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 31 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine							
42206#	Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg						
	(Cont.) TRT	1 TO 262	27	27	R: PRIMARY HERPES INFECTION OROPHARYNGEAL S: Infections and infestations P: 口腔ヘルペス L: Oral herpes	E: 31 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine								
42206#	Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
	(Cont.)	POST 263 TO 408	12	274	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 290 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				274	R: INFECTIOUS PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 290 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111789) TRT: Venetoclax 400 mg QD + Azacitidine								
42206#	Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
	(Cont.)	POST	263 TO 408	27	289	R: E. COLI SEPTIC SHOCK S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 289 O: No L: 1 Day I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
					289	R: E. COLI SEPTIC SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 289 O: No L: 1 Day I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110535) TRT: Venetoclax 400 mg QD + Azacitidine								
44101#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.0 kg							
		TRT	1 TO 45	21	21	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 28 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110535) TRT: Venetoclax 400 mg QD + Azacitidine							
44101#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.0 kg						
		(Cont.) POST 46 TO 61	3	48	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 56 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			4	49	R: CANDIDOSIS SEPSIS S: Infections and infestations P: カンジダ性敗血症 L: Candida sepsis	E: 55 O: No L: 7 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine								
74001#	Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
		TRT	1 TO 49	3	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 10 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT WAS NEUTROPENIC PRIOR TO STUDY ENTRY AND THE PROLONGED NEUTROPENIA IS THE PROBABLE CAUSE FOR PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine								
74001# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg								
(Cont.) TRT		1 TO 49	12	12	R: ACUTE CORONARY SYNDROM S: Cardiac disorders P: 急性冠動脈症候群 L: Acute coronary syndrome	E: 12 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, ECHOCARDIOGRAM	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OTHER RISK FACTORS:AGE,SEX,HYPERTENSION. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine								
74001#	Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
(Cont.)		TRT 1 TO 49	18	18	R: ACUTE MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Acute myocardial infarction	E: 18 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: RISK FACTORS:AGE,SEX,HYPERTENSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine							
74001# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
(Cont.) TRT		1 TO 49	21	21	R: CEREBRO VASCULAR ACCIDENT S: Nervous system disorders P: 脳血管発作 L: Accident cerebrovascular	E: 49 O: No L: 29 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: LEFT HEART CHARACTERISATION,HYPERTENSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine							
74001# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
(Cont.) TRT		1 TO 49	38	38	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 49 O: No L: 12 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine							
74001# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
(Cont.) TRT		1 TO 49	44	44	R: NOSE FRACTURE S: Injury, poisoning and procedural complications P: 顔面骨骨折 L: Fractured nose	E: 49 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PAST CVA. PATIENT MAINLY CONFUSED DUE TO CVA AND ALSO TREATED WITH OPIATE TARGIN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (116710) TRT: Placebo + Azacitidine							
74001# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
(Cont.) TRT		1 TO 49 Day 44	44	R: FALL S: Injury, poisoning and procedural complications P: 転倒 L: Fall	E: 44 O: No L: 1 Day I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PAST CVA. PATIENT MAINLY CONFUSED DUE TO CVA AND ALSO TREATED WITH OPIATE TARGIN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Placebo + Azacitidine							
70201# Age:8[redacted] Sex:Male Race:WHITE Weight:70.0 kg							
	TRT	1 TO 2	2	R: WORSENING OF PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia aggravated	E: 50 O: No L: 49 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONIA IN MEDICAL HISTORY AND AML DISEASE AND NATURE OF PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Placebo + Azacitidine							
70205# Age:7[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	TRT	1 TO 16	14	14	R: WORSENING OF GENERAL CONDITION S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 17 O: No L: 4 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine								
70202# Age:6[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 64	17	17	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 27 O: No L: 11 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70202# Age:6[redacted] Sex:Male Race:WHITE Weight:70.0 kg							
	(Cont.) TRT	1 TO 64	27	27	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 63 O: No L: 37 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO THE GENERAL COURSE OF THE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70202# Age:6[redacted] Sex:Male Race:WHITE Weight:70.0 kg							
(Cont.)	TRT	1 TO 64	64	64	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 141 O: No L: 78 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: CYCLE2 POSTPONED DUE AE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC FEVER-INDUCED INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine								
70204#	Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg							
	TRT	1 TO 11	1	1	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 57 O: No L: 57 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO DISEASE COURSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70204# Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg							
(Cont.)	TRT	1 TO 11	10	10	R: WORSENING OF GENERAL CONDITION S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 57 O: No L: 48 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70204#	Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg						
	(Cont.)	POST 12 TO 58	18	29	R: FUNGAL PNEUMONIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 57 O: No L: 29 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT HAD NEUTROPENIC FEVER AND GENERAL CONDITION DETERIORATION. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70208#	Age:7[redacted] Sex:Female Race:WHITE Weight:86.0 kg						
		TRT 1 TO 175	75	R: BACTERIAL INFECTION IN BLOOD S: Infections and infestations P: 菌血症 L: Bacteremia	E: 217 O: No L: 143 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70208# Age:7[redacted] Sex:Female Race:WHITE Weight:86.0 kg							
(Cont.)	TRT	1 TO 175	75	75	R: BACTERIAL INFECTION IN URINE S: Infections and infestations P: 細菌性尿路感染 L: Urinary tract infection bacterial	E: 217 O: No L: 143 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70208# Age:7[redacted] Sex:Female Race:WHITE Weight:86.0 kg							
(Cont.)	TRT	1 TO 175	84	84	R: FUNGAL PNEUMONIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 217 O: No L: 134 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BONE MARROW APLASIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (98758) TRT: Venetoclax 400 mg QD + Azacitidine							
70208#	Age:7[redacted] Sex:Female Race:WHITE Weight:86.0 kg						
		(Cont.) POST 176 TO 218	12	187	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 217 O: No L: 31 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine								
14308#	Age:7[redacted] Sex:Female Race:WHITE Weight:73.3 kg							
	TRT	1 TO 84	13	13	R: BILATERAL PLEURAL EFFUSION S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Bilateral pleural effusion	E: 27 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLY PULMONARY EDEMA THAT EXISTED AS PART OF MEDICAL HISTORY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine							
14308#	Age:7[redacted] Sex:Female Race:WHITE Weight:73.3 kg						
(Cont.)		TRT 1 TO 84	26	26	R: ACUTE KIDNEY INJURY S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 36 O: No L: 11 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE CAUSE IS EFFECT OF VANCOMYCIN AND/OR ACYCLOVIR. EACH HAS BEEN SWITCHED OR DISCONTINUED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine								
14309# Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg								
	TRT	1 TO 103	2	2	R: HYPOXIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Hypoxic respiratory failure	E: 4 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PULMONARY EDEMA SECONDARY TO FLUID OVERLOAD V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine								
14309# Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg								
(Cont.)	TRT	1 TO 103	24	24	R: CONSTIPATION S: Gastrointestinal disorders P: 便秘 L: Constipation	E: 27 O: No L: 4 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			32	32	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 42 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine							
14309# Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg							
(Cont.) TRT	1 TO 103	32	32	R: SUPRAVENTRICULAR TACHYCARDIA S: Cardiac disorders P: 上室性頻脈 L: Supraventricular tachycardia	E: 35 O: No L: 4 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine								
14309# Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg								
(Cont.) TRT		1 TO 103	62	62	R: CONSTIPATION S: Gastrointestinal disorders P: 便秘 L: Constipation	E: 70 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS HAD HISTORY OF CONSTIPATION AND RECENT ILEUS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine							
14309# Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg							
(Cont.)	TRT	1 TO 103	102	102	R: SEVERE HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 116 O: No L: 15 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Placebo + Azacitidine								
14309#	Age:8[redacted] Sex:Male Race:BLACK OR AFRICAN AMERICAN Weight:86.9 kg							
	(Cont.)	POST 104 TO 180	3	106	R: ACUTE RENAL FAILURE S: Renal and urinary disorders P: 急性腎障害 L: Acute renal failure	E: 124 O: No L: 19 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POSSIBLY RELATED TO UNDERLYING CARDIAC ISSUES V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine								
14301	Age:7[redacted] Sex:Female Race:WHITE Weight:56.7 kg							
		TRT 1 TO	1	1	R: CONSTIPATION S: Gastrointestinal disorders P: 便秘 L: Constipation	E: 13 O: No L: 13 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OPOID USE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			25	25	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 31 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine							
14301	Age:7[redacted] Sex:Female Race:WHITE Weight:56.7 kg						
	(Cont.) TRT	1 TO 474	474	R: BOWEL OBSTRUCTION S: Gastrointestinal disorders P: 腸閉塞 L: Bowel obstruction	E: 477 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OBSTRUCTION IS LIKELY RELATED TO ADHESION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine								
14301	Age:7[redacted] Sex:Female Race:WHITE Weight:56.7 kg							
(Cont.)	TRT	1 TO	628	628	R: ALTERED MENTAL STATUS S: Psychiatric disorders P: 精神状態変化 L: Mental status changes	E: 631 O: No L: 4 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POLYPHARMACY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine							
14306# Age:6[redacted] Sex:Female Race:WHITE Weight:69.9 kg							
	TRT	1 TO 20	12	12	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 14 O: No L: 3 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine							
14306# Age:6[redacted] Sex:Female Race:WHITE Weight:69.9 kg							
(Cont.)	TRT	1 TO 20	20	20	R: MULTIFOCAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 48 O: No L: 29 Days I: No	D: No G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine								
14306#	Age:6[redacted] Sex:Female Race:WHITE Weight:69.9 kg							
	(Cont.)	POST	21 TO 643	12	32	R: TORSADE DE POINTES S: Cardiac disorders P: トルサード ド ポアント L: Torsade de pointes	E: 46 O: No L: 15 Days I: No	D: No G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: TORSADES DE POINTES OCCURRED IN SETTING OF HYPOKALEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine									
14312#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.3 kg								
		TRT	1 TO 62	15	15	R: HYPOXIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Hypoxic respiratory failure	E: 49 O: No L: 35 Days I: No	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MULTIFACTORIAL. CONSOLIDATION IN LUNG. POSSIBLY PULMONARY EDEMA AND POSSIBLY GLOBAL LV DYSFUNCTION PRESENT AT BASELINE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (48886) TRT: Venetoclax 400 mg QD + Azacitidine								
14312#	Age:7[redacted] Sex:Female Race:WHITE Weight:69.3 kg							
	(Cont.)	POST	63 TO 72	2	64	R: CELLULITIS OF FINGER S: Infections and infestations P: 蜂巣炎 L: Cellulitis of finger	E: 71 O: No L: 8 Days I: No	D: No G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RED, SWOLLEN, WITH BLOOD COLLECTION ON MEDIAL ASPECT OF THIRD R. DIGIT. LIKELY 2/2 TRAUMA FROM PATIENT ATTEMPT TO REMOVE FOREIGN OBJECT. NO EVIDENCE OF FOREIGN BODY OR OSTEOMYELITIS ON HAND X RAY. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Placebo + Azacitidine								
10603#	Age:6[redacted] Sex:Male Race:WHITE Weight:106.6 kg							
	TRT	1 TO 144	4	4	R: HYPOXIA S: Respiratory, thoracic and mediastinal disorders P: 低酸素症 L: Hypoxia	E: 36 O: No L: 33 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SLEEP APNEA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Placebo + Azacitidine								
10603#	Age:6[redacted] Sex:Male Race:WHITE Weight:106.6 kg							
	(Cont.)	TRT 1 TO 144	29	29	R: DELIRIUM S: Psychiatric disorders P: 譫妄 L: Delirium	E: 36 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: CYCLE 2 START DELAYED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: HYPOXIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Placebo + Azacitidine							
10603#	Age:6[redacted] Sex:Male Race:WHITE Weight:106.6 kg						
	(Cont.)	POST 145 TO 184	28	172	R: CONGESTIVE HEART FAILURE S: Cardiac disorders P: うっ血性心不全 L: Congestive heart failure	E: 178 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: WORSENING OF CHRONIC CONGESTIVE HEART FAILURE. 2NDARY TO CORONARY ARTERY DISEASE , ISCHEMIA CARDIAC EVENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Placebo + Azacitidine							
10603#	Age:6[redacted] Sex:Male Race:WHITE Weight:106.6 kg						
		(Cont.) POST 145 TO 184	28	172	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 182 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Venetoclax 400 mg QD + Azacitidine							
10604 Age:8[redacted] Sex:Male Race:WHITE Weight:104.5 kg							
	TRT	1 TO	1	1	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 202 O: No L: 202 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DOSE REDUCED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Venetoclax 400 mg QD + Azacitidine							
10604 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:104.5 kg				
(Cont.) TRT	1	TO 22	22	R: E COLI BLOOD INFECTION S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 23 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Venetoclax 400 mg QD + Azacitidine							
10604 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:104.5 kg				
(Cont.) TRT	1 TO	84	84	R: ENTEROCOCCUS FAECIUM S: Infections and infestations P: 腸球菌感染 L: Enterococcus faecium infection	E: 85 O: No L: 2 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (128067) TRT: Venetoclax 400 mg QD + Azacitidine								
10604 Age:8[redacted] Sex:Male Race:WHITE Weight:104.5 kg								
(Cont.) TRT	1 TO		379	379	R: COMMUNITY ACQUIRED PNEUMONIA S: Infections and infestations P: 肺炎 L: Community acquired pneumonia	E: 388 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			463	463	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 466 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82114) TRT: Placebo + Azacitidine								
52102#	Age:7[redacted] Sex:Male Race:WHITE Weight:59.0 kg							
		TRT	1 TO 169	169	169	R: PROGRESSION OF PRE-EXISTING CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	E: 214 O: No L: 46 Days I: No	D: No G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGEDHOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INEFFECTIVE TREATMENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82114) TRT: Placebo + Azacitidine								
52103# Age:6[redacted] Sex:Male Race:WHITE Weight:76.0 kg								
		TRT	1 TO 167	20	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 29 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA DUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82114) TRT: Placebo + Azacitidine							
52103#	Age:6[redacted] Sex:Male Race:WHITE Weight:76.0 kg						
	(Cont.)	TRT 1 TO 167	34	34	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 43 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA DUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82114) TRT: Placebo + Azacitidine							
52103#	Age:6[redacted] Sex:Male Race:WHITE Weight:76.0 kg						
	(Cont.)	TRT 1 TO 167	154	154	R: PSEUDOMONAS AERUGINOSA SEPSIS S: Infections and infestations P: シュードモナス性敗血症 L: Pseudomonal sepsis	E: 181 O: No L: 28 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82114) TRT: Venetoclax 400 mg QD + Azacitidine								
52105#	Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
		TRT	1 TO 19	8	8	R: SEPSIS DUE TO CLOSTRIDIUM DIFFICILE S: Infections and infestations P: クロストリジウム性敗血症 L: Clostridium difficile sepsis	E: 18 O: No L: 11 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
	TRT	1 TO 287	2	2	R: WORSENING HEMATURIA S: Renal and urinary disorders P: 血尿 L: Hematuria aggravated	E: 13 O: No L: 12 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, ULTRASOUND OF ABDOMEN/PELVIS, FOLEY CATHETER INSERTION WITH CONTINUOUS BLADDER IRRIGATION. C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
(Cont.)	TRT	1 TO 287	59	59	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 61 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101#	Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg						
(Cont.)		TRT 1 TO 287	60	60	R: SUBDURAL HEMORRHAGE DUE TO TRAUMA OF HITTING HER HEAD. S: Injury, poisoning and procedural complications P: 頭部損傷 L: Head injury	E: 107 O: No L: 48 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS HISTORY OF SUBDURAL HEMATOMA AND THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101#	Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg						
(Cont.)		TRT 1 TO 287	60	60	R: SUBDURAL HEMORRHAGE DUE TO TRAUMA OF HITTING HER HEAD. S: Injury, poisoning and procedural complications P: 硬膜下出血 L: Subdural hemorrhage	E: 107 O: No L: 48 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS HISTORY OF SUBDURAL HEMATOMA AND THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
(Cont.)	TRT	1 TO 287	107	107	R: DIZZINESS CAUSING FALL WITH INJURY S: Nervous system disorders P: 浮動性めまい L: Dizziness	A E: 109 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, CT HEAD, XRAY LEFT HAND, RIGHT SHOULDER XRAY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101#	Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg						
(Cont.)		TRT 1 TO 287	107	107	R: DIZZINESS CAUSING FALL WITH INJURY S: Injury, poisoning and procedural complications P: 転倒 L: Fall	A E: 109 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, CT HEAD, XRAY LEFT HAND, RIGHT SHOULDER XRAY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
(Cont.)	TRT	1 TO 287	107	107	R: DIZZINESS CAUSING A FALL WITH INJURY S: Injury, poisoning and procedural complications P: 損傷 L: Traumatic injury	E: 109 O: No L: 3 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, CT HEAD, XRAY LEFT HAND, RIGHT SHOULDER XRAY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
(Cont.)	TRT	1 TO 287	143	143	R: FUNGAL PNEUMONIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 306 O: No L: 164 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted](111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101#	Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg						
(Cont.)		TRT 1 TO 287	145	145	R: MENINGITIS S: Infections and infestations P: 髄膜炎 L: Meningitis	E: 193 O: No L: 49 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10101# Age:7[redacted] Sex:Female Race:ASIAN Weight:58.7 kg							
(Cont.)	TRT	1 TO 287	236	236	R: ACUTE CHOLECYSTITIS WITHOUT BILIARY OBSTRUCTION S: Hepatobiliary disorders P: 急性胆嚢炎 L: Acute cholecystitis	E: 284 O: No L: 49 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, INSERTION OF CHOLECYSTOSTOMY DRAIN C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULTRASOUND SHOWED THICKENED GALLBLADDER FILLED WITH SLUDGE AND MULTIPLE CALCULI. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine								
10102#	Age:8[redacted] Sex:Female Race:WHITE Weight:57.4 kg							
		POST 30 TO 71	20	49	R: E COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 70 O: No L: 22 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10102# Age:8[redacted] Sex:Female Race:WHITE Weight:57.4 kg							
(Cont.)		POST 30 TO 71	28	57	R: CONGESTIVE HEART FAILURE S: Cardiac disorders P: うっ血性心不全 L: Congestive heart failure	E: 70 O: No L: 14 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: BIPAP C: Yes	S: Yes, LIFE THREATENING O: ACUTE CAUSE IS LIKELY INFECTION AND ANEMIA CAUSING TACHYCARDIA AND PRECIPITATING CHF. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine								
10103	Age:7[redacted] Sex:Male Race:WHITE Weight:79.1 kg							
	TRT	1 TO #	1	1	R: TLS S: Metabolism and nutrition disorders P: 腫瘍崩壊症候群 L: Tumor lysis syndrome	E: 3 O: No L: 3 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, ECHO C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: Yes

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10103 Age:7[redacted] Sex:Male Race:WHITE Weight:79.1 kg							
(Cont.) TRT	1 TO	77	77	R: HEMATURIA WITH CLOT RETENTION S: Renal and urinary disorders P: 血尿 L: Hematuria	E: 179 O: No L: 103 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, URGENT CYSTOSCOPY INDWELLING FOLEY CATHETER INSERTION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MORE LIKELY CAUSE OF HEMATURIA AT THIS TIMEPOINT IS THE TRAUMA TO URETHRA FROM THE FREQUENT INSERTION OF CATHETERS OVER THE LAST SEVERAL WEEKS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10103 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:79.1 kg				
(Cont.) TRT	1	TO	77	77	R: HEMATURIA WITH CLOT RETENTION S: Renal and urinary disorders P: 尿路出血 L: Blood clot in urine	E: 179 O: No L: 103 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, URGENT CYSTOSCOPY INDWELLING FOLEY CATHETER INSERTION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MORE LIKELY CAUSE OF HEMATURIA AT THIS TIMEPOINT IS THE TRAUMA TO URETHRA FROM THE FREQUENT INSERTION OF CATHETERS OVER THE LAST SEVERAL WEEKS. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted].sas

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10103	Age:7[redacted] Sex:Male Race:WHITE Weight:79.1 kg						
(Cont.)	TRT	1 TO 120	120	R: HEART FAILURE WITH LEFT VENTRICULAR DYSFUNCTION S: Cardiac disorders P: 心不全 L: Heart failure	E: 319 O: No L: 200 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUBJECT WAS ON IV NS 2 LITERS PER DAY TO MITIGATE THE RISK HEMATURIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10103	Age:7[redacted] Sex:Male Race:WHITE Weight:79.1 kg						
(Cont.)	TRT	1 TO 120	120	R: HEART FAILURE WITH LEFT VENTRICULAR DYSFUNCTION S: Cardiac disorders P: 左室機能不全 L: Left ventricular dysfunction	E: 319 O: No L: 200 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUBJECT WAS ON IV NS 2 LITERS PER DAY TO MITIGATE THE RISK HEMATURIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111171) TRT: Venetoclax 400 mg QD + Azacitidine							
10103	Age:7[redacted] Sex:Male Race:WHITE Weight:79.1 kg						
(Cont.)	TRT	1 TO	318	318	R: HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 320 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: ORDERED BLOOD CULTURES C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: (DEHYDRATION)DRINKED LESS FLUIDS AND BP MEDICINE THAT WAS DISCONITUED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113456) TRT: Placebo + Azacitidine								
70107#	Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg							
		POST 638 TO 709	11	648	R: PROGRESSION OF PRE-EXISTING MALIGNANCY S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: POST STUDY TREATMENT WAS PLANNED AND STARTED.	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML D?SEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113456) TRT: Venetoclax 400 mg QD + Azacitidine							
70102	Age:7[redacted] Sex:Male Race:WHITE Weight:80.0 kg						
	TRT	1 TO #	232	232	R: URINARY SYSTEM INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 247 O: No L: 16 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT HAD A URINARY TRACT INFECTION BECAUSE HE COULD NOT CONSUME ENOUGH WATER. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113456) TRT: Venetoclax 400 mg QD + Azacitidine							
70108#	Age:7[redacted] Sex:Male Race:WHITE Weight:79.5 kg						
		TRT 1 TO 96 Day 86	86	R: FEBRIL NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 90 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			86	R: ANORECTAL ABSCESS S: Infections and infestations P: 直腸膿瘍 L: Anorectal abscess	E: 102 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113456) TRT: Venetoclax 400 mg QD + Azacitidine							
70108#	Age:7[redacted] Sex:Male Race:WHITE Weight:79.5 kg						
	(Cont.)	POST 97 TO 103	4	100	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 102 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: REFRACTORY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121987) TRT: Placebo + Azacitidine							
47903 Age:7[redacted]	Sex:Female	Race:WHITE	Weight:65.0 kg				
	TRT	1 TO 593	26	26	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 65 O: No L: 40 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121987) TRT: Venetoclax 400 mg QD + Azacitidine							
47902#	Age:7[redacted] Sex:Female Race:WHITE Weight:83.0 kg						
		TRT 1 TO 38	15	15	R: PNEUMONIA KLEBSIELLA PNEUMONIAE S: Infections and infestations P: クレブシエラ菌性肺炎 L: Klebsiella pneumoniae pneumonia	E: 48 O: No L: 34 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THIS EVENT IS OFTEN CAUSED BY CHEMOTHERAPY IN GENERAL FOR THE LOWERING OF IMMUNITY DEFENSES V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (121987) TRT: Venetoclax 400 mg QD + Azacitidine								
47902#	Age:7[redacted] Sex:Female Race:WHITE Weight:83.0 kg							
	(Cont.)	POST	39 TO 146	1	39	R: WATERHOUSE FRIDERICHSEN SYNDROME S: Infections and infestations P: ウォーターハウス・フリーデリクセン症候群 L: Waterhouse-Friderichsen syndrome	E: 56 O: No L: 18 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: SEPSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine								
47004#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
	TRT	1 TO 381	62	62	R: ENTEROBACTER HORMAECHEI PNEUMONIA S: Infections and infestations P:エンテロバクター性肺炎 L: Enterobacter pneumonia	E: 133 O: No L: 72 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine							
47004# Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
(Cont.)	TRT	1 TO 381	235	235	R: LEFT LEG CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 252 O: No L: 18 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA AML ASSOCIATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine							
47004#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
(Cont.)		TRT 1 TO 381	352	352	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 363 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA LINKED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine							
47004#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
(Cont.)	TRT	1 TO 381	371	371	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 394 O: No L: 24 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA AML ASSOCIATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine								
47007#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.5 kg							
	TRT	1 TO 266	7	7	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 22 O: No L: 16 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine								
47008#	Age:8[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
	TRT	1 TO 409	260	260	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 272 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA LINKED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Placebo + Azacitidine							
47008# Age:8[redacted] Sex:Female Race:WHITE Weight:69.6 kg							
(Cont.) TRT		1 TO 409	293	293	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 301 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, CHEST X-RAY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA LINKED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Venetoclax 400 mg QD + Azacitidine								
47001#	Age:7[redacted] Sex:Male Race:WHITE Weight:76.5 kg							
		TRT	1 TO 162	161	161	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 180 O: No L: 20 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE CAUSE OF SAE IS AML PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Venetoclax 400 mg QD + Azacitidine							
47002 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:98.0 kg				
	TRT	1 TO	100	100	R: E. COLI BACTERIEMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 115 O: No L: 16 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Venetoclax 400 mg QD + Azacitidine							
47003# Age:9[redacted] Sex:Female Race:WHITE Weight:50.0 kg							
	TRT	1 TO 463	332	332	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 365 O: No L: 34 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNODEPRESSION LINKED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Venetoclax 400 mg QD + Azacitidine								
47003# Age:9[redacted] Sex:Female Race:WHITE Weight:50.0 kg								
(Cont.) TRT		1 TO 463	391	391	R: HYPOSTHENIA RIGHT UPPER LIMB S: General disorders and administration site conditions P: 無力症 L: Hyposthenia	E: 396 O: No L: 6 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, BRAIN CT SCAN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT'S AGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (117823) TRT: Venetoclax 400 mg QD + Azacitidine							
47003# Age:9[redacted] Sex:Female Race:WHITE Weight:50.0 kg							
	(Cont.) TRT	1 TO 463	463	463	R: RIGHT LEG CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 494 O: No L: 32 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (264419) TRT: Venetoclax 400 mg QD + Azacitidine							
87001	Age:8[redacted] Sex:Male Race:ASIAN Weight:60.3 kg						
		TRT 1 TO	141	141	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 156 O: No L: 16 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (264419) TRT: Venetoclax 400 mg QD + Azacitidine							
87001 Age:8[redacted]	Sex:Male	Race:ASIAN	Weight:60.3 kg				
(Cont.) TRT	1	TO	504	504	R: GASTROINTESTINAL BLEEDING S: Gastrointestinal disorders P: 胃腸出血 L: Gastrointestinal bleeding	E: 513 O: No L: 10 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, TRANSFUSIONS,ARGON PLASMA?COAGULATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (264419) TRT: Venetoclax 400 mg QD + Azacitidine							
87001	Age:8[redacted] Sex:Male Race:ASIAN Weight:60.3 kg						
	(Cont.) TRT	1 TO	533	533	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 540 O: No L: 8 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (78377) TRT: Venetoclax 400 mg QD + Azacitidine								
86301#	Age:7[redacted] Sex:Male Race:ASIAN Weight:63.3 kg							
	TRT	1 TO 134	56	56	R: NEUTOPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 124 O: No L: 69 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: AZACITIDINE|DOSE REDUCED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	135 TO 303	7	141	R: FEBRIL NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 154 O: No L: 14 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (78377) TRT: Venetoclax 400 mg QD + Azacitidine								
86302#	Age:6[redacted] Sex:Male Race:ASIAN Weight:68.1 kg							
		POST	31 TO 187	4	34	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (78377) TRT: Venetoclax 400 mg QD + Azacitidine								
86303#	Age:7[redacted] Sex:Female Race:ASIAN Weight:45.0 kg							
		TRT 1 TO 26	26	26	R: ACUTE CIRCULATORY FAILURE S: Vascular disorders P: 循環虚脱 L: Acute circulatory failure	E: 28 O: No L: 3 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				26	R: METABOLIC ACIDOSIS S: Metabolism and nutrition disorders P: 代謝性アシドーシス L: Metabolic acidosis	E: 28 O: No L: 3 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118377) TRT: Venetoclax 400 mg QD + Azacitidine							
85903#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg						
	TRT	1 TO 299	51	R: WORSENING OF DEPRESSION S: Psychiatric disorders P: うつ病 L: Depression worsened	E: 108 O: No L: 58 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT MEDICATION?DOGMATYL),LONG-TERM HOSPITALIZATION,ANXIETY ABOUT LIFE EXPECTANCY DUE TO DISEASE NAME ANNOUNCEMENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118377) TRT: Venetoclax 400 mg QD + Azacitidine								
85903#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg							
(Cont.)		TRT	1 TO 299	127	127	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 165 O: No L: 39 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118377) TRT: Venetoclax 400 mg QD + Azacitidine							
85903# Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg							
(Cont.) TRT	1 TO 299	235	235	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 372 O: No L: 138 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
		297	297	R: HEPATIC ABSCESS S: Infections and infestations P: 肝膿瘍 L: Liver abscess	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118377) TRT: Venetoclax 400 mg QD + Azacitidine								
85903#	Age:8[redacted] Sex:Female Race:ASIAN Weight:51.8 kg							
		(Cont.) POST	300 TO 418	17	316	R: DRUG-INDUCED PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 374 O: No L: 59 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AMBISOME,FUNGUARD V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74404# Age:8[redacted] Sex:Male Race:WHITE Weight:84.0 kg							
	TRT	1 TO 366	365	365	R: LOWER GASTROINTESTINAL BLEEDING S: Gastrointestinal disorders P: 下部消化管出血 L: Lower gastrointestinal bleeding	E: 383 O: No L: 19 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE BACTERIAL INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine								
74405 Age:7[redacted] Sex:Male Race:WHITE Weight:70.7 kg								
	TRT	1 TO	16	16	R: PAIN IN HIGH ABDOMEN S: Gastrointestinal disorders P: 上腹部痛 L: Upper abdominal pain	E: 17 O: No L: 2 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCORDING TO PI, NOT RELATED TO STUDY DRUG. PATIENT HAD NO PERITONEAL SIGNS NOR POSITIVE MICROBIOLOGY. WHAT MAY HAVE CAUSED THE EVENT IS UNKNOWN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74405 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:70.7 kg				
(Cont.) TRT	1 TO	23	23	R: INFLUENZA S: Infections and infestations P: インフルエンザ L: Influenza	E: 39 O: No L: 17 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PT HAVE NEUTROPENIA, AND IS IMMUNE SYSTEM IS WEAK DUE TO HIS ACUTE LEUKEMIA DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74405 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:70.7 kg				
(Cont.) TRT	1 TO	80	80	R: INFECTION DIARRHEA - CAMPYLOBACTER S: Infections and infestations P:カンピロバクター胃腸炎 L: Diarrhea campylobacter	E: 102 O: No L: 23 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted] Sex:Male Race:WHITE Weight:81.0 kg							
	TRT	1 TO	25	25	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 38 O: No L: 14 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1 TO	94	94	R: INTERMITTENT FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 105 O: No L: 12 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1 TO	159	159	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 171 O: No L: 13 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1 TO	212	212	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 215 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PT WITH AML ARE PRONE TO NEUTROPENIC FEVER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1	TO 325	325	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 331 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1 TO	405	405	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 411 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112186) TRT: Venetoclax 400 mg QD + Azacitidine							
74408 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:81.0 kg				
(Cont.) TRT	1 TO	554	554	R: CELLULITIS LEFT FOREARM S: Infections and infestations P: 蜂巣炎 L: Cellulitis of arm	E: 556 O: No L: 3 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		603	603	R: PERINASAL CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of face	E: 606 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (97401) TRT: Venetoclax 400 mg QD + Azacitidine							
65901# Age:6[redacted] Sex:Male Race:WHITE Weight:110.0 kg							
	TRT	1 TO 3	3	3	R: THROMBOEMBOLISM OF THE PULMONARY ARTERY S: Respiratory, thoracic and mediastinal disorders P: 肺動脈血栓症 L: Pulmonary artery thrombosis	E: 10 O: No L: 8 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHRONIC STABLE ANGINA, PAROXISMAL ATRIAL FIBRILATION, ARTERIAL HYPERTENSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (97401) TRT: Venetoclax 400 mg QD + Azacitidine							
65902# Age:6[redacted] Sex:Female Race:WHITE Weight:76.0 kg							
	TRT	1 TO 17	17	R: ISCHEMIC STROKE IN BOTH HEMISPHERES OF THE BRAIN S: Nervous system disorders P: 虚血性脳卒中 L: Ischemic stroke	E: 19 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TROMBOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110902) TRT: Venetoclax 400 mg QD + Azacitidine							
38502#	Age:9[redacted] Sex:Female Race:WHITE Weight:66.2 kg						
	TRT	1 TO 28	5	5	R: PULMONARY EDEMA S: Respiratory, thoracic and mediastinal disorders P: 肺水腫 L: Pulmonary edema	E: 11 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO FLUID OVERLAOD, DIURETICS WERE GIVEN AND THE PATIENT IMPORVED. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110902) TRT: Venetoclax 400 mg QD + Azacitidine								
38502#	Age:9[redacted] Sex:Female Race:WHITE Weight:66.2 kg							
(Cont.)		TRT	1 TO 28	25	25	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 30 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53154) TRT: Venetoclax 400 mg QD + Azacitidine								
90401# Age:8[redacted] Sex:Female Race:WHITE Weight:70.4 kg								
	TRT	1 TO 8	8	8	R: ACUTE RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 9 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112047) TRT: Placebo + Azacitidine								
55302#	Age:7[redacted] Sex:Male Race:WHITE Weight:86.0 kg							
		TRT	1 TO 28	28	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 32 O: No L: 5 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: IMMUNOCOMPROMISED PATIENT WITH OVERALL DETERIORATION OF THE PATIENT'S CONDITION (FATIQUE RELATED TO ANEMIA). V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine								
42101#	Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
	TRT	1 TO 231	9	9	R: PROFOUND CYTOPENIAS(NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA) S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: RBC AND PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101# Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
	(Cont.) TRT	1 TO 231	9	9	R: PROFOUND CYTOPENIAS(NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA) S: Blood and lymphatic system disorders P: 血球減少症 L: Cytopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: RBC AND PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101# Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
(Cont.) TRT	1 TO 231	9	9	R: PROFOUND CYTOPENIAS(NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA) S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: RBC AND PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101# Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
(Cont.) TRT	1 TO 231	9	9	R: PROFOUND CYTOPENIAS(NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA) S: Blood and lymphatic system disorders P: 血小板减少症 L: Thrombocytopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: RBC AND PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine								
42101#	Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
	(Cont.)	TRT 1 TO 231	67	67	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 76 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101#	Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg						
(Cont.)	TRT	1 TO 231 Day 81	81	R: FAINTING S: Nervous system disorders P: 失神 L: Fainting	E: 85 O: No L: 5 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ORTHOSTATIC HYPOTENSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101#	Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg						
	(Cont.) TRT	1 TO 231	101	101	R: ORTHOSTATIC HYPOTENSION S: Vascular disorders P: 起立性低血圧 L: Orthostatic hypotension	E: 106 O: No L: 6 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANTIHYPERTENSION TREATMENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101# Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg							
(Cont.)	TRT	1 TO 231	157	157	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 160 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	232 TO 698	12	243	R: GASTRO-ENTERITIS S: Infections and infestations P: 胃腸炎 L: Gastroenteritis	E: 250 O: No L: 8 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53330) TRT: Venetoclax 400 mg QD + Azacitidine							
42101#	Age:7[redacted] Sex:Male Race:WHITE Weight:91.3 kg						
	(Cont.)	POST 232 TO 698	23	254	R: COLITIS S: Gastrointestinal disorders P: 大腸炎 L: Colitis	E: 264 O: No L: 11 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER INVESTIGATOR: COLITIS WITHOUT DOCUMENTATION, DUE TO ONGOING CYTOPENIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (44347) TRT: Placebo + Azacitidine							
38401# Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
	TRT	1 TO 421	306	306	R: OBLICAL FRACTURE OF THE LEFT HUMERUS S: Injury, poisoning and procedural complications P: 上腕骨骨折 L: Fracture of humerus	E: 397 O: No L: 92 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THIS INJURY WAS CAUSED BY A FALL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (44347) TRT: Placebo + Azacitidine							
38401# Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
(Cont.) TRT		1 TO 421	318	318	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 324 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFLUENZA VIRUS A H3N2 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (44347) TRT: Placebo + Azacitidine								
38401#	Age:7[redacted] Sex:Female Race:WHITE Weight:67.0 kg							
		(Cont.) POST 422 TO 456	22	443	R: ACUTE RENAL FAILURE S: Renal and urinary disorders P: 急性腎障害 L: Acute renal failure	E: 455 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE RENAL FAILURE OF PRERENAL ORIGIN IN A PATIENT WITH REFRACTORY AML. ACUTE RENAL FAILURE DUE TO THE PROGRESSION OF THE DISEASE. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110986) TRT: Placebo + Azacitidine								
58201#	Age:7[redacted] Sex:Male Race:WHITE Weight:98.0 kg							
	TRT	1 TO 127	3	3	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 12 O: No L: 10 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110986) TRT: Venetoclax 400 mg QD + Azacitidine							
58203#	Age:6[redacted] Sex:Male Race:WHITE Weight:86.0 kg						
	TRT	1 TO 220	10	10	R: INFECTIOUS GASTROENTEROCOLITIS S: Infections and infestations P: 胃腸炎 L: Infective gastroenteritis	E: 14 O: No L: 5 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DIARRHOEA 3-4 TIMES A DAY (SEMILIQUID STOOLS AND NAUSEA), WITH NASAL SECRETION INDICATING VIRAL INFECTION. ADMITTED TO WARD FOR OBSERVATION DUE TO REMOTE PLACE OF RESIDENCE. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110986) TRT: Venetoclax 400 mg QD + Azacitidine							
58203#	Age:6[redacted] Sex:Male Race:WHITE Weight:86.0 kg						
	(Cont.) TRT	1 TO 220	208	208	R: RIGHT EAR INFECTION S: Infections and infestations P: 耳感染 L: Ear infection	E: 229 O: No L: 22 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: Multiple: MEDICAL PROCEDURE, MASTOIDECTOMY WITH MEATOPLASTY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS CONDITION, A CASE OF MASTOIDITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110986) TRT: Venetoclax 400 mg QD + Azacitidine							
58203#	Age:6[redacted] Sex:Male Race:WHITE Weight:86.0 kg						
	(Cont.)	POST 221 TO 564	11	231	R: POST OPERATIVE RIGHT EAR INFECTION S: Infections and infestations P: 処置後感染 L: Postoperative infection	O: Yes I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: HOSPITALISATION DUE TO PAIN MANAGEMENT C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RECENT MASTOIDECTOMY WITH MEATOPLASTY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110901) TRT: Placebo + Azacitidine							
38301# Age:7[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	TRT	1 TO 580	564	564	R: FEBRILE SYNDROME WITHOUT SPOT FOCUS S: General disorders and administration site conditions P: 発熱 L: Febrile reaction	E: 572 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION SUSPECT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110901) TRT: Placebo + Azacitidine								
38301#	Age:7[redacted] Sex:Male Race:WHITE Weight:77.0 kg							
	(Cont.)	POST 581 TO 624	8	588	R: MALIGNANT NEOPLASM PROGRESSION S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Malignant neoplasm progression	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESIVE DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110901) TRT: Venetoclax 400 mg QD + Azacitidine							
38302	Age:7[redacted] Sex:Male Race:WHITE Weight:87.5 kg						
	TRT	1 TO	432	432	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 437 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110901) TRT: Venetoclax 400 mg QD + Azacitidine							
38302	Age:7[redacted] Sex:Male Race:WHITE Weight:87.5 kg						
(Cont.) TRT		1 TO	464	464	R: PERIANAL ABSCESS S: Infections and infestations P: 肛門膿瘍 L: Perianal abscess	E: 506 O: No L: 43 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HEMORRHOIDS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Placebo + Azacitidine								
47204#	Age:7[redacted] Sex:Male Race:WHITE Weight:83.0 kg							
	TRT	1 TO 277	41	41	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 57 O: No L: 17 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VIRUS OR BACTERIAL V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Placebo + Azacitidine							
47204# Age:7[redacted] Sex:Male Race:WHITE Weight:83.0 kg							
	(Cont.) TRT	1 TO 277 Day 49	49	R: CARCINOMA KIDNEY S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 腎癌 L: Carcinoma kidney	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE ARE UNK: AMBIENT, THERAPY, ALIMENTATION, LIFE??.. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Placebo + Azacitidine							
47204# Age:7[redacted] Sex:Male Race:WHITE Weight:83.0 kg							
(Cont.) TRT		1 TO 277	236	236	R: SEPSI (E. COLI) S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 252 O: No L: 17 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GRAM NEGATIVE INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Placebo + Azacitidine								
47204#	Age:7[redacted] Sex:Male Race:WHITE Weight:83.0 kg							
	(Cont.)	POST 278 TO 343	23	300	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 342 O: No L: 43 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Venetoclax 400 mg QD + Azacitidine							
47203# Age:8[redacted] Sex:Male Race:WHITE Weight:89.0 kg							
	TRT	1 TO 48	48	48	R: BRONCHOPNEUMONIA S: Infections and infestations P: 肺炎 L: Bronchopneumonia	E: 70 O: No L: 23 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION (NO INFORMATION, PATIENT HOSPITALIZED IN OTHER CENTER) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Venetoclax 400 mg QD + Azacitidine							
47205# Age:8[redacted] Sex:Female Race:WHITE Weight:49.0 kg							
	TRT	1 TO 555	155	155	R: SEPSIS (PSEUDOMONAS AERUGINOSA) S: Infections and infestations P: シュードモナス性敗血症 L: Pseudomonal sepsis	E: 192 O: No L: 38 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Venetoclax 400 mg QD + Azacitidine							
47205# Age:8[redacted] Sex:Female Race:WHITE Weight:49.0 kg							
	(Cont.) TRT	1 TO 555	168	168	R: PULMONARY ASPERGILLOSIS S: Infections and infestations P: 気管支肺アスペルギルス症 L: Pulmonary aspergillosis	E: 225 O: No L: 58 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL INFECTION AND NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (486430) TRT: Venetoclax 400 mg QD + Azacitidine							
47205#	Age:8[redacted] Sex:Female Race:WHITE Weight:49.0 kg						
		(Cont.) POST 556 TO 569	7	562	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 568 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML, FEBRILE NEUTROPENIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine								
90201#	Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
		TRT	1 TO 468	344	344	R: PULMONARY FUNGAL ABSCESS S: Infections and infestations P: 真菌性膿瘍 L: Abscess fungal	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90201# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.) TRT		1 TO 468 Day 457	457	R: FALL CAUSING FRACTURE OF L3 S: Injury, poisoning and procedural complications P: 転倒 L: Fall	E: 470 O: No L: 14 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL IN HOSPITAL LOSING BALANCE WHILST HOLDING ONTO ROTATING DOOR, FALLING DOWN AND STRIKING BACK V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90201# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 468	457	457	R: FALL CAUSING FRACTURE OF L3 S: Injury, poisoning and procedural complications P: 腰椎骨折 L: Lumbar vertebral fracture L3	E: 470 O: No L: 14 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL IN HOSPITAL LOSING BALANCE WHILST HOLDING ONTO ROTATING DOOR, FALLING DOWN AND STRIKING BACK V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90201# Age:8[redacted] Sex:Male Race:WHITE Weight:73.0 kg							
(Cont.)	TRT	1 TO 468	461	461	R: PROCTITIS S: Gastrointestinal disorders P: 直腸炎 L: Proctitis	O: Yes I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90203#	Age:8[redacted] Sex:Male Race:WHITE Weight:85.1 kg						
		TRT 1 TO 322	50	50	R: INFECTIVE ENDOARDITIS S: Infections and infestations P: 心内膜炎 L: Endocarditis infective	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STREPTOCOCCUS SANGUINIS GROUP- AEROBIC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90203# Age:8[redacted] Sex:Male Race:WHITE Weight:85.1 kg							
(Cont.)	TRT	1 TO 322	50	50	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 53 O: No L: 4 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90203# Age:8[redacted] Sex:Male Race:WHITE Weight:85.1 kg							
(Cont.)	TRT	1 TO 322	67	67	R: PULMONARY INVASIVE ASPERGILLUS S: Infections and infestations P: 気管支肺アスペルギルス症 L: Pulmonary aspergillosis	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSALITY - AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113238) TRT: Placebo + Azacitidine							
90203#	Age:8[redacted] Sex:Male Race:WHITE Weight:85.1 kg						
	(Cont.)	POST 323 TO 465	23	345	R: KLEBSIELLA SEPSIS S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	E: 360 O: No L: 16 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55002 Age:8[redacted] Sex:Female Race:WHITE Weight:71.0 kg							
	TRT	1 TO #	188	188	R: INFECTION OF GASTROINTESTINAL TRACT S: Infections and infestations P: 消化管感染 L: Gastrointestinal infection	E: 198 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55005#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
	TRT	1 TO 49 Day 27	27	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 50 O: No L: 24 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55005#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
(Cont.)	TRT	1 TO 49	29	29	R: E. COLI INFECTION OF URINARY TRACT S: Infections and infestations P: 大腸菌性尿路感染 L: Escherichia urinary tract infection	E: 38 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DESCRIPTION IS PART OF SAE 55005010. INFECTION OF URINARY TRACT WAS CAUSED BY E.COLI. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55005#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
(Cont.)	TRT	1 TO 49	45	45	R: UPPER RESPIRATORY INFECTION, DYSPEPTIC SYNDROME CAUSED BY USING ANTIBIOTICS S: Gastrointestinal disorders P: 消化不良 L: Dyspepsia	E: 68 O: No L: 24 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION OF UPPER RESPIRATORY TRACT (PROBABLY DUE TO NEUTROPENIA GR. 4), INTOLERANCE LIQUIDS AND MEALS IN USING ANTIBIOTICS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55005#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
(Cont.)	TRT	1 TO 49	45	45	R: UPPER RESPIRATORY INFECTION, DYSPEPTIC SYNDROME CAUSED BY USING ANTIBIOTICS S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 68 O: No L: 24 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION OF UPPER RESPIRATORY TRACT (PROBABLY DUE TO NEUTROPENIA GR. 4), INTOLERANCE LIQUIDS AND MEALS IN USING ANTIBIOTICS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55005#	Age:7[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
(Cont.)	TRT	1 TO 49	48	48	R: DIVERTICULITIS S: Infections and infestations P: 憩室炎 L: Diverticulitis	E: 68 O: No L: 21 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DIVERTICULOSIS (MEDICAL HISTORY), NEUTROPENIA GR.IV V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53435) TRT: Venetoclax 400 mg QD + Azacitidine							
55007# Age:6[redacted] Sex:Male Race:WHITE Weight:97.0 kg							
	TRT	1 TO 172	1	1	R: INFECTION OF URINARY TRACT S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 13 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS FEVERS, INFECTIOUS COMPLICATION (CRP ELEVATION) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Placebo + Azacitidine							
74304# Age:8[redacted] Sex:Male Race:WHITE Weight:82.0 kg							
	TRT	1 TO 43	29	R: VOMITING S: Gastrointestinal disorders P: 嘔吐 L: Vomiting	E: 30 O: No L: 2 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			37	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 46 O: No L: 10 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine								
74301#	Age:7[redacted] Sex:Male Race:WHITE Weight:57.5 kg							
		TRT	1 TO 53	52	52	R: SEPTIC SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 58 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine							
74302# Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg							
	TRT	1 TO 137	16	16	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 25 O: No L: 10 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA ASSOCIATED WITH LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine							
74302#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg						
(Cont.)		TRT 1 TO 137	25	25	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 47 O: No L: 23 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA ASSOCIATED WITH LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine							
74302# Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg							
(Cont.)	TRT	1 TO 137	60	60	R: VASOVAGAL SYNCOPE S: Nervous system disorders P: 失神 L: Syncope vasovagal	E: 78 O: No L: 19 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE EVENT OCCURED AFTER A MEAL IN A PATIENT WITH DIABETES AND ANEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine								
74302#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg							
	(Cont.) TRT	1 TO 137	121	121	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 128 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA ASSOCIATED WITH LEUKEMIA. PATIENT ADMIITTED DUE TO FEVER. ON PHYSICAL EXAMINATION NO FINDINGS FOR THE FEVER. BLOOD TESTS TAKEN AND TREATMENT WITH PIPERACILLIN WAS STARTED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112190) TRT: Venetoclax 400 mg QD + Azacitidine							
74302#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg						
(Cont.)	TRT	1 TO 137	132	132	R: GENERAL WEAKNESS S: General disorders and administration site conditions P: 無力症 L: Weakness generalized	E: 231 O: No L: 100 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TRANSFUSIONS WERE GIVEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WEAKNESS DUE TO ANEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine								
50002#	Age:6[redacted] Sex:Female Race:WHITE Weight:74.0 kg							
	TRT	1 TO 361	43	43	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 49 O: No L: 7 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION URINARY TRACK WITHOUT SPECIFICATION, DUE TO IMMUNOSUPRESSION FROMAML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine							
50002#	Age:6[redacted] Sex:Female Race:WHITE Weight:74.0 kg						
(Cont.)	TRT	1 TO 361	79	79	R: WORSENING ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	E: 84 O: No L: 6 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROBABILITY INFECTION WITHOUT SPECIFICATION, DUE TO IMMUNOSUPRESSION FROM AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine							
50002# Age:6[redacted] Sex:Female Race:WHITE Weight:74.0 kg							
(Cont.)	TRT	1 TO 361	131	131	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 141 O: No L: 11 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION DUE TO AML AND CISTIC KIDNEY DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine								
50002# Age:6[redacted] Sex:Female Race:WHITE Weight:74.0 kg								
(Cont.) TRT		1 TO 361	225	225	R: INFECTION OF URINARY TRACT S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 229 O: No L: 5 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, BACTERIOLOGICAL EXAMINATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RECURRENT INFECTION OF UTRINARY TRACT IS IN MEDICLA HISTORY OF THAT PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine							
50004#	Age:7[redacted] Sex:Male Race:WHITE Weight:105.0 kg						
		TRT 1 TO 119	21	R: ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 23 O: No L: 3 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			50	R: ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 57 O: No L: 8 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Placebo + Azacitidine								
50004#	Age:7[redacted] Sex:Male Race:WHITE Weight:105.0 kg							
	(Cont.)	TRT 1 TO 119	79	79	R: ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 103 O: No L: 25 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Venetoclax 400 mg QD + Azacitidine							
50001# Age:7[redacted] Sex:Female Race:WHITE Weight:58.4 kg							
	TRT	1 TO 125	24	R: UROSEPSIS S: Infections and infestations P: 尿路性敗血症 L: Urosepsis	E: 43 O: No L: 20 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			60	R: SEPSIS KLEBSIELLA PNEUMONIAE S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	E: 78 O: No L: 19 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Venetoclax 400 mg QD + Azacitidine								
50001#	Age:7[redacted] Sex:Female Race:WHITE Weight:58.4 kg							
		(Cont.) TRT	1 TO 125	82	82	R: RIGHT BUTTOCK ABSCESS S: Infections and infestations P: 皮下組織膿瘍 L: Abscess on buttock	E: 94 O: No L: 13 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: DELAYED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Venetoclax 400 mg QD + Azacitidine							
50001#	Age:7[redacted] Sex:Female Race:WHITE Weight:58.4 kg						
(Cont.)		TRT 1 TO 125	125	125	R: SEPTIC SCHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 141 O: No L: 17 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (42254) TRT: Venetoclax 400 mg QD + Azacitidine								
50003#	Age:7[redacted] Sex:Female Race:WHITE Weight:82.5 kg							
		POST	29 TO 160	11	39	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 41 O: No L: 3 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY: TROMBOCYTOPENIA IS CONNECTED WITH DISEASE UNDER STUDY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (982302) TRT: Placebo + Azacitidine							
15301#	Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg						
	TRT	1 TO 314	35	35	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 39 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PANCYTOPENIA DUE TO LEUKEMIA. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (982302) TRT: Placebo + Azacitidine								
15301#	Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg							
	(Cont.) TRT	1 TO 314	149	149	R: HYPERKALEMIA S: Metabolism and nutrition disorders P: 高カリウム血症 L: Hyperkalemia	E: 150 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RENAL INSUFFICIENCY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (982302) TRT: Placebo + Azacitidine							
15301# Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg							
(Cont.)	TRT	1 TO 314	159	159	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 162 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (982302) TRT: Placebo + Azacitidine							
15301# Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg							
(Cont.)	TRT	1 TO 314	159	159	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 162 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE UNKNOWN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (982302) TRT: Placebo + Azacitidine							
15301#	Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg						
	(Cont.)	TRT 1 TO 314	175	175	R: BILATERAL DEEP VEIN THROMBOSIS (BLE) S: Vascular disorders P: 深部静脈血栓症 L: Deep vein thrombosis leg	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE FROM IVC PLACEMENT FROM 2009 V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Placebo + Azacitidine								
40205#	Age:7[redacted] Sex:Female Race:WHITE Weight:72.3 kg							
	TRT	1 TO 180	45	45	R: INFLUENZA B S: Infections and infestations P: インフルエンザ L: Influenza B virus infection	E: 58 O: No L: 14 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMMUNITY ACQUIRED INFECTION IN ELDERLY PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Venetoclax 400 mg QD + Azacitidine							
40202#	Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg						
	TRT	1 TO 15	14	14	R: WORSENING OF HEART INSUFFICIENCY S: Cardiac disorders P: 心不全 L: Cardiac failure aggravated	E: 23 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Venetoclax 400 mg QD + Azacitidine							
40202#	Age:7[redacted] Sex:Male Race:WHITE Weight:92.0 kg						
	(Cont.) TRT	1 TO 15	14	14	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 22 O: No L: 9 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Venetoclax 400 mg QD + Azacitidine							
40203# Age:6[redacted] Sex:Male Race:WHITE Weight:119.7 kg							
	TRT	1 TO 82	36	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 101 O: No L: 66 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			56	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 59 O: No L: 4 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Venetoclax 400 mg QD + Azacitidine							
40203# Age:6[redacted] Sex:Male Race:WHITE Weight:119.7 kg							
(Cont.)	TRT	1 TO 82	66	66	R: WORSENING OF THROMBOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombopenia	E: 101 O: No L: 36 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: PLATELETS CONCENTRATES ADMINISTERED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (113026) TRT: Venetoclax 400 mg QD + Azacitidine							
40203#	Age:6[redacted] Sex:Male Race:WHITE Weight:119.7 kg						
	(Cont.)	TRT 1 TO 82	82	82	R: PROGRESSION OF PRE-EXISTING CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性新生物進行 L: Progression of pre-existing cancer	E: 101 O: No L: 20 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HOSPITALIZED DUE TO FEVER, LOCAL LABORAOTRY SHOWS LEUCOCYTOSIS, AML PROGRESSSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97201# Age:7[redacted] Sex:Female Race:ASIAN Weight:96.7 kg							
	TRT	1 TO 33	15	15	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 18 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97201# Age:7[redacted] Sex:Female Race:ASIAN Weight:96.7 kg							
(Cont.)	TRT	1 TO 33	20	20	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 36 O: No L: 17 Days I: No	D: No G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine								
97201#	Age:7[redacted] Sex:Female Race:ASIAN Weight:96.7 kg							
	(Cont.)	POST 34 TO 37	1	34	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 35 O: No L: 2 Days I: No	D: No G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine								
97203# Age:8[redacted] Sex:Male Race:ASIAN Weight:61.8 kg								
	TRT	1 TO 304	28	28	R: BLOOD TRANSFUSION REACTION S: Injury, poisoning and procedural complications P: 輸血反応 L: Transfusion reaction	E: 28 O: No L: 1 Day I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED BLOOD TRANSFUSION REACTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97203#	Age:8[redacted] Sex:Male Race:ASIAN Weight:61.8 kg						
(Cont.)		TRT 1 TO 304	30	30	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 44 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED AML RELATED IMMUNOCOMPROMISED STATE, OR INFECTION RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97203# Age:8[redacted] Sex:Male Race:ASIAN Weight:61.8 kg							
(Cont.)	TRT	1 TO 304	303	303	R: SEPSIS (ESCHERICHIA COLI) S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 305 O: No L: 3 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ESCHERICHIA COLI V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97204#	Age:7[redacted] Sex:Male Race:ASIAN Weight:75.9 kg						
		TRT 1 TO 224	5	5	R: ALANINE AMINOTRANSFERASE INCREASED S: Investigations P: アラニンアミノトランスフェラーゼ増加 L: Alanine aminotransferase increased	E: 21 O: No L: 17 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MEDICAL SIGNIFICANT, COUSE IS UNKNOWN, AND MAYBE SUSPECTED THE SIDE-EFFECT OF VALACICLOVIR V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine								
97204#	Age:7[redacted] Sex:Male Race:ASIAN Weight:75.9 kg							
(Cont.)		TRT 1 TO 224	5	5	R: ASPARTATE AMINOTRANSFERASE INCREASED S: Investigations P: アスパラギン酸アミノトランスフェラーゼ増加 L: Aspartate aminotransferase increased	E: 14 O: No L: 10 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MEDICAL SIGNIFICANT, COUSE IS UNKNOWN, AND MAYBE SUSPECTED THE SIDE-EFFECT OF VALACICLOVIR. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Placebo + Azacitidine							
97208	Age:7[redacted] Sex:Female Race:ASIAN Weight:52.2 kg						
	TRT	1 TO 33	33	R: ANOREXIA S: Metabolism and nutrition disorders P: 食欲減退 L: Anorexia	E: 50 O: No L: 18 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205#	Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg						
	TRT	1 TO 397	34	34	R: STAPHYLOCOCCUS AUREUS (MRSA)OF ANAL S: Infections and infestations P: ブドウ球菌感染 L: Staphylococcal infection	E: 35 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STAPHYLOCOCCUS AUREUS(MRSA) INFECTION MAY BE RELATED WITH IMMUNOSUPPRESSION DUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205# Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
(Cont.)	TRT	1 TO 397	42	42	R: ANAL ABSCESS S: Infections and infestations P: 肛門膿瘍 L: Anal abscess	E: 75 O: No L: 34 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WOUND INFECTIN WITH STAPHYLOCOCCUS AUREUS(MRSA) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205# Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
(Cont.) TRT	1 TO 397	55	55	R: INVASIVE PULMONARY ASPERGILLOSIS S: Infections and infestations P: 気管支肺アスペルギルス症 L: Invasive bronchopulmonary aspergillosis	E: 151 O: No L: 97 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGUS INFECTION WITH ASPERGILLOSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine 97205# Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
		(Cont.) TRT 1 TO 397	111	111	R: PERIANAL ABSCESS S: Infections and infestations P: 肛門膿瘍 L: Perianal abscess	E: 130 O: No L: 20 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ENTEROCOCCUS FAECIUM(VRE) AND LECLERCIA ADECARBOXYLATA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205# Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
(Cont.) TRT	1 TO 397	145	145	R: ANOREXIA S: Metabolism and nutrition disorders P: 食欲減退 L: Anorexia	E: 158 O: No L: 14 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205#	Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg						
(Cont.)	TRT	1 TO 397	169	169	R: PERIANAL ABSCESS S: Infections and infestations P: 肛門膿瘍 L: Perianal abscess	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ESCHERICHIA COLI V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine								
97205#	Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
		(Cont.) TRT	1 TO 397	291	291	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 355 O: No L: 65 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED BACTERIA INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine								
97205#	Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
		(Cont.) TRT	1 TO 397	356	356	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 393 O: No L: 38 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED FUNGUS INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53268) TRT: Venetoclax 400 mg QD + Azacitidine							
97205# Age:7[redacted] Sex:Female Race:ASIAN Weight:45.8 kg							
(Cont.)	TRT	1 TO 397 Day 385	385	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 393 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED COMPLICATION OF THE UNDERLYINGOF AML RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130298) TRT: Placebo + Azacitidine								
93902#	Age:7[redacted] Sex:Male Race:ASIAN Weight:83.2 kg							
		TRT	1 TO 19	11	11	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 30 O: No L: 20 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130298) TRT: Venetoclax 400 mg QD + Azacitidine								
93904#	Age:6[redacted] Sex:Male Race:ASIAN Weight:71.0 kg							
		TRT	1 TO 169	70	70	R: NEUTROPHIL COUNT DECREASED S: Investigations P: 好中球数減少 L: Neutrophil count decreased	E: 149 O: No L: 80 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130298) TRT: Venetoclax 400 mg QD + Azacitidine							
93906#	Age:7[redacted] Sex:Male Race:ASIAN Weight:50.0 kg						
	TRT	1 TO 28 Day 22	22	R: SEPTICEMIA S: Infections and infestations P: 敗血症 L: Septicemia	E: 30 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111506) TRT: Venetoclax 400 mg QD + Azacitidine							
80202# Age:8[redacted] Sex:Female Race:ASIAN Weight:56.2 kg							
	TRT	1 TO 331	15	15	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 35 O: No L: 21 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111506) TRT: Venetoclax 400 mg QD + Azacitidine								
80203#	Age:7[redacted] Sex:Female Race:ASIAN Weight:56.4 kg							
		TRT	1 TO 437	267	267	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 268 O: No L: 2 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111506) TRT: Venetoclax 400 mg QD + Azacitidine								
80203#	Age:7[redacted] Sex:Female Race:ASIAN Weight:56.4 kg							
		(Cont.) POST	438 TO 506	12	449	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	O: Yes I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111506) TRT: Venetoclax 400 mg QD + Azacitidine							
80204# Age:7[redacted] Sex:Male Race:ASIAN Weight:68.0 kg							
	TRT	1 TO 266	63	63	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 74 O: No L: 12 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (95116) TRT: Placebo + Azacitidine								
14704#	Age:7[redacted] Sex:Female Race:BLACK OR AFRICAN AMERICAN Weight:75.3 kg							
		POST	9 TO 121	2	10	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 33 O: No L: 24 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (95116) TRT: Placebo + Azacitidine							
14706#	Age:7[redacted] Sex:Male Race:WHITE Weight:121.0 kg						
	TRT	1 TO 133	79	79	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 88 O: No L: 10 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (95116) TRT: Placebo + Azacitidine							
14706#	Age:7[redacted] Sex:Male Race:WHITE Weight:121.0 kg						
	(Cont.) TRT	1 TO 133	133	133	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 140 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PI BELIEVED TO BE RELATED TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (95116) TRT: Placebo + Azacitidine							
14706#	Age:7[redacted] Sex:Male Race:WHITE Weight:121.0 kg						
	(Cont.)	POST 134 TO 163	10	143	R: LEFT-SIDED PLEURAL EFFUSION S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Pleural effusion	E: 162 O: No L: 20 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WAS RECENTLY ADMITTED TO THE HOSPITAL WITH PNEUMONIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (95116) TRT: Venetoclax 400 mg QD + Azacitidine							
14708#	Age:7[redacted] Sex:Female Race:WHITE Weight:76.8 kg						
	TRT	1 TO 100 Day 57	57	R: PAROTITIS S: Infections and infestations P: 耳下腺炎 L: Parotitis	E: 67 O: No L: 11 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted]							
TRT: Venetoclax 400 mg QD + Azacitidine							
14708#	Age:7[redacted] Sex:Female Race:WHITE Weight:76.8 kg						
	(Cont.) TRT	1 TO 100 Day	100	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 115 O: No L: 16 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118344) TRT: Venetoclax 400 mg QD + Azacitidine							
85701 Age:8[redacted]	Sex:Female	Race:ASIAN	Weight:60.4 kg				
	TRT	1 TO	260	260	R: PULMONARY MYCOSIS S: Infections and infestations P: 肺真菌症 L: Pulmonary mycosis	E: 320 O: No L: 61 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION ASSOCIATED WITH NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118344) TRT: Venetoclax 400 mg QD + Azacitidine							
85701 Age:8[redacted]		Sex:Female	Race:ASIAN	Weight:60.4 kg			
(Cont.) TRT		1 TO	372	372	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 421 O: No L: 50 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			379	379	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 477 O: No L: 99 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (97396) TRT: Placebo + Azacitidine								
65001# Age:6[redacted] Sex:Female Race:WHITE Weight:78.4 kg								
		POST	315 TO 325	8	322	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 323 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine								
13503#	Age:7[redacted] Sex:Male Race:WHITE Weight:103.9 kg							
	TRT	1 TO 198	20	20	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 23 O: No L: 4 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13503# Age:7[redacted] Sex:Male Race:WHITE Weight:103.9 kg							
(Cont.)	TRT	1 TO 198 Day	32	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 35 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERSISTENT ACUTE MYELOGENOUS LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13503# Age:7[redacted] Sex:Male Race:WHITE Weight:103.9 kg							
(Cont.) TRT		1 TO 198 Day 149	149	R: GASTROINTESTINAL BLEED S: Gastrointestinal disorders P: 胃腸出血 L: Gastrointestinal bleed	E: 152 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13503# Age:7[redacted] Sex:Male Race:WHITE Weight:103.9 kg							
(Cont.) TRT		1 TO 198	177	177	R: GASTROINTESTINAL BLEED S: Gastrointestinal disorders P: 胃腸出血 L: Gastrointestinal bleed	E: 180 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13503#	Age:7[redacted] Sex:Male Race:WHITE Weight:103.9 kg						
	(Cont.)	POST 199 TO 386	28	226	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERSISTENT ACUTE MYELOGENOUS LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13505 Age:7[redacted]	Sex:Female	Race:WHITE	Weight:106.7 kg				
	TRT	1 TO 9	9	R: RIGORS S: General disorders and administration site conditions P: 悪寒 L: Rigors	E: 11 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE/SURROUNDING SKIN INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13505 Age:7[redacted]	Sex:Female	Race:WHITE	Weight:106.7 kg				
(Cont.) TRT		1 TO 151	151	R: ASPIRATION PNEUMONIA S: Respiratory, thoracic and mediastinal disorders P: 誤嚥性肺炎 L: Aspiration pneumonia	E: 152 O: No L: 2 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ASPIRATION PNEUMONITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53272) TRT: Placebo + Azacitidine							
13505	Age:7[redacted] Sex:Female Race:WHITE Weight:106.7 kg						
(Cont.)	TRT	1 TO 206	206	R: RIGHT FEMORAL NECK FRACTURE S: Injury, poisoning and procedural complications P: 大腿骨頚部骨折 L: Femoral neck fracture	E: 210 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, PARTIAL HIP REPLACEMENT C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: SUBJECT FELL DUE TO BECOMING TANGLED IN OXYGEN TUBING AT HOME. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
	TRT	1 TO 223	21	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 28 O: No L: 8 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
	(Cont.) TRT	1 TO 223	57	57	R: SEVERE ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 85 O: No L: 29 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, TRANSFUSION OF RED BLOOD CELL CONCENTRATE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: CONSEQUENCE OF THE UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
	(Cont.)	TRT 1 TO 223	59	59	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 69 O: No L: 11 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: COMPLICATION OF UPPER RESPIRATORY TRACK INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine								
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
(Cont.)	TRT	1 TO 223	86	86	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 92 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, RED BLOOD CELLS TRANSFUSIONS ADMINISTERED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
	(Cont.)	TRT 1 TO 223	86	86	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 92 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
(Cont.)		TRT 1 TO 223	86	86	R: WORSENING THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia aggravated	E: 92 O: No L: 7 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: PLATELET TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine								
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
(Cont.)		TRT 1 TO 223	156	156	R: ILEUS S: Gastrointestinal disorders P: イレウス L: Ileus	E: 179 O: No L: 24 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: BOWEL INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
(Cont.)		TRT 1 TO 223	172	172	R: RIGHT-SIDED PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 179 O: No L: 8 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
(Cont.)		TRT 1 TO 223	184	184	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 197 O: No L: 14 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (110994) TRT: Placebo + Azacitidine							
50401#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg						
	(Cont.)	POST 224 TO 257	1	224	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 242 O: No L: 19 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: INFECTION OF UNKNOWN ORIGIN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (96470) TRT: Placebo + Azacitidine							
85204#	Age:7[redacted] Sex:Male Race:ASIAN Weight:65.3 kg						
	TRT	1 TO 129	52	52	R: NEUTROPENIC ENTEROCOLITIS S: Gastrointestinal disorders P: 好中球減少性大腸炎 L: Neutropenic enterocolitis	O: Yes I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (96470) TRT: Placebo + Azacitidine							
85204#	Age:7[redacted] Sex:Male Race:ASIAN Weight:65.3 kg						
(Cont.)	TRT	1 TO 129	129	129	R: HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	O: Yes I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13401	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
		TRT 1 TO #	88	88	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 99 O: No L: 12 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13401	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
	(Cont.) TRT	1 TO	95	95	R: MORAXELLA BRONCHITIS S: Infections and infestations P: モラクセラ性気管支炎 L: Bronchitis moraxella	E: 108 O: No L: 14 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RESPIRATORY VIRUS PANEL POSITIVE FOR MORAXELLA CATARRHALIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13402#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.5 kg						
	TRT	1 TO 654	14	14	R: SPONTANEOUS PNEUMOTHORAX S: Respiratory, thoracic and mediastinal disorders P: 自然気胸 L: Spontaneous tension pneumothorax	E: 29 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMPLICATION FROM COPD V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13402# Age:7[redacted] Sex:Male Race:WHITE Weight:112.5 kg							
	(Cont.) TRT	1 TO 654	106	106	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 110 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13402#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.5 kg						
	(Cont.) TRT	1 TO 654	389	389	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 399 O: No L: 11 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, HOSPITALIZED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13402#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.5 kg						
	(Cont.)	TRT 1 TO 654	623	623	R: (SMALL BOWEL OBSTRUCTION) S: Gastrointestinal disorders P: 小腸閉塞 L: Small bowel obstruction	E: 627 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO PREVIOUS SURGERIES V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13402#	Age:7[redacted] Sex:Male Race:WHITE Weight:112.5 kg						
(Cont.)	TRT	1 TO 654	654	654	R: LEFT EYE INFECTION S: Infections and infestations P: 眼感染 L: Eye infection	O: Yes I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13404# Age:6[redacted] Sex:Male Race:WHITE Weight:101.4 kg							
	TRT	1 TO 494	38	38	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 42 O: No L: 5 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			95	95	R: DEVICE RELATED INFECTION-PORT INFECTION S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 99 O: No L: 5 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13404# Age:6[redacted] Sex:Male Race:WHITE Weight:101.4 kg							
	(Cont.)	POST 495 TO 638	2	496	R: VIRAL PNEUMONIA S: Infections and infestations P: ウイルス性肺炎 L: Viral pneumonia	E: 501 O: No L: 6 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
13405 Age:7[redacted] Sex:Male Race:WHITE Weight:130.7 kg							
	TRT	1 TO	22	22	R: ACUTE RIGHT MAXILLARY SINUSITIS S: Infections and infestations P: 急性副鼻腔炎 L: Acute maxillary sinusitis	E: 30 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13405	Age:7[redacted] Sex:Male Race:WHITE Weight:130.7 kg						
	(Cont.) TRT	1 TO	22	22	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 30 O: No L: 9 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13405 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:130.7 kg				
(Cont.) TRT	1 TO	80	80	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 83 O: No L: 4 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CROHN'S DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115535) TRT: Venetoclax 400 mg QD + Azacitidine							
13405	Age:7[redacted] Sex:Male Race:WHITE Weight:130.7 kg						
	(Cont.) TRT	1 TO	161	161	R: URINARY RETENTION S: Renal and urinary disorders P: 尿閉 L: Urinary retention	E: 164 O: No L: 4 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: CATHETER PLACED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BENIGN PROSTATIC HYPERTROPHY (BPH) WITH OUTFLOW OBSTRUCTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	TRT	1 TO	32	32	R: ACUTE ON CHRONIC RENAL INSUFFICIENCY S: Renal and urinary disorders P: 急性腎障害 L: Acute renal insufficiency	E: 36 O: No L: 5 Days I: No	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: IV HYDRATION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13803 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:75.3 kg					
(Cont.) TRT	1	TO	32	32	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 32 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.) TRT	1 TO	32	32	R: HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 32 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.) TRT	1 TO	50	50	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 70 O: No L: 21 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.) TRT	1 TO	268	268	R: SEPSIS SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 283 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOCYTOPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.)	TRT 1 TO	287	287	R: OSTEOARTHRITIS S: Musculoskeletal and connective tissue disorders P: 変形性関節症 L: Osteoarthritis	O: No I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BASELINE HISTORY OF OSTEOARTHRITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
(Cont.)	TRT	1 TO 411	411	R: PERICARDITIS S: Cardiac disorders P: 心膜炎 L: Pericarditis	E: 414 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, PER EMR VIEWED ON 04OCT2018, PATIENT HAD A FOLLOW-UP VISIT AT CEDARS SINAI FOR PERICARDIAL EFFUSION AS AN OUTPATIENT MEDICAL PROCEDURE OF PERICARDIOCENTESIS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERICARDIAL EFFUSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13803 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:75.3 kg					
(Cont.) TRT	1	TO	422	422	R: PERICARDIAL TAMPONADE S: Cardiac disorders P: 心タンポナーデ L: Pericardial tamponade	E: 428 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERICARDITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13803 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:75.3 kg					
(Cont.) TRT		1 TO	422	422	R: LARGE PERICARDIAL EFFUSION S: Cardiac disorders P: 心嚢液貯留 L: Pericardial effusion	E: 428 O: No L: 7 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERICARDITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
(Cont.)	TRT	1 TO	760	760	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 785 O: No L: 26 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:75.3 kg				
(Cont.) TRT	1	TO	763	763	R: HEMATOMA - LEFT HIP FROM SURGERY INCISION S: Injury, poisoning and procedural complications P: 切開部位血腫 L: Incision site hematoma	E: 785 O: No L: 23 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HIP SURGERY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803 Age:8[redacted]	Sex:Male	Race:WHITE	Weight:75.3 kg				
(Cont.) TRT	1	TO	778	778	R: PAIN IN LEFT WRIST WITH SWELLING S: Musculoskeletal and connective tissue disorders P: 関節痛 L: Wrist pain	E: 896 O: No L: 119 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE - ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.)	TRT 1 TO	778	778	R: PAIN IN LEFT WRIST WITH SWELLING S: Musculoskeletal and connective tissue disorders P: 関節腫脹 L: Swelling of wrists	E: 896 O: No L: 119 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE - ACUTE MYELOID LEUKEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13803	Age:8[redacted] Sex:Male Race:WHITE Weight:75.3 kg						
	(Cont.) TRT	1 TO	882	882	R: SKIN ABSCESS (BACK) S: Infections and infestations P: 皮下組織膿瘍 L: Back abscess	O: No I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED STATE DUE TO CHEMOTHERAPY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804	Age:9[redacted] Sex:Female Race:WHITE Weight:59.5 kg						
		TRT 1 TO	23	23 R: SINUSITIS S: Infections and infestations P: 副鼻腔炎 L: Sinusitis	E: 38 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: Multiple: MEDICAL PROCEDURE, SPHENOIDOTOMY C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			258	258 R: PERIRECTAL CELLULITUS S: Infections and infestations P: 肛門直腸蜂巣炎 L: Anorectal cellulitis	E: 304 O: No L: 47 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804	Age:9[redacted] Sex:Female Race:WHITE Weight:59.5 kg						
	(Cont.) TRT	1 TO 258	258	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 266 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804	Age:9[redacted] Sex:Female Race:WHITE Weight:59.5 kg						
	(Cont.)	TRT 1 TO	258	258	R: PSEUDOMONAS SEPSIS S: Infections and infestations P: シュードモナス性敗血症 L: Pseudomonal sepsis	E: 274 O: No L: 17 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804	Age:9[redacted] Sex:Female Race:WHITE Weight:59.5 kg						
	(Cont.) TRT	1 TO 258	258	R: URINARY TRACT INFECTION WITH ENTEROCOCCUS FAECALIS S: Infections and infestations P: 腸球菌性尿路感染 L: Enterococcal urinary tract infection	E: 274 O: No L: 17 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERIRECTAL CELLULITIS,ENTEROCOCCUS FAECALIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804 Age:9[redacted]	Sex:Female	Race:WHITE	Weight:59.5 kg				
(Cont.) TRT	1 TO	361	361	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 365 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PAROXYSMAL ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13804 Age:9[redacted]	Sex:Female	Race:WHITE	Weight:59.5 kg				
(Cont.) TRT	1 TO	361	361	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 365 O: No L: 5 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		577	577	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 583 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13806#	Age:7[redacted] Sex:Female Race:WHITE Weight:52.5 kg							
	TRT	1 TO 28	28	28	R: FATIGUE S: General disorders and administration site conditions P: 疲労 L: Fatigue	E: 31 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine							
13806#	Age:7[redacted] Sex:Female Race:WHITE Weight:52.5 kg						
	(Cont.)	TRT 1 TO 28	28	28	R: FUNGAL SEPSIS S: Infections and infestations P: 真菌性敗血症 L: Fungal sepsis	E: 31 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13806#	Age:7[redacted] Sex:Female Race:WHITE Weight:52.5 kg							
(Cont.)	TRT	1 TO 28	28	28	R: NAUSEA S: Gastrointestinal disorders P: 悪心 L: Nausea	E: 31 O: No L: 4 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13807#	Age:7[redacted] Sex:Male Race:WHITE Weight:66.7 kg							
		TRT	1 TO 268	137	137	R: PICC LINE INFECTION, RIGHT UPPER ARM S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 142 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53503) TRT: Venetoclax 400 mg QD + Azacitidine								
13808	Age:7[redacted] Sex:Male Race:ASIAN Weight:55.8 kg							
	TRT	1 TO	229	229	R: PICC LINE INFECTION LEFT UPPER ARM S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection	E: 240 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109760) TRT: Venetoclax 400 mg QD + Azacitidine							
34001# Age:7[redacted] Sex:Male Race:WHITE Weight:81.2 kg							
	TRT	1 TO 350	2	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 13 O: No L: 12 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109760) TRT: Venetoclax 400 mg QD + Azacitidine								
34001# Age:7[redacted] Sex:Male Race:WHITE Weight:81.2 kg								
(Cont.)	TRT	1 TO 350	22	22	R: 'SERONEGATIVE INFLAMMATORY ARTHROPATHIES S: Musculoskeletal and connective tissue disorders P: 血清反応陰性関節炎 L: Seronegative arthropathy	E: 29 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MYELODYSPLASTIC SYNDROME V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109760) TRT: Venetoclax 400 mg QD + Azacitidine								
34001#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.2 kg							
(Cont.)	TRT	1 TO 350	54	54	R: PSOAS ABCESS S: Infections and infestations P: 腰筋膿瘍 L: Psoas abscess	E: 72 O: No L: 19 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			84	84	R: PSOAS ABSESS INCREASE UNDER CIPROXINE S: Infections and infestations P: 腰筋膿瘍 L: Psoas abscess	E: 122 O: No L: 39 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109760) TRT: Venetoclax 400 mg QD + Azacitidine							
34001#	Age:7[redacted] Sex:Male Race:WHITE Weight:81.2 kg						
(Cont.)	TRT	1 TO 350	120	120	R: ACUTE CHOLECYSTITIS S: Hepatobiliary disorders P: 急性胆嚢炎 L: Acute cholecystitis	E: 187 O: No L: 68 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, CHOLECYSTECTOMY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHOLELITHIASIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (109760) TRT: Venetoclax 400 mg QD + Azacitidine							
34001# Age:7[redacted] Sex:Male Race:WHITE Weight:81.2 kg							
	(Cont.) TRT	1 TO 350	162	162	R: OROPHARYNGEAL CANDIDIASIS S: Infections and infestations P: 中咽頭カンジダ症 L: Oropharyngeal candidiasis	E: 173 O: No L: 12 Days I: No	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66101 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:76.0 kg				
	TRT	1 TO	63	63	R: HYPOTENSION S: Vascular disorders P: 低血圧 L: Hypotension	E: 63 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: IV INFUSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPOVOLEMIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66101 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:76.0 kg				
(Cont.) TRT	1 TO	91	91	R: ACUTE TONSILLITIS S: Infections and infestations P: 扁桃炎 L: Acute tonsillitis	E: 99 O: No L: 9 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
		266	266	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 273 O: No L: 8 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: PLATELET TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66101	Age:7[redacted] Sex:Male Race:WHITE Weight:76.0 kg						
(Cont.) TRT		1 TO	653	653	R: ATRIOVENTRICULAR BLOCK S: Cardiac disorders P: 房室ブロック L: Atrioventricular block	E: 659 O: No L: 7 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CONCOMITANT PATHOLOGY OF THE CARDIOVASCULAR SYSTEM V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66102	Age:6[redacted] Sex:Female Race:WHITE Weight:64.0 kg						
	TRT	1 TO	147	147	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 154 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66102	Age:6[redacted] Sex:Female Race:WHITE Weight:64.0 kg						
	(Cont.) TRT	1 TO 420	420	R: ACUTE RHINITIS WITH FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 424 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: REDUCED IMMUNITY AGAINST THE BACKGROUND OF THE UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66102	Age:6[redacted] Sex:Female Race:WHITE Weight:64.0 kg							
(Cont.)	TRT	1 TO	420	420	R: ACUTE RHINITIS WITH FEVER S: Infections and infestations P: 鼻炎 L: Acute rhinitis	E: 424 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: REDUCED IMMUNITY AGAINST THE BACKGROUND OF THE UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66103	Age:8[redacted] Sex:Female Race:WHITE Weight:70.0 kg							
	TRT	1 TO	71	71	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 74 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: Multiple: MEDICAL PROCEDURE, BLOOD TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66103 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:70.0 kg				
(Cont.) TRT	1 TO	465	465	R: CEREBROVASCULAR ACCIDENT ON ISCHEMIC TYPE S: Nervous system disorders P: 虚血性脳卒中 L: Ischemic stroke	E: 501 O: No L: 37 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: Multiple: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CEREBRAL ATHEROSCLEROSIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66103 Age:8[redacted]	Sex:Female	Race:WHITE	Weight:70.0 kg				
(Cont.) TRT	1 TO	503	503	R: ADENOCARCINOMA OF THE SIGMOID COLON S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 結腸腺癌 L: Adenocarcinoma of colon	E: 560 O: No L: 58 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AN ALTERNATIVE CAUSE IS UNKNOWN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66104#	Age:6[redacted] Sex:Female Race:WHITE Weight:88.0 kg							
	TRT	1 TO 192	192	192	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 193 O: No L: 2 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: SEE TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
	POST	193 TO 692	6	198	R: BILATERAL FOCAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 219 O: No L: 22 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66105 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:72.0 kg					
	TRT	1 TO	8	8	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 8 O: No L: 1 Day I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING O: ANEMIA AND CONCOMITANT CARDIAC PATHOLOGY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66105	Age:7[redacted] Sex:Male Race:WHITE Weight:72.0 kg						
(Cont.)	TRT	1 TO	76	76	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 81 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66106#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg						
		POST 7 TO 16	1	7	R: SEPSIS-ESCHERICHIA COLI.ENTEROCOCCUS FAECALIS S: Infections and infestations P: 腸球菌性敗血症 L: Enterococcal sepsis	E: 15 O: No L: 9 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66106#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg						
		(Cont.) POST 7 TO 16	1	7	R: SEPSIS-ESCHERICHIA COLI.ENTEROCOCCUS FAECALIS S: Infections and infestations P: 大腸菌性敗血症 L: Escherichia sepsis	E: 15 O: No L: 9 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine							
66106#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg						
		(Cont.) POST 7 TO 16	1	7	R: NECROTIC ENTEROPATHY S: Gastrointestinal disorders P: 壊死性大腸炎 L: Necrotizing enterocolitis	E: 12 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66106#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg							
		(Cont.) POST	7 TO 16	8	14	R: EXTENSIVE INTRACEREBRAL HEMATOMA OF THE LEFT TEMPORO-PARIETO-OCCIPITAL REGION S: Nervous system disorders P: 脳血腫 L: Intracerebral hematoma	E: 14 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TRANSFUSION DEPENDENT THROMBOCYTOPENIA GRADE 4 . V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (114329) TRT: Venetoclax 400 mg QD + Azacitidine								
66107#	Age:7[redacted] Sex:Male Race:WHITE Weight:69.2 kg							
		TRT	1 TO 118	118	118	R: PAROXYSM OF ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Paroxysmal atrial fibrillation	E: 118 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT PATHOLOGY OF THE CARDIOVASCULAR SYSTEM V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Placebo + Azacitidine								
58005#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg							
	TRT	1 TO 28	17	17	R: DIVERTICULLITIS S: Infections and infestations P: 憩室炎 L: Diverticulitis	E: 29 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DIVERTICULOSIS THAT BECAME INFLAMED DUE TO NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Placebo + Azacitidine							
58005#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg						
	(Cont.)	POST 29 TO 76	4	32	R: E. FAECIUM VRE URINARY TRACT INFECTION S: Infections and infestations P: 腸球菌感染 L: Enterococcus faecium infection	E: 42 O: No L: 11 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Placebo + Azacitidine							
58005#	Age:7[redacted] Sex:Female Race:WHITE Weight:49.0 kg						
	(Cont.)	POST 29 TO 76	18	46	R: P. AERUGINOSA SEPSIS S: Infections and infestations P: シュードモナス性敗血症 L: Pseudomonal sepsis	E: 75 O: No L: 30 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58002#	Age:7[redacted] Sex:Male Race:WHITE Weight:93.0 kg							
		TRT 1	1	1	R: CARDIAC FAILURE - DECOMPENSATED ISCHEMIC CARDIOMIOPATHY, PERMANENT ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Permanent atrial fibrillation	E: 6 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: Multiple: MEDICAL PROCEDURE, INTUBATION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DECOMPENSATED PREVIOUS ISCHAEMIC CARDIOMYOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine 58002# Age:7[redacted] Sex:Male Race:WHITE Weight:93.0 kg							
(Cont.) TRT	1	1	1	R: CARDIAC FAILURE - DECOMPENSATED ISCHEMIC CARDIOMIOPATHY, PERMANENT ATRIAL FIBRILLATION S: Cardiac disorders P: 心不全 L: Cardiac failure	E: 6 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: Multiple: MEDICAL PROCEDURE, INTUBATION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DECOMPENSATED PREVIOUS ISCHAEMIC CARDIOMYOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine 58002# Age:7[redacted] Sex:Male Race:WHITE Weight:93.0 kg							
(Cont.) TRT	1	1	1	R: CARDIAC FAILURE - DECOMPENSATED ISCHEMIC CARDIOMIOPATHY, PERMANENT ATRIAL FIBRILLATION S: Cardiac disorders P: 虚血性心筋症 L: Ischemic cardiomyopathy	E: 6 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: Multiple: MEDICAL PROCEDURE, INTUBATION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DECOMPENSATED PREVIOUS ISCHAEMIC CARDIOMYOPATHY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58003# Age:6[redacted] Sex:Male Race:WHITE Weight:115.0 kg							
	TRT	1 TO 115	26	26	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 47 O: No L: 22 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58003#	Age:6[redacted] Sex:Male Race:WHITE Weight:115.0 kg						
	(Cont.)	POST 116 TO 198	14	129	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 144 O: No L: 16 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION SUSCEPTIBILITY DUE TO DISEASE PROGRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58004 Age:6[redacted] Sex:Female Race:WHITE Weight:51.0 kg								
		TRT	1 TO	232	232	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 246 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEVER DUE TO PROLONGED NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58004	Age:6[redacted] Sex:Female Race:WHITE Weight:51.0 kg						
	(Cont.) TRT	1 TO	735	735	R: S. AUREUS BLOOD INFECTION S: Infections and infestations P: ブドウ球菌性敗血症 L: Staphylococcus aureus septicemia	E: 749 O: No L: 15 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERSISTENT NEUTROPENIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58006 Age:6[redacted] Sex:Female Race:WHITE Weight:89.0 kg								
	TRT	1 TO	28	28	R: E. FAECIUM CYSTITIS S: Infections and infestations P: 腸球菌性尿路感染 L: Enterococcal urinary tract infection	E: 63 O: No L: 36 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED A: Other: TREATMENT POSTPONED FOR 3 DAYS C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: E. FAECIUM INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58006 Age:6[redacted]	Sex:Female	Race:WHITE	Weight:89.0 kg				
(Cont.) TRT	1 TO	388	388	R: PULMONARY NOCARDIOSIS S: Infections and infestations P: 肺ノカルジア症 L: Pulmonary nocardiosis	E: 393 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROLONGED NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58007#	Age:7[redacted] Sex:Male Race:WHITE Weight:60.0 kg							
		TRT 1 TO 57	28	28	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 34 O: No L: 7 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58008# Age:6[redacted] Sex:Male Race:WHITE Weight:75.0 kg								
	TRT	1 TO 346	268	268	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE S: Cardiac disorders P: 心房細動 L: Atrial fibrillation with rapid ventricular response	E: 268 O: No L: 1 Day I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEVER V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58008# Age:6[redacted] Sex:Male Race:WHITE Weight:75.0 kg							
	(Cont.) TRT	1 TO 346	268	268	R: P. AERUGINOSA RESPIRATORY TRACT INFECTION S: Infections and infestations P: シュードモナス感染 L: Infection Pseudomonas aeruginosa	E: 275 O: No L: 8 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC FEVER, P. AERUGINOSA WAS ISOLATED IN SPUTUM AND PATIENT WAS GIVEN ANTIBIOTICS ACCORDINGLY TO ANTIBIOGRAM V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:66.0 kg				
	TRT	1 TO	15	15	R: TONSILLOPHARYNGITIS S: Infections and infestations P: 咽頭扁桃炎 L: Pharyngotonsillitis	E: 19 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
(Cont.)	TRT	1 TO	17	17	R: NSTEMI - ACUTE CORONARY SYNDROME S: Cardiac disorders P: 急性冠動脈症候群 L: Non ST segment elevation acute coronary syndrome	E: 18 O: No L: 2 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RAPID ATRIAL FIBRILLATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
(Cont.) TRT		1 TO #	71	71	R: FEMORO-POPLITEAL BYPASS OCCLUSION S: Injury, poisoning and procedural complications P: 動脈バイパス閉塞 L: Femoropopliteal artery bypass occlusion	E: 72 O: No L: 2 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PERIPHERAL ARTERIAL DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine								
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg							
(Cont.) TRT		1 TO	95	95	R: FEMORO POPLITEAL BYPASS REOCCLUSION S: Injury, poisoning and procedural complications P: 動脈バイパス閉塞 L: Femoropopliteal artery bypass occlusion	E: 100 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PERIPHERAL ARTERIAL DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
	(Cont.) TRT	1 TO	281	281	R: BRONCHEOLITIS S: Infections and infestations P: 細気管支炎 L: Bronchiolitis	E: 303 O: No L: 23 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:66.0 kg				
(Cont.) TRT	1 TO	344	344	R: K. PNEUMONIAE SEPSIS S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	E: 360 O: No L: 17 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROLONGED NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
	(Cont.) TRT	1 TO	406	406	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 410 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UPPER RESPIRATORY TRACT INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:66.0 kg				
(Cont.) TRT	1 TO	456	456	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 477 O: No L: 22 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
(Cont.) TRT		1 TO #	534	534	R: E. COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 542 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNINARY INFECTION WITH E.COLI V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009	Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg						
	(Cont.) TRT	1 TO	564	564	R: K. PNEUMONIAE AND P. MIRABILIS BLOOD INFECTION S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	E: 582 O: No L: 19 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROLONGED NEUTROPENIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch / Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (111121) TRT: Venetoclax 400 mg QD + Azacitidine							
58009 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:66.0 kg				
(Cont.) TRT	1 TO	564	564	R: K. PNEUMONIAE AND P. MIRABILIS BLOOD INFECTION S: Infections and infestations P: プロテウス感染 L: Proteus infection	E: 582 O: No L: 19 Days I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROLONGED NEUTROPENIA V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine								
44203#	Age:8[redacted] Sex:Male Race:WHITE Weight:84.0 kg							
		POST 9 TO 15	4	12	R: ROTATORY VERTIGO S: Ear and labyrinth disorders P: 回転性めまい L: Rotatory vertigo	E: 14 O: No L: 3 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THIS IS PLAUSIBLE WITH MEDICAL HISTORY TACHYARRHYTMIA ABSOLUTA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine								
44204# Age:7[redacted] Sex:Female Race:WHITE Weight:85.0 kg								
	TRT	1 TO 6	4	4	R: INFECTION OF UNKNOWN ORIGIN S: Infections and infestations P: 感染 L: Infection	E: 9 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine								
44204#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.0 kg							
		(Cont.) TRT 1 TO 6	5	5	R: INSTABLE ANGINA PECTORIS S: Cardiac disorders P: 不安定狭心症 L: Angina pectoris unstable	E: 9 O: No L: 5 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING CARDIAC MEDICAL HISTORY V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine							
44204# Age:7[redacted] Sex:Female Race:WHITE Weight:85.0 kg							
(Cont.) TRT	1 TO 6	6	6	R: UROSEPSIS S: Infections and infestations P: 尿路性敗血症 L: Urosepsis	E: 9 O: No L: 4 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: URINARY TRACT INFECTION NO INFORMATIONS AVAILABLE, UNDERLYING DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine								
44204#	Age:7[redacted] Sex:Female Race:WHITE Weight:85.0 kg							
	(Cont.)	POST 7 TO 10	1	7	R: CHOLECYSTITIS S: Hepatobiliary disorders P: 胆嚢炎 L: Cholecystitis	E: 9 O: No L: 3 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AGE RELATED V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine								
44205#	Age:7[redacted] Sex:Female Race:WHITE Weight:64.2 kg							
	TRT	1 TO 119	47	47	R: ERYSIPELE INFECTION OF RIGHT HAND S: Infections and infestations P: 丹毒 L: Erysipelas	E: 92 O: No L: 46 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED STATE OF AML PATIENT V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53326) TRT: Venetoclax 400 mg QD + Azacitidine 44205# Age:7[redacted] Sex:Female Race:WHITE Weight:64.2 kg							
	(Cont.)	POST 120 TO 776	7	126	R: KLEBSIELLA PNEUMONIA S: Infections and infestations P: クレブシエラ菌性肺炎 L: Klebsiella pneumonia	E: 153 O: No L: 28 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUGWITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Placebo + Azacitidine								
94206#	Age:6[redacted] Sex:Female Race:ASIAN Weight:75.0 kg							
		TRT 1 TO 38	8	8	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Placebo + Azacitidine							
94209# Age:6[redacted] Sex:Male Race:ASIAN Weight:63.5 kg							
	TRT	1 TO 286	69	69	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	O: Yes I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Placebo + Azacitidine							
94212# Age:6[redacted] Sex:Male Race:ASIAN Weight:53.0 kg							
	TRT	1 TO 86	42	42	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 58 O: No L: 17 Days I: Yes	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LEUKOPENIA NEUTROPENIA V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	87 TO 237	24	110	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	O: Yes I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine								
94203# Age:6[redacted] Sex:Female Race:ASIAN Weight:57.0 kg								
	TRT	1 TO 232	2	2	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	O: Yes I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
				2	R: TRANSFUSION DEPENDENT THROMBCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	O: Yes I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine								
94204# Age:6[redacted] Sex:Female Race:ASIAN Weight:66.0 kg								
	TRT	1 TO 28	27	27	R: HEMOLYSIS S: Blood and lymphatic system disorders P: 溶血 L: Hemolysis	E: 38 O: No L: 12 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
	POST	29 TO 39	5	33	R: BACTEREMIA,BURKHOLDERIA ONION S: Infections and infestations P: 菌血症 L: Bacteremia	E: 38 O: No L: 6 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine							
94204# Age:6[redacted] Sex:Female Race:ASIAN Weight:66.0 kg							
(Cont.)	POST	29 TO 39	5	33	R: BACTEREMIA,BURKHOLDERIA ONION S: Infections and infestations P: バークホルデリア感染 L: Burkholderia infection	E: 38 O: No L: 6 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, LIFE THREATENING V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			9	37	R: BILATERAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Bilateral pneumonia	E: 38 O: No L: 2 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine							
94207 Age:6[redacted] Sex:Male Race:ASIAN Weight:63.0 kg							
	TRT	1 TO	341	341	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 348 O: No L: 8 Days I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine								
94208# Age:8[redacted] Sex:Male Race:ASIAN Weight:64.7 kg								
		TRT 1 TO 203	22	22	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	O: Yes I: Yes	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			39	39	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	O: Yes I: Yes	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended of Rx Day O:Ongoing as L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine							
94210# Age:7[redacted] Sex:Male Race:ASIAN Weight:56.0 kg							
	TRT	1 TO 69	69	69	R: COMA AND CONVULSIONS S: Nervous system disorders P: 昏睡 L: Coma	E: 70 O: No L: 2 Days I: No	D: No G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: 1.DIABETES 2.ADVANCED AGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine							
94210# Age:7[redacted] Sex:Male Race:ASIAN Weight:56.0 kg							
(Cont.)	TRT	1 TO 69	69	69	R: COMA AND CONVULSIONS S: Nervous system disorders P: 痙攣発作 L: Convulsions	E: 70 O: No L: 2 Days I: No	D: No G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG INTERRUPTED, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: 1.DIABETES 2.ADVANCED AGE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (115026) TRT: Venetoclax 400 mg QD + Azacitidine							
94213 Age:7[redacted] Sex:Female Race:ASIAN Weight:55.0 kg							
	TRT	1 TO #	216	216	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: No I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118610) TRT: Venetoclax 400 mg QD + Azacitidine							
85501	Age:8[redacted] Sex:Male Race:ASIAN Weight:51.0 kg						
	TRT	1 TO 86	86	R: INFLUENZA A VIRUS INFECTION S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 92 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT WAS SUSCEPTIBLE TO VIRAL INFECTION DUE TO REDUCED IMMUNITY. V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (118610) TRT: Venetoclax 400 mg QD + Azacitidine							
85501 Age:8[redacted] Sex:Male Race:ASIAN Weight:51.0 kg							
(Cont.) TRT	1 TO	279	279	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 291 O: No L: 13 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
		380	380	R: INTESTINAL INFECTION S: Infections and infestations P: 消化管感染 L: Gastrointestinal infection	E: 394 O: No L: 15 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION. V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Placebo + Azacitidine							
74202#	Age:8[redacted] Sex:Female Race:WHITE Weight:76.7 kg						
		POST 19 TO 41	5	23	R: FATIGUE S: General disorders and administration site conditions P: 疲労 L: Fatigue	E: 40 O: No L: 18 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Placebo + Azacitidine								
74203#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
	TRT	1 TO 294	1	1	R: HYPERSENSITIVITY REACTION TO AZACITIDINE S: Immune system disorders P: 薬物過敏症 L: Drug hypersensitivity	E: 8 O: No L: 8 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Placebo + Azacitidine								
74203#	Age:7[redacted] Sex:Male Race:WHITE Weight:74.0 kg							
		(Cont.) TRT	1 TO 294	232	232	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 235 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Placebo + Azacitidine								
74206#	Age:7[redacted] Sex:Male Race:WHITE Weight:63.0 kg							
		POST	162 TO 166	1	162	R: HYPONATREMIA S: Metabolism and nutrition disorders P: 低ナトリウム血症 L: Hyponatremia	E: 165 O: No L: 4 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: FLUID RESTRICTION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MOST LIKELY DUE TO DISEASE PROGRESION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Venetoclax 400 mg QD + Azacitidine								
74204#	Age:7[redacted] Sex:Female Race:WHITE Weight:73.0 kg							
	TRT	1 TO 124	121	121	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 126 O: No L: 6 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Venetoclax 400 mg QD + Azacitidine								
74205#	Age:7[redacted] Sex:Female Race:WHITE Weight:68.0 kg							
	TRT	1 TO 108	4	4	R: ABDOMINAL WALL CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of abdominal wall	E: 29 O: No L: 26 Days I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ABDOMINAL CELLULITIS DUE TO SUB CUTANEOUS INJECTIONS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Venetoclax 400 mg QD + Azacitidine								
74205#	Age:7[redacted] Sex:Female Race:WHITE Weight:68.0 kg							
(Cont.)	TRT	1 TO 108	73	73	R: HEMATEMESIS S: Gastrointestinal disorders P: 吐血 L: Hematemesis	E: 196 O: No L: 124 Days I: Yes	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: Yes	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TREATMENT WITH COUMADIN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (112188) TRT: Venetoclax 400 mg QD + Azacitidine							
74205#	Age:7[redacted] Sex:Female Race:WHITE Weight:68.0 kg						
(Cont.)	TRT	1 TO 108	108	108	R: SOFT TISSUE BLEEDING S: Musculoskeletal and connective tissue disorders P: 軟部組織出血 L: Soft tissue bleeding	E: 124 O: No L: 17 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, AZACITIDINE|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130299) TRT: Venetoclax 400 mg QD + Azacitidine							
94102# Age:8[redacted] Sex:Male Race:ASIAN Weight:51.0 kg							
	TRT	1 TO 105	2	2	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	O: Yes I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKOWEN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
			105	105	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板减少症 L: Thrombocytopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None O: BLOOD TRANSFUSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130299) TRT: Venetoclax 400 mg QD + Azacitidine								
94102#	Age:8[redacted] Sex:Male Race:ASIAN Weight:51.0 kg							
	(Cont.)	POST	106 TO 147	18	123	R: PANHEMATOPENIA S: Blood and lymphatic system disorders P: 汎血球減少症 L: Pancytopenia	O: Yes I: No	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: BLOOD TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF DISEASE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130308) TRT: Venetoclax 400 mg QD + Azacitidine								
93105	Age:6[redacted] Sex:Male Race:ASIAN Weight:83.5 kg							
		TRT	1 TO	87	87	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 95 O: No L: 9 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No
93107#	Age:7[redacted] Sex:Male Race:ASIAN Weight:51.0 kg							
		POST	71 TO 263	3	73	R: LEUKOPENIA S: Blood and lymphatic system disorders P: 白血球減少症 L: Leukopenia	E: 76 O: No L: 4 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130308) TRT: Venetoclax 400 mg QD + Azacitidine							
93107#	Age:7[redacted] Sex:Male Race:ASIAN Weight:51.0 kg						
		(Cont.) POST 71 TO 263	3	73 R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 87 O: No L: 15 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			4	74 R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	O: Yes I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: TRANSFUSION C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (130308) TRT: Venetoclax 400 mg QD + Azacitidine							
93107#	Age:7[redacted] Sex:Male Race:ASIAN Weight:51.0 kg						
		(Cont.) POST 71 TO 263	7	77	R: LEUKOPENIA S: Blood and lymphatic system disorders P: 白血球減少症 L: Leukopenia	E: 87 O: No L: 11 Days I: No	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION R: No

Data included are subject to a cutoff date of 04JAN2020. POST = Post study drug treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82705) TRT: Venetoclax 400 mg QD + Azacitidine							
52001#	Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg						
	TRT	1 TO 70	29	29	R: ERYTHEMA PAPULA ON BODY SKIN, ON THE RIGHT SIDE OF BACK S: Skin and subcutaneous tissue disorders P: 丘疹性皮疹 L: Erythropapular rash	E: 34 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VASCULITIS V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (82705) TRT: Venetoclax 400 mg QD + Azacitidine								
52001# Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg								
(Cont.)	TRT	1 TO 70	66	66	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 67 O: No L: 2 Days I: Yes	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52401	Age:6[redacted] Sex:Female Race:WHITE Weight:44.0 kg						
	TRT	1 TO 22	22	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 27 O: No L: 6 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE OF AE WAS MOST LIKELY INFECTION, BUT EXACT INFECTIOUS SOURCE WAS NOT FOUND. IT WAS NOT CAUSED BY STUDY DRUG. V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52401 Age:6[redacted]	Sex:Female	Race:WHITE	Weight:44.0 kg				
(Cont.) TRT	1 TO	152	152	R: STREPTOCOCCUS PNEUMONIAE PNEUMONIA S: Infections and infestations P: 肺炎球菌性肺炎 L: Streptococcus pneumoniae pneumonia	E: 160 O: No L: 9 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STREPTOCOCCUS PNEUMONIAE INFECTION AND AML THAT CAUSES AN IMMUNOSUPRESSION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch	Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine								
52402#	Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg							
		TRT	1 TO 267	6	R: COLITIS S: Gastrointestinal disorders P: 大腸炎 L: Colitis	E: 17 O: No L: 12 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAD SEVERE NEUTROPENIA, COLITIS COULD HAVE BEEN CAUSED BY ANY BACTERIA, BUT EXACT CAUSE IS UNKNOWN V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52402#	Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
	(Cont.) TRT	1 TO 267 Day 61	61	R: PSEUDOMONAS AERUGINOSA INFECTION S: Infections and infestations P: シュードモナス感染 L: Pseudomonas infection	E: 67 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS AML AND IMMUNODEFICIENCY DUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine 52402# Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg							
	(Cont.)	TRT 1 TO 267	82	R: OTITIS MEDIA (RIGHT EAR) S: Infections and infestations P: 中耳炎 L: Otitis media	E: 101 O: No L: 20 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION (PSEUDOMONAS AERUGINOSA WAS DETECTED IN BLOOD CULTURES) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52402#	Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
	(Cont.)	TRT 1 TO 267	120	120	R: INJECTION SITE INFLAMMATION S: General disorders and administration site conditions P: 注射部位炎症 L: Injection site inflammation	E: 124 O: No L: 5 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52402#	Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
(Cont.)	TRT	1 TO 267	187	187	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 208 O: No L: 22 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTION AND MMUNOSUPRESSION CAUSED BY HEMATOLOGICAL MALIGNANCY (AML) V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52402#	Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg						
(Cont.)	TRT	1 TO 267 Day 249	249	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 261 O: No L: 13 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTION (NO DEFINITIVE CAUSE CAN BE NAMED), AND PATIENT HAD IMMUNOSUPRESSION DIUE TO AML V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine								
52403	Age:7[redacted] Sex:Male Race:WHITE Weight:99.0 kg							
	TRT	1 TO	44	44	R: CARCINOMA SPINOCELLULARE OF THE ARM S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 皮膚有棘細胞癌 L: Spinocellular carcinoma	E: 45 O: No L: 2 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None O: MEDICAL PROCEDURE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE: SPINOCELLULAR CARCINOMA. POSSIBLE CAUSE: ULTRAVIOLET RADIATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52403 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:99.0 kg				
(Cont.) TRT	1 TO	80	80	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 86 O: No L: 7 Days I: No	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52403 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:99.0 kg				
(Cont.) TRT	1 TO	210	210	R: INFLUENZA A INFECTION S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 218 O: No L: 9 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: Multiple: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, AZACITIDINE|DRUG INTERRUPTED C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOSUPPRESSION CAUSED BY AML MAY BE ANOTHER REASON V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (53952) TRT: Venetoclax 400 mg QD + Azacitidine							
52403 Age:7[redacted]	Sex:Male	Race:WHITE	Weight:99.0 kg				
(Cont.) TRT	1 TO	259	259	R: PAROTITIS (RIGHT SIDE) S: Infections and infestations P: 耳下腺炎 L: Parotitis	E: 261 O: No L: 3 Days I: No	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SIALOADENITIS MIGHT HAVE BEEN THE CAUSE V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Day	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (349769) TRT: Venetoclax 400 mg QD + Azacitidine								
93801#	Age:6[redacted] Sex:Male Race:ASIAN Weight:77.1 kg							
	TRT	1 TO 200	24	24	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 96 O: No L: 73 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 1__11.4

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M15-656 Group 1 and Group 2)

Subject Number	Name	Epoch Interval	Rx Day of AE	Rx Day of AE Onset	R:Reported Term S:System Organ Class P:MedDRA 21.0 Preferred Term L:Lower Level Term	E:Rx Day Ended O:Ongoing as of Rx Day L:Length I:Intermittent?	D:DLT Event G:NCI Toxicity R:Relationship to Venetoclax/Placebo Z:Relationship to AZA A:Actions Taken O:Other Actions Taken C:Concomitant or Additional Treatment Given	S:Serious AE? O:Other Cause of Event V:Abbvie Opinion of Venetoclax/Placebo Causality A:Abbvie Opinion of Azacitidine Causality R:AE Related to TLS
INV: [redacted] (349769) TRT: Venetoclax 400 mg QD + Azacitidine								
93803	Age:7[redacted]	Sex:Male Race:ASIAN Weight:49.0 kg						
	TRT	1 TO	21	21	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 60 O: No L: 40 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No
			78	78	R: HEMOCYTOPENIA AFTER CHEMOTHERAPY S: Blood and lymphatic system disorders P: 血球減少症 L: Cytopenia	E: 109 O: No L: 32 Days I: No	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: None C: Yes	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION V: REASONABLE POSSIBILITY A: REASONABLE POSSIBILITY R: No

Data included are subject to a cutoff date of 04JAN2020. TRT = On study treatment.
AZA = Azacitidine. Group 1: Enrolled under original protocol. Group 2: Enrolled not under original protocol.
# Subject prematurely discontinued.

Program Source Code: [redacted]