表 2.7.4-99. 重篤な有害事象を発現した被験者一覧（M14-358 試験）

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53182) TRT:Venetocla 400 mg + DEC 10505# Age:7[redacted] Sex:Female Race:White Weight:60.3 kg								
	OPEN	1 TO 103	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 L: 10 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53182) TRT:Venetocla 400 mg + DEC 10505# Age:7[redacted] Sex:Female Race:White Weight:60.3 kg								
(Cont.)	POST	104 TO	9	112	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 119 L: 8 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
10507# Age:7[redacted] Sex:Male Race:White Weight:78.3 kg								
	POST	59 TO	4	62	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 68 L: 7 Days I: No	G: Grade 4 R1: Reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53182) TRT:Venetocla 800 mg + DEC 10504# Age:6[redacted] Sex:Male Race:White Weight:91.6 kg									
	OPEN	1 TO 103	18	18		R: NEUTROPENIA FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 21 L: 4 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			103	103		R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 106 L: 4 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53182) TRT:Venetocla 800 mg + DEC 10509# Age:7[redacted] Sex:Male Race:White Weight:77.6 kg									
	OPEN	1 TO 26	26	26		R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 31 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
	POST	27 TO	9	35		R: ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L: MENTAL STATUS CHANGES	E: 43 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocl x 400 mg + AZA 12707	Age:8[redacted]	Sex:Male	Race:White		Weight:73.6 kg			
	OPEN	1 TO	318	318	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 320 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			720	720	R: RIGHT LOWER EXTREMITY INFECTION S: INFECTIONS AND INFESTATIONS P: 限局性感染 L: LEG INFECTION	E: 729 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RIGHT LOWER EXTREMITY DOG BITE C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12701# Age:7[redacted] Sex:Female Race:White Weight:51.4 kg								
	OPEN	1 TO 28	20	20	R: RIGHT SIDED MAXILARY SINUSITIS S: INFECTIONS AND INFESTATIONS P: 副鼻腔炎 L: MAXILLARY SINUSITIS	E: 28 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility
	POST	29 TO	6	34	R: RIGHT UPPER LUNG CONSOLIDATION S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺硬化 L: LUNG CONSOLIDATION	E: 38 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12702# Age:7[redacted] Sex:Male Race:White Weight:100.0 kg								
	OPEN	1 TO 45	10	10	R: PICC ASSOCIATED CELLULITIS S: INFECTIONS AND INFESTATIONS P: カテーテル留置部位蜂巣炎 L: CATHETER SITE CELLULITIS	E: 17 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility
			36	36	R: STAPHYLOCOCCUS EPIDERMIDIS BACTEREMIA S: INFECTIONS AND INFESTATIONS P: ブドウ球菌性菌血症 L: STAPHYLOCOCCAL BACTERAEMIA	E: 46 L: 11 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12702# Age:7[redacted] Sex:Male Race:White Weight:100.0 kg								
(Cont.)		POST	46 TO	4	49	R: KLEBSIELLA SEPSIS S: INFECTIONS AND INFESTATIONS P: クレブシエラ性敗血症 L: KLEBSIELLA SEPSIS	E: 50 L: 2 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12705# Age:8[redacted] Sex:Male Race:White Weight:84.5 kg								
	OPEN	1 TO 84	9	9	R: DIARRHEA S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHEA	E: 16 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO TAKING MULTIPLE ANTIBIOTICS C: No reasonable possibility
			70	70	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 74 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53184) TRT:Venetocla 800 mg + AZA 12705# Age:8[redacted] Sex:Male Race:White Weight:84.5 kg								
(Cont.)	OPEN	1 TO 84	82	82	R: PULMONARY ASPERGILLOSIS S: INFECTIONS AND INFESTATIONS P: 気管支肺アスペルギルス症 L: PULMONARY ASPERGILLOSIS	E: 96 L: 15 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CHEST X-RAY, CT NTAP, BRONCHOSCOPY ULTRASOUND	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
12706# Age:8[redacted] Sex:Male Race:White Weight:76.9 kg								
	OPEN	1 TO 789	14	14	R: ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L: MENTAL STATUS CHANGES	E: 17 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12706# Age:8[redacted] Sex:Male Race:White Weight:76.9 kg								
(Cont.)	OPEN	1 TO 789	254	254	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 266 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	790 TO	14	803	R: BONE PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨痛 L: BONE PAIN	E: 818 L: 16 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BONE PAIN FROM GRANIX INJECTIONS. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53184) TRT:Venetocla 800 mg + AZA 12706# Age:8[redacted] Sex:Male Race:White Weight:76.9 kg								
(Cont.)	POST	790 TO	22	811	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 818 L: 8 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15103# Age:7[redacted] Sex:Male Race:White Weight:87.4 kg								
	OPEN	1 TO 1091	71	71	R: ADJUSTMENT DISORDER WITH ANXIETY S: PSYCHIATRIC DISORDERS P: 不安を伴う適応障害 L: ADJUSTMENT DISORDER WITH ANXIETY	E: 91 L: 21 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: NEURO CONSULT, PSYCH EVALUATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PSYCHIATRIC ILLNESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15103# Age:7[redacted] Sex:Male Race:White Weight:87.4 kg								
	(Cont.)	OPEN	1 TO 1091	427	R: COPD EXACERBATION S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 慢性閉塞性肺疾患 L: COPD EXACERBATION	E: 430 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
				445	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 449 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEVER C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15103# Age:7[redacted] Sex:Male Race:White Weight:87.4 kg									
	(Cont.)	OPEN	1 TO 1091	755	755	R: COPD EXACERBATION S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 慢性閉塞性肺疾患 L: COPD EXACERBATION	E: 761 L: 7 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF COPD. C: No reasonable possibility
				1079	1079	R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎障害 L: ACUTE KIDNEY INJURY	E: 1088 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](52791) TRT:Venetocla 400 mg + DEC 15103# Age:7[redacted] Sex:Male Race:White Weight:87.4 kg								
(Cont.)		POST	1092 TO	17	1108	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 1115 L: 8 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PATIENT WAS GIVEN IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15106# Age:7[redacted] Sex:Female Race:White Weight:73.9 kg								
	POST	335 TO	15	349	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 360 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15107# Age:6[redacted] Sex:Female Race:White Weight:63.5 kg								
		OPEN	1 TO 141	46	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 49 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNCLEAR ETIOLOGY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15107# Age:6[redacted] Sex:Female Race:White Weight:63.5 kg								
(Cont.)	OPEN	1 TO 141	52	52	R: BONE PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨痛 L: BONE PAIN	E: 63 L: 12 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			72	72	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 77 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day	of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15108# Age:8[redacted] Sex:Female Race:White Weight:69.0 kg									
	OPEN	1 TO 66	60	60		R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 71 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED C: No reasonable possibility
	POST	67 TO	11	77		R: WORSENING FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE AGGRAVATED	E: 117 L: 41 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 800 mg + DEC 15108# Age:8[redacted] Sex:Female Race:White Weight:69.0 kg								
(Cont.)	POST	67 TO	18	84	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 105 L: 22 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT DISEASE C: No reasonable possibility
			19	85	R: ATRIAL FIBRILLATION, HYPOTENSION S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION	E: 105 L: 21 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRE-EXISTING CHRONIC CARDIAC CONDITION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15108# Age:8[redacted] Sex:Female Race:White Weight:69.0 kg								
(Cont.)		POST	67 TO 85	19	R: ATRIAL FIBRILLATION, HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION		--Same as Above--	
15110# Age:8[redacted] Sex:Female Race:White Weight:62.8 kg								
		OPEN	1 TO 224	102	R: CHEST PAIN(NON-CARDIAC) S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 非心臓性胸痛 L: CHEST PAIN (NON-CARDIAC)	E: 104 L: 3 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THOUGHT AS RELATED TO EPIGASTRIC AILMENT. NO FURTHER INVESTIGATION DONE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15110# Age:8[redacted] Sex:Female Race:White Weight:62.8 kg								
(Cont.)	OPEN	1 TO 224	146	146	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 155 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML, INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15110# Age:8[redacted] Sex:Female Race:White Weight:62.8 kg								
(Cont.)	OPEN	1 TO 224	175	175	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 181 L: 7 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29401# Age:7[redacted] Sex:Female Race:White Weight:61.5 kg								
	POST	29 TO	13	41	R: PHARYNGITIS S: INFECTIONS AND INFESTATIONS P: 咽頭炎 L: PHARYNGITIS	E: 45 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29402# Age:7[redacted] Sex:Male Race:White Weight:89.8 kg									
		POST	439 TO	10	448	R: MUCOSITIS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 粘膜の炎症 L: MUCOSITIS	E: 459 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, AML C: No reasonable possibility
				14	452	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 459 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29402# Age:7[redacted] Sex:Male Race:White Weight:89.8 kg								
(Cont.)	POST	439 TO	24	462	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 473 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
29405# Age:7[redacted] Sex:Male Race:White Weight:88.6 kg								
	OPEN	1 TO 76	50	50	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 57 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29405# Age:7[redacted] Sex:Male Race:White Weight:88.6 kg								
(Cont.)	OPEN	1 TO 76	71	71	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 75 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
29406# Age:7[redacted] Sex:Male Race:White Weight:74.8 kg								
	OPEN	1 TO 233	113	113	R: CERVICAL LYMPHADENOPATHY S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: リンパ節症 L: LYMPHADENOPATHY CERVICAL	E: 130 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29406# Age:7[redacted] Sex:Male Race:White Weight:74.8 kg								
(Cont.)	OPEN	1 TO 233	156	156	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 164 L: 9 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29406# Age:7[redacted] Sex:Male Race:White Weight:74.8 kg								
(Cont.)	OPEN	1 TO 233	232	232	R: GENERALIZED WEAKNESS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: WEAKNESS GENERALIZED	E: 268 L: 37 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](52791) TRT:DDI Venet_clax 400 mg 29406# Age:7[redacted] Sex:Male Race:White Weight:74.8 kg								
(Cont.)	POST	234 TO	1	234	R: ILEUS S: GASTROINTESTINAL DISORDERS P: イレウス L: ILEUS	E: 268 L: 35 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COLON CANCER, HEMICOLECTOMY C: No reasonable possibility
			12	245	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 267 L: 23 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONIA, POSITIVE BLOOD CULTURES C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet clax 400 mg 29407# Age:8[redacted] Sex:Male Race:White Weight:85.7 kg								
	OPEN	1 TO 57	53	53	R: VOLVULUS S: GASTROINTESTINAL DISORDERS P: 腸の軸捻転 L: VOLVULUS	E: 57 L: 5 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF PREEXISTING VOLVOLUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](52791) TRT:DDI Venet_clax 400 mg 29408# Age:7[redacted] Sex:Female Race:White Weight:82.7 kg								
	OPEN	1 TO 128	22	22	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 40 L: 19 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet clax 400 mg 29408# Age:7[redacted] Sex:Female Race:White Weight:82.7 kg								
(Cont.)	OPEN	1 TO 128	87	87	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 89 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
29411# Age:7[redacted] Sex:Male Race:Asian Weight:75.6 kg								
	OPEN	1 TO 1271	63	63	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 70 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA SECONDARY TO THE DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29411# Age:7[redacted] Sex:Male Race:Asian Weight:75.6 kg								
(Cont.)	OPEN	1 TO 1271	1185	1185	R: VOLUME OVERLOAD S: METABOLISM AND NUTRITION DISORDERS P: 水分過負荷 L: VOLUME OVERLOAD	E: 1189 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: FLUID RESTRICTION AND REQUIRED OXYGEN THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TRANSFUSIONS AND MISSED DOSES OF DIURETICS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29411# Age:7[redacted] Sex:Male Race:Asian Weight:75.6 kg								
(Cont.)	OPEN	1 TO 1271	1190	1190	R: RIGHT FOOT DROP S: NERVOUS SYSTEM DISORDERS P: 腓骨神経麻痺 L: FOOT DROP	E: 1195 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: EMG, NEUROPATHY WORK UP	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUROPATHY C: No reasonable possibility
			1215	1215	R: INTRA CRANIAL HEMORRHAGE S: NERVOUS SYSTEM DISORDERS P: 頭蓋内出血 L: INTRACRANIAL HEMORRHAGE	E: 1218 L: 4 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: PLATELET AND FFP TRANSFUSIONS	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:DDI Venet_clax 400 mg 29411#	Age:7[redacted] Sex:Male Race:Asian Weight:75.6 kg							
(Cont.)	POST	1272 TO	14	1285	R: RESPIRATORY DISTRESS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸窮迫 L: RESPIRATORY DISTRESS	E: 1286 L: 2 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML, CONCERN FOR LUNG INFECTION C: No reasonable possibility
29413#	Age:8[redacted] Sex:Female Race:White Weight:69.8 kg							
	POST	29 TO	15	43	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 45 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, INFECTION, ASPIRATION OF VOMITUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet_clax 400 mg 29414# Age:8[redacted] Sex:Female Race:White Weight:73.4 kg								
	OPEN	1 TO 22	4	4	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 25 L: 22 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:DDI Venet clax 400 mg 29414# Age:8[redacted] Sex:Female Race:White Weight:73.4 kg								
(Cont.)	OPEN	1 TO 22	22	22	R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎障害 L: ACUTE KIDNEY INJURY	E: 25 L: 4 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CRRT PERFORMED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION, ANTI FUNGAL MEDICATIONS C: No reasonable possibility
	POST	23 TO	2	24	R: STROKE S: NERVOUS SYSTEM DISORDERS P: 脳血管発作 L: STROKE	E: 25 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPERTENSION, AGE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 400 mg + DEC 15512# Age:7[redacted] Sex:Female Race:American Indian/Alaska Native Weight:59.0 kg									
	OPEN	1 TO 130	70	70		R: DIARRHEA S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHEA	E: 77 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
	POST	131 TO	13	143		R: CELLULITIS S: INFECTIONS AND INFESTATIONS P: 蜂巣炎 L: CELLULITIS	E: 164 L: 22 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML,SKIN LACERATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15512# Age:7[redacted] Sex:Female Race:American Indian/Alaska Native Weight:59.0 kg								
(Cont.)	POST	131 TO	20	150	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, AML C: No reasonable possibility
15514# Age:8[redacted] Sex:Male Race:White Weight:85.6 kg								
	OPEN	1 TO 173	82	82	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 89 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](52791) TRT:Venetocla 400 mg + DEC 15514# Age:8[redacted] Sex:Male Race:White Weight:85.6 kg								
(Cont.)	OPEN	1 TO 173	168	168	R: LUNG INFECTION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	E: 179 L: 12 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, AML C: No reasonable possibility
	POST	174 TO	9	182	R: LUNG INFECTION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	E: 194 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocl x 400 mg + DEC 15521 Age:6[redacted] Sex:Female Race:White Weight:53.4 kg								
	OPEN	1 TO	139	139	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 141 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
15522# Age:6[redacted] Sex:Male Race:White Weight:114.0 kg								
	OPEN	1 TO 787	28	28	R: SCROTAL INFECTION S: INFECTIONS AND INFESTATIONS P: 陰嚢感染 L: SCROTAL INFECTION	E: 41 L: 14 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15524# Age:6[redacted] Sex:Male Race:Black Weight:111.0 kg								
	OPEN	1 TO 112	23	23	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 27 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			54	54	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 112 L: 59 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, CONCURRENT ILLNESS PRIOR TO STUDY ENTRY. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15525# Age:7[redacted] Sex:Male Race:White Weight:82.7 kg								
		OPEN	1 TO 100	53	R: MULTI FOCAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 106 L: 54 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE-AML C: No reasonable possibility
15526# Age:7[redacted] Sex:Female Race:White Weight:65.8 kg								
		POST	99 TO	9	R: OCULOMOTOR NERVE DISORDER S: NERVOUS SYSTEM DISORDERS P: 第3脳神経障害 L: OCULOMOTOR NERVE DISORDER	E: 132 L: 26 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF DISEASE SUSPECTED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 400 mg + DEC 15526# Age:7[redacted] Sex:Female Race:White Weight:65.8 kg								
(Cont.)	POST	99 TO	26	124	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 132 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
15529# Age:7[redacted] Sex:Female Race:White Weight:101.4 kg								
	OPEN	1 TO 171	10	10	R: CARDIAC ARREST S: CARDIAC DISORDERS P: 心停止 L: CARDIAC ARREST	E: 25 L: 16 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF CORONARY ARTERY DISEASE, CORONARY VASO SPASM C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + DEC 15529# Age:7[redacted] Sex:Female Race:White Weight:101.4 kg								
(Cont.)	OPEN	1 TO 171	30	30	R: ESOPHAGITIS S: GASTROINTESTINAL DISORDERS P: 食道炎 L: ESOPHAGITIS	E: 35 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: CARDIAC WORKUP	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: GASTRIC REFLUX C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15515# Age:7[redacted] Sex:Male Race:White Weight:86.4 kg								
		POST	84 TO	8	R: LUNG INFECTIION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	E: 103 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
				25	R: MESENTERIC ADENITIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: リンパ節炎 L: MESENTERIC ADENITIS	E: 112 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONSTIPATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 800 mg + DEC 15516# Age:7[redacted] Sex:Female Race:White Weight:79.8 kg								
		POST	29 TO	11	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 58 L: 20 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
				15	R: ENCEPHALOPATHY S: NERVOUS SYSTEM DISORDERS P: 脳症 L: ENCEPHALOPATHY	E: 58 L: 16 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: EEG	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: METABOLIC ABNORMALITY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 800 mg + DEC 15528# Age:7[redacted] Sex:Male Race:White Weight:86.2 kg								
	POST	205 TO	24	228	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
TRT:Venetoclax 400 mg + AZA 15930# Age:7[redacted] Sex:Male Race:White Weight:92.8 kg								
	OPEN	1 TO 193	105	105	R: ASPIRATION PNEUMONIA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 誤嚥性肺炎 L: ASPIRATION PNEUMONIA	E: 107 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, BARIUM SWALLOW PROCEDURE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 400 mg + AZA 15930# Age:7[redacted] Sex:Male Race:White Weight:92.8 kg								
(Cont.)	OPEN	1 TO 193	173	173	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 176 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			189	189	R: ORTHOSTATIC HYPOTENSION S: VASCULAR DISORDERS P: 起立性低血圧 L: ORTHOSTATIC HYPOTENSION	E: 190 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: HE WAS GIVEN SUPPORTIVE THERAPY WITH TRANSFUSIONS. RECORDS REQUESTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WEAKNESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + AZA 15931# Age:6[redacted] Sex:Male Race:White Weight:123.6 kg								
	POST	65 TO	9	73	R: INFECTION INFESTATION OTHER-BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 80 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
15932# Age:8[redacted] Sex:Male Race:White Weight:63.6 kg								
	OPEN	1 TO 83	30	30	R: MULTIFOCAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 86 L: 57 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREEXISTING LUNG INFECTION, BRONCHITIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + AZA 15932# Age:8[redacted] Sex:Male Race:White Weight:63.6 kg								
(Cont.)	POST	84 TO	2	85	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 86 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, AML C: No reasonable possibility
15935# Age:6[redacted] Sex:Male Race:White Weight:100.0 kg								
	OPEN	1 TO 160	60	60	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 64 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 400 mg + AZA 15935# Age:6[redacted] Sex:Male Race:White Weight:100.0 kg								
(Cont.)	OPEN	1 TO 160	77	77	R: NON NEUTROPENIC FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 89 L: 13 Days I: Yes	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE AML C: No reasonable possibility
			119	119	R: FAILURE TO THRIVE S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	E: 156 L: 38 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: NUTRITION SUPPLEMENT, PT/OT	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + AZA 15935# Age:6[redacted] Sex:Male Race:White Weight:100.0 kg								
(Cont.)	OPEN	1 TO 160	129	129	R: NON-NEUTROPENIC FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 156 L: 28 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
	POST	161 TO	6	166	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 175 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (52791) TRT:Venetocla 400 mg + AZA 15936# Age:8[redacted] Sex:Male Race:White Weight:97.2 kg								
		POST	29 TO	1	R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎障害 L: ACUTE KIDNEY INJURY	E: 31 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: DIALYSIS	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility
					R: LEUKOCYTOSIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 白血球増加症 L: LEUKOCYTOSIS	E: 31 L: 3 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocla 400 mg + AZA 15937# Age:6[redacted] Sex:Male Race:Black Weight:77.0 kg								
	POST	57 TO	4	60	R: ALLERGIC TRANSFUSION REACTION S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: アレルギー性輸血反応 L: ALLERGIC TRANSFUSION REACTION	E: 62 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TRANSFUSIONS C: No reasonable possibility
15938 Age:8[redacted] Sex:Male Race:White Weight:103.1 kg								
	OPEN	1 TO	170	170	R: DIVERTICULOSIS S: GASTROINTESTINAL DISORDERS P: 憩室 L: DIVERTICULOSIS	E: 175 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CYTOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocl x 400 mg + AZA 15939	Age:8[redacted]	Sex:Male	Race:White	Weight:73.6 kg				
	OPEN	1 TO	45	45	R: DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 47 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			136	136	R: VASCULAR ACCESS COMPLICATION S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 血管確保合併症 L: VASCULAR ACCESS COMPLICATION	E: 138 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE COMPLICATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (52791) TRT:Venetocl x 400 mg + AZA 15939	Age:8[redacted] Sex:Male Race:White Weight:73.6 kg						
	(Cont.)	OPEN	1 TO 317	317	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 323 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (38145) TRT:Venetocla 400 mg + DEC 16507# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg							
	OPEN	1 TO 299	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: 30 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (38145) TRT:Venetocla 400 mg + DEC 16507# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
(Cont.)	OPEN	1 TO 299	69	69	R: LEG SKIN INFECTION S: INFECTIONS AND INFESTATIONS P: 限局性感染 L: LEG INFECTION	E: 76 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION LIKELY RESULTED FROM DEBRIDEMENT OF PREVIOUSLY EXCISED SQUAMOUS CELL CARCINOMA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (38145) TRT:Venetocla 400 mg + DEC 16507# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
(Cont.)	POST	300 TO	18	317	R: LEUKOCYTOSIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 白血球増加症 L: LEUKOCYTOSIS	E: 332 L: 16 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: LABS, MR, BONE MARROW	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (38145) TRT:Venetocla 800 mg + DEC 16503# Age:8[redacted] Sex:Female Race:White Weight:61.6 kg								
	OPEN	1 TO 77	26	26	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPOTENSION THOUGHT TO BE SECONDARY TO VOLUME OVERLOAD. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (38145) TRT:Venetocla 800 mg + DEC 16503# Age:8[redacted] Sex:Female Race:White Weight:61.6 kg								
(Cont.)	OPEN	1 TO 77	26	26	R: HYPOXIA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 低酸素症 L: HYPOXIA	E: 64 L: 39 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: PATIENT RECEIVING OXYGEN VIA NASAL CANNULA	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPOXIA THOUGHT TO BE SECONDARY TO VOLUME OVERLOAD. C: No reasonable possibility
			59	59	R: ANOREXIA S: METABOLISM AND NUTRITION DISORDERS P: 食欲減退 L: ANOREXIA	O: Yes I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (38145) TRT:Venetocla 800 mg + DEC 16503# Age:8[redacted] Sex:Female Race:White Weight:61.6 kg								
(Cont.)	OPEN	1 TO 77	59	59	R: FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE	O: Yes I: Yes	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			77	77	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 78 L: 2 Days I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	78 TO	1	78	R: BLOOD BILIRUBIN INCREASED S: INVESTIGATIONS P: 血中ビリルビン増加 L: BLOOD BILIRUBIN INCREASED	O: Yes I: Yes	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + DEC 17102# Age:7[redacted] Sex:Female Race:White Weight:72.4 kg								
	OPEN	1 TO 16	3	3	R: LUNG INFECTION (PNEUMONIA) S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 22 L: 20 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: "WERE ASSOCIATED TO PATIENT'S UNDERLYING DISEASE DUE TO NON-INFECTIOUS ETIOLOGY CHARACTERISTICS" C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53186) TRT:Venetocla 400 mg + DEC 17102# Age:7[redacted] Sex:Female Race:White Weight:72.4 kg								
(Cont.)	OPEN	1 TO 16	14	14	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 21 L: 8 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: INTUBATION	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: DISEASE RELATED, COMPLICATIONS OF PNEUMONIA, WERE ASSOCIATED TO PATIENT'S UNDERLYING DISEASE DUE TO NON-INFECTIOUS ETIOLOGY CHARACTERISTICS. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 1200 mg + DEC 17105# Age:7[redacted] Sex:Male Race:White Weight:99.5 kg								
	OPEN	1 TO 745	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: 29 L: 2 Days I: No	D: No G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 1200 mg + DEC 17105# Age:7[redacted] Sex:Male Race:White Weight:99.5 kg								
(Cont.)	OPEN	1 TO 745	28	28	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 30 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPHIL COUNT DECREASED; OTHER CAUSE UNKNOWN C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 1200 mg + DEC 17105# Age:7[redacted] Sex:Male Race:White Weight:99.5 kg								
(Cont.)	OPEN	1 TO 745	725	725	R: SECONDARY MALIGNANCY-MELANOMA-UPPER BACK S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 悪性黒色腫 L: MELANOMA	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MEDICAL HISTORY OF MELANOMA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 1200 mg + DEC 17106# Age:7[redacted] Sex:Male Race:White Weight:91.0 kg								
	OPEN	1 TO 314	151	151	R: PICC LINE INFECTION S: INFECTIONS AND INFESTATIONS P: 血管デバイス感染 L: VASCULAR DEVICE INFECTION	E: 158 L: 8 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PICC LINE REMOVED AND REPLACED WITH NEW ONE.	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: COAGULASE NEGATIVE STAPHYLOCOCCUS,GRAM POSITIVE BACTEREMIA , ALSO MAY BE RELATED TO STUDY DRUGS PER PI C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53186) TRT:Venetocla 1200 mg + DEC 17106# Age:7[redacted] Sex:Male Race:White Weight:91.0 kg								
(Cont.)	POST	315 TO	5	319	R: FAILURE TO THRIVE S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	O: Yes I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
	OPEN	1 TO	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: 12 L: 2 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
	(Cont.)	OPEN	1 TO	11	11	R: DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 14 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			236	236	R: KLEBSIELLA SEPSIS S: INFECTIONS AND INFESTATIONS P: クレブシエラ性敗血症 L: KLEBSIELLA SEPSIS	E: 244 L: 9 Days I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			535	535	R: DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 545 L: 11 Days I: Yes	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
	(Cont.)	OPEN	1 TO	613	613	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: 625 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS HISTORY OF C. DIFF INFECTIONS C: No reasonable possibility
				649	649	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: 778 L: 130 Days I: Yes	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg									
	(Cont.)	OPEN	1 TO	691	691	R: BACTEREMIA (ENTEROBACTERIACEAE) S: INFECTIONS AND INFESTATIONS P: エンテロバクター性菌血症 L: ENTEROBACTER BACTEREMIA	E: 710 L: 20 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
				769	769	R: OVARIAN CYST S: REPRODUCTIVE SYSTEM AND BREAST DISORDERS P: 卵巣嚢胞 L: OVARIAN CYST	E: 796 L: 28 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: LAPAROSCOPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SPONTANEOUS OCCURRENCE C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
(Cont.)	OPEN	1 TO	777	777	R: SMALL BOWEL OBSTRUCTION S: GASTROINTESTINAL DISORDERS P: 小腸閉塞 L: SMALL BOWEL OBSTRUCTION	E: 808 L: 32 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: NG TUBE PLACEMENT, ELECTROLYTE REPLACEMENT, TPN SUPPLEMENTATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RECENT SURGERY FOR OVARIAN CYST C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
(Cont.)	OPEN	1 TO	856	856	R: COLITIS S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: COLITIS	E: 865 L: 10 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			865	865	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 873 L: 9 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17508 Age:7[redacted] Sex:Female Race:White Weight:83.0 kg								
(Cont.)	OPEN	1 TO	899	899	R: KLEBSIELLA BACTEREMIA S: INFECTIONS AND INFESTATIONS P: クレブシエラ性菌血症 L: KLEBSIELLA BACTEREMIA	E: 902 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			950	950	R: CHOLECYSTITIS INFECTIVE (KLEBSIELLA) S: INFECTIONS AND INFESTATIONS P: クレブシエラ感染 L: KLEBSIELLA INFECTION	E: 978 L: 29 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + DEC 17510 Age:6[redacted] Sex:Male Race:White Weight:64.1 kg								
	OPEN	1 TO	60	60	R: BACTEREMIA (STAPHYLOCOCCUS EPIDERMIDIS) S: INFECTIONS AND INFESTATIONS P: ブドウ球菌性菌血症 L: STAPHYLOCOCCAL BACTEREMIA	E: 63 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			100	100	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 110 L: 11 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186)									
TRT:Venetocl x 400 mg + DEC									
17510	Age:6[redacted]	Sex:Male	Race:White		Weight:64.1 kg				
(Cont.)	OPEN	1 TO		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: 137 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
17513#	Age:7[redacted]	Sex:Male	Race:Native Hawaiian Or Pacific Islander		Weight:51.6 kg				
	OPEN	1 TO	468	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: 24 L: 8 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + DEC 17513# Age:7[redacted] Sex:Male Race:Native Hawaiian Or Pacific Islander Weight:51.6 kg								
	(Cont.)	OPEN	1 TO 468	115	115	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 121 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
				298	298	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 301 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + DEC 17513# Age:7[redacted] Sex:Male Race:Native Hawaiian Or Pacific Islander Weight:51.6 kg								
(Cont.)	OPEN	1 TO 468	342	342	R: PNEUMONIA (METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS) S: INFECTIONS AND INFESTATIONS P: ブドウ球菌性肺炎 L: METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS PNEUMONIA	E: 396 L: 55 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
	POST	469 TO	8	476	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 496 L: 21 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PI, PNEUMONIA IS UNLIKELY RELATED TO STUDY THERAPY AND PROBABLY RELATED TO AML DISEASE PROGRESSION. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + DEC 17513# Age:7[redacted] Sex:Male Race:Native Hawaiian Or Pacific Islander Weight:51.6 kg								
(Cont.)	POST	469 TO	8	476	R: BACTREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 497 L: 22 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PI, BACTEREMIA UNLIKELY RELATED TO STUDY DRUGS, PROBABLY RELATED TO AML DISEASE PROGRESSION AND PNEUMONIA. C: No reasonable possibility
			16	484	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 495 L: 12 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HIGH FLOW OXYGEN	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML PROGRESSION AND PNEUMONIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + DEC 17513# Age:7[redacted] Sex:Male Race:Native Hawaiian Or Pacific Islander Weight:51.6 kg								
(Cont.)	POST	469 TO	27	495	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 497 L: 3 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: PATIENT CONTINUED ON OXYGEN ON TOBI MIST ON 35% FIO2, 35L	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML PROGRESSION AND PNEUMONIA C: No reasonable possibility
			28	496	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 497 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER PI, PNEUMONIA IS UNLIKELY RELATED TO STUDY THERAPY AND PROBABLY RELATED TO AML PROGRESSION. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17914# Age:7[redacted] Sex:Female Race:White Weight:63.1 kg								
		OPEN	1 TO 195	122	R: LUNG INFECTION (PNEUMONIA) S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 137 L: 16 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17914# Age:7[redacted] Sex:Female Race:White Weight:63.1 kg								
(Cont.)	POST	196 TO	1	196	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 217 L: 22 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
17915 Age:7[redacted] Sex:Male Race:White Weight:83.1 kg								
	OPEN	1 TO	32	32	R: LUNG INFECTION (FUNGAL PNEUMONIA) S: INFECTIONS AND INFESTATIONS P: 真菌性肺炎 L: PNEUMONIA FUNGAL	E: 182 L: 151 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocl x 400 mg + AZA 17915	Age:7[redacted]	Sex:Male	Race:White	Weight:83.1 kg				
(Cont.)	OPEN	1 TO	107	107	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 109 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
17916#	Age:7[redacted]	Sex:Male	Race:White	Weight:79.4 kg				
	POST	545 TO	23	567	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 589 L: 23 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17917#	Age:7[redacted] Sex:Female Race:White Weight:74.9 kg							
	POST	14 TO	25	38	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 42 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
17918#	Age:8[redacted] Sex:Male Race:White Weight:84.8 kg							
	OPEN	1 TO 166	100	100	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 107 L: 8 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17918# Age:8[redacted] Sex:Male Race:White Weight:84.8 kg								
(Cont.)	POST	167 TO	3	169	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 172 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
			22	188	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 193 L: 6 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			26	192	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 193 L: 2 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: OTHER: SUPPLEMENTAL OXYGEN VENTILATION	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
	OPEN	1 TO 690	2	2	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	O: Yes I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: OTHER: BLOOD TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			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: 23 L: 8 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
	(Cont.)	OPEN	1 TO 690	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: 34 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
				96	96	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 114 L: 19 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
(Cont.)	OPEN	1 TO 690	147	147	R: BACTEREMIA (ESCHERICHIA COLI AND STAPH EPIDERMIDIS) S: INFECTIONS AND INFESTATIONS P: 大腸菌性菌血症 L: ESCHERICHIA COLI BACTEREMIA R: BACTEREMIA (ESCHERICHIA COLI AND STAPH EPIDERMIDIS) S: INFECTIONS AND INFESTATIONS P: ブドウ球菌性菌血症 L: STAPHYLOCOCCAL BACTEREMIA	E: 164 L: 18 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED --Same as Above--	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
(Cont.)	OPEN	1 TO 690	254	254	R: INTRA-ABDOMINAL COMPLEX ABSCESS S: INFECTIONS AND INFESTATIONS P: 腹部膿瘍 L: INTRA-ABDOMINAL ABSCESS	O: Yes I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT GUIDED BIOPSY, ABSCESS DRAINAGE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility
					R: BACTEREMIA (C. DIFFICILE, ESCHERICHIA COLI) S: INFECTIONS AND INFESTATIONS P: クロストリジウム性菌血症 L: CLOSTRIDIUM BACTEREMIA	E: 261 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RECENT LIVER BIOPSY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
(Cont.)	OPEN	1 TO 690	254	254	R: BACTEREMIA (C. DIFFICILE, ESCHERICHIA COLI) S: INFECTIONS AND INFESTATIONS P: 大腸菌性菌血症 L: ESCHERICHIA COLI BACTEREMIA		--Same as Above--	
			609	609	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 615 L: 7 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17919# Age:8[redacted] Sex:Male Race:White, Native Hawaiian Or Pacific Islander Weight:93.0 kg								
(Cont.)	POST	691 TO	10	700	R: ECTHYMA GANGRENOSUM OF LEFT NARE SKIN S: INFECTIONS AND INFESTATIONS P: 膿瘡 L: ECTHYMA GANGRENOSUM	E: 706 L: 7 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
17920# Age:7[redacted] Sex:Female Race:White Weight:75.2 kg								
	POST	30 TO	2	31	R: LEUKOSTASIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 白血球停滞症候群 L: LEUKOSTASIS	E: 34 L: 4 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: LEUKOPHERESIS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RESISTANT DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53186) TRT:Venetocla 400 mg + AZA 17920# Age:7[redacted] Sex:Female Race:White Weight:75.2 kg								
(Cont.)	POST	30 TO	2	31	R: MULTI-ORGAN FAILURE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 多臓器機能不全症候群 L: MULTI-ORGAN FAILURE	E: 34 L: 4 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility
			3	32	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 34 L: 3 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO DEFINITIVE CAUSE FOR PNEUMONIA FOUND, ONLY DEEMED "MULTIFOCAL". C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](948415) TRT:Venetocla 400 mg + AZA 28904# Age:6[redacted] Sex:Male Race:White Weight:75.3 kg								
		OPEN	1 TO 343	108	R: CHOLEDOCHOLITHIASIS S: HEPATOBILIARY DISORDERS P: 胆管結石 L: CHOLEDOCHOLITHIASIS	E: 112 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: BILIARY SPHINCTEROTOMY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HEPATIC IRON DEPOSITION WITH SUSPECTED CONCOMITANT HEPATIC STEATOSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (948415) TRT:Venetocla 400 mg + AZA 28904# Age:6[redacted] Sex:Male Race:White Weight:75.3 kg								
(Cont.)	OPEN	1 TO 343	109	109	R: CHOLECYSTITIS S: HEPATOBILIARY DISORDERS P: 胆嚢炎 L: CHOLECYSTITIS	E: 111 L: 3 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: CHOLESTYSTECTOMY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: GANGRENOUS GALLBLADDER C: No reasonable possibility
			237	237	R: C. DIFF POSITIVE S: INVESTIGATIONS P: クロストリジウム検査陽性 L: CLOSTRIDIUM DIFFICILE TEST POSITIVE	E: 238 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRIOR HISTORY OF C. DIFF INFECTION (19-21JUL2017) C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (948415) TRT:Venetocla 400 mg + AZA 28904# Age:6[redacted] Sex:Male Race:White Weight:75.3 kg								
(Cont.)	OPEN	1 TO 343	242	242	R: OVERDOSE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 過量投与 L: OVERDOSE	E: 242 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CANNABIS OVERDOSE C: No reasonable possibility
	POST	344 TO	5	348	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 360 L: 13 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMORBID CONDITION - IMMUNE SUPPRESSION DUE TO ACUTE MYELOID LEUKEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (948415) TRT:Venetocla 400 mg + AZA 28905# Age:7[redacted] Sex:Female Race:White Weight:78.7 kg								
	OPEN	1 TO 67	8	8	R: WRIST FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 手首関節骨折 L: WRIST FRACTURE	O: Yes I: No	G: Grade 1 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: WRIST SPLINTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GAIT DISTURBANCE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](948415) TRT:Venetocla 400 mg + AZA 28905# Age:7[redacted] Sex:Female Race:White Weight:78.7 kg								
(Cont.)	OPEN	1 TO 67	17	17	R: FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY, DISCHARGED TO SUBACUTE REHAB	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: WRIST FRACTURE AND DECREASED PERFORMANCE STATUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](948415) TRT:Venetocla 400 mg + AZA 28905# Age:7[redacted] Sex:Female Race:White Weight:78.7 kg									
(Cont.)	OPEN	1 TO 67	17	17		R: MALAISE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 倦怠感 L: MALAISE	O: Yes I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: DUE TO WRIST FRACTURE AND DECREASED PERFORMANCE STATUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](948415) TRT:Venetocla 400 mg + AZA 28905# Age:7[redacted] Sex:Female Race:White Weight:78.7 kg								
(Cont.)	OPEN	1 TO 67	17	17	R: GAIT DISTURBANCE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 歩行障害 L: GAIT DISTURBANCE	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY, DISCHARGED TO SUBACUTE REHAB	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: DUE TO WRIST FRACTURE AND DECREASED PERFORMANCE STATUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18201# Age:8[redacted] Sex:Female Race:Black Weight:68.6 kg								
	OPEN	1 TO 970	94	94	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 96 L: 3 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: HOSPITALIZATION, CT SCAN ABDOMEN/PELVIS, ENEMA IN ED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS HISTORY OF CONSTIPATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 400 mg + AZA 18201# Age:8[redacted] Sex:Female Race:Black Weight:68.6 kg								
(Cont.)	OPEN	1 TO 970	94	94	R: CONSTIPATION S: GASTROINTESTINAL DISORDERS P: 便秘 L: CONSTIPATION	E: 96 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: HOSPITALIZATION, CT SCAN ABDOMEN/PELVIS, ENEMA IN ED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS HISTORY OF CONSTIPATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 400 mg + AZA 18201# Age:8[redacted] Sex:Female Race:Black Weight:68.6 kg								
	(Cont.)	OPEN	1 TO 970	391	391	R: GI BLEED S: GASTROINTESTINAL DISORDERS P: 胃腸出血 L: GI BLEED	E: 414 L: 24 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
		POST	971 TO	22	992	R: PROCTOCOLITIS S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: PROCTOCOLITIS	O: Yes I: No	D: No G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: CULTURES TAKEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 1200 mg + AZA 18203# Age:7[redacted] Sex:Male Race:White, Asian Weight:70.5 kg								
	OPEN	1 TO 12	12	12	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 27 L: 16 Days I: Yes	G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 1200 mg + AZA 18203# Age:7[redacted] Sex:Male Race:White, Asian Weight:70.5 kg								
(Cont.)	OPEN	1 TO 12	12	12	R: PROCTITIS S: GASTROINTESTINAL DISORDERS P: 直腸炎 L: PROCTITIS	E: 27 L: 16 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
18204# Age:8[redacted] Sex:Female Race:White Weight:68.7 kg								
	POST	182 TO	9	190	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 218 L: 29 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DENTAL ABSCESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18706# Age:8[redacted] Sex:Male Race:White Weight:94.7 kg								
	OPEN	1 TO 73	73	73	R: MULTIFOCAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 79 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL PNEUMONIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18706# Age:8[redacted] Sex:Male Race:White Weight:94.7 kg								
(Cont.)	OPEN	1 TO 73	73	73	R: HEMOPTYSIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 喀血 L: HEMOPTYSIS	E: 83 L: 11 Days I: Yes	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL PNEUMONIA C: No reasonable possibility
	POST	74 TO	6	79	R: FUNGAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 真菌性肺炎 L: PNEUMONIA FUNGAL	E: 83 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING O: PROLONGED NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18706# Age:8[redacted] Sex:Male Race:White Weight:94.7 kg								
(Cont.)	POST	74 TO	10	83	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 83 L: 1 Day I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, LIFE THREATENING O: HEMOPTYSIS C: No reasonable possibility
					R: CARDIAC ARREST S: CARDIAC DISORDERS P: 心停止 L: CARDIAC ARREST	E: 83 L: 1 Day I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: MASK VENTILATION, CHEST COMPRESSIONS, AND MEDICAL RESUSCITATION PERFORMED	S: Yes, LIFE THREATENING O: RESPIRATORY FAILURE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18707# Age:7[redacted] Sex:Female Race:White Weight:79.3 kg								
	OPEN	1 TO 194	180	180	R: DIARRHEA S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHEA	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION C: No reasonable possibility
			181	181	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 194 L: 14 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CHEST X-RAY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18707# Age:7[redacted] Sex:Female Race:White Weight:79.3 kg									
	(Cont.)	POST	195 TO	20	214	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 220 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CULTURES TAKEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
18711# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg									
		OPEN	1 TO 200	30	30	R: RIGHT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 45 L: 16 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18711# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
(Cont.)	OPEN	1 TO 200	96	96	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 111 L: 16 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 400 mg + AZA 18711# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
(Cont.)	OPEN	1 TO 200	133	133	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 149 L: 17 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 A: OTHER: PATIENT WAS NOT TAKING DRUG AT THIS TIME. SHE WAS DUE TO START CYCLE 5 ON 11/29/2016. TREATMENT START DATE IS BEING DELAYED AT THIS TIME. O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 400 mg + AZA 18711# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
(Cont.)	OPEN	1 TO 200	186	186	R: PERINEAL CELLULITIS S: INFECTIONS AND INFESTATIONS P: 会陰蜂巣炎 L: PERINEAL CELLULITIS	E: 192 L: 7 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION C: No reasonable possibility
			200	200	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 207 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 400 mg + AZA 18713# Age:7[redacted] Sex:Male Race:White Weight:101.1 kg								
	POST	90 TO	10	99	R: RIGHT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL INFECTION C: No reasonable possibility
18715# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
	OPEN	1 TO 162	153	153	R: FUNGAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 真菌性肺炎 L: PNEUMONIA FUNGAL	E: 179 L: 27 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL INFECTION CONSISTENT WITH ASPERGILLUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 400 mg + AZA 18715# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
(Cont.)	POST	163 TO	17	179	R: FUNGAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 真菌性肺炎 L: PNEUMONIA FUNGAL	O: Yes I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL INFECTION CONSISTENT WITH ASPERGILLUS C: No reasonable possibility
TRT:Venetocla 800 mg + AZA 18708# Age:8[redacted] Sex:Male Race:White Weight:94.3 kg								
	OPEN	1 TO 436	236	236	R: CORONARY ARTERY DISEASE S: CARDIAC DISORDERS P: 冠動脈疾患 L: CORONARY ARTERY DISEASE	E: 354 L: 119 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: EKG	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNSTABLE ANGINA AND CORONARY ARTERY DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50839) TRT:Venetocla 800 mg + AZA 18708# Age:8[redacted] Sex:Male Race:White Weight:94.3 kg								
(Cont.)	OPEN	1 TO 436	353	353	R: UNSTABLE ANGINA S: CARDIAC DISORDERS P: 不安定狭心症 L: UNSTABLE ANGINA	O: Yes I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: STENT PLACEMENT	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ATRIAL FLUTTER C: No reasonable possibility
18709# Age:7[redacted] Sex:Male Race:White Weight:99.7 kg								
	POST	256 TO	18	273	R: DISSEMINATED INTRAVASCULAR COAGULATION S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 播種性血管内凝固 L: DISSEMINATED INTRAVASCULAR COAGULATION	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: RECEIVED PLATELETS AND FIBRINOGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELAPSE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 800 mg + AZA 18712# Age:7[redacted] Sex:Female Race:White Weight:66.1 kg									
	OPEN	1 TO 92	6	6		R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 92 L: 87 Days I: Yes	G: Grade 2 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ICE PACKS WERE APPLIED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			31	31		R: URINARY TRACT INFECTION FOR E.COLI S: INFECTIONS AND INFESTATIONS P: 大腸菌性尿路感染 L: ESCHERICHIA URINARY TRACT INFECTION	E: 36 L: 6 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:Venetocla 800 mg + AZA 18714# Age:7[redacted] Sex:Female Race:White Weight:58.2 kg									
	OPEN	1 TO 146	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: 31 L: 8 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	147 TO	23	169		R: ENTEROBACTER BACTEREMIA S: INFECTIONS AND INFESTATIONS P: エンテロバクター性菌血症 L: ENTEROBACTER BACTEREMIA	E: 173 L: 5 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (84581) TRT:Venetocla 400 mg + AZA 55901# Age:7[redacted] Sex:Female Race:White Weight:65.6 kg								
	OPEN	1 TO 52	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: 58 L: 11 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83585) TRT:Venetocla 400 mg + AZA 42703# Age:8[redacted] Sex:Male Race: Weight:71.4 kg								
	OPEN	1 TO 373	11	11	R: ERYTHRODERMA S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 全身性剥脱性皮膚炎 L: ERYTHRODERMA	E: 18 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: WORSENING OF PREXISTING PSORIASIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83585) TRT:Venetocla 400 mg + AZA 42703# Age:8[redacted] Sex:Male Race: Weight:71.4 kg								
(Cont.)	OPEN	1 TO 373	50	50	R: INFECTIOUS ENDOCARDITIS S: INFECTIONS AND INFESTATIONS P: 心内膜炎 L: ENDOCARDITIS INFECTIVE	E: 94 L: 45 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20208# Age:7[redacted] Sex:Female Race:White Weight:78.0 kg									
	OPEN	1 TO 115	60	60		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 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20209# Age:8[redacted] Sex:Female Race:White Weight:50.1 kg								
	OPEN	1 TO 392	6	6	R: TAKOTSUBO'S CARDIOMYOPATHY S: CARDIAC DISORDERS P: ストレス心筋症 L: TAKO-TSUBO CARDIOMYOPATHY	E: 8 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CONCURRENT CARDIAC DISORDERS; MEDICAL HISTORY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20209# Age:8[redacted] Sex:Female Race:White Weight:50.1 kg								
(Cont.)	OPEN	1 TO 392	144	144	R: NON-CARDIAC CHEST PAIN S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 非心臓性胸痛 L: NON-CARDIAC CHEST PAIN	E: 145 L: 2 Days I: Yes	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANXIETY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20212# Age:6[redacted] Sex:Male Race:White Weight:116.8 kg								
	OPEN	1 TO 65	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: 40 L: 16 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:Venetocla 800 mg + AZA 20212# Age:6[redacted] Sex:Male Race:White Weight:116.8 kg								
(Cont.)	OPEN	1 TO 65	42	42	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 44 L: 3 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA C: No reasonable possibility
			43	43	R: WORSENING PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA AGGRAVATED	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNGAL INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20213# Age:7[redacted] Sex:Female Race:White Weight:88.7 kg								
	OPEN	1 TO 200	27	27	R: ALLERGIC TRANSFUSION REACTION S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: アレルギー性輸血反応 L: ALLERGIC TRANSFUSION REACTION	E: 33 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PLATELET TRANSFUSION REACTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20213# Age:7[redacted] Sex:Female Race:White Weight:88.7 kg								
	(Cont.)	OPEN	1 TO 200	184	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 204 L: 21 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE C: No reasonable possibility
		POST	201 TO	4	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 207 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COAG NEGATIVE STAPH INFECTION IN URINE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20214# Age:8[redacted] Sex:Female Race:White Weight:78.3 kg								
	OPEN	1 TO 46	3	3	R: ATRIAL FIBRILATION S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION	O: Yes I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: VOLUME OF IVF REQUIRED PER PROTOCOL TO MITIGATE TLS INCREASED THE RISK FOR A-FIB C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 1200 mg + AZA 20216# Age:8[redacted] Sex:Male Race:White Weight:77.9 kg								
	OPEN	1 TO 21	16	16	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 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION OF UNKNOWN SOURCE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20719# Age:7[redacted] Sex:Male Race:White Weight:86.3 kg								
	OPEN	1 TO 8	8	8	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 12 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:Venetocla 400 mg + AZA 20719# Age:7[redacted] Sex:Male Race:White Weight:86.3 kg								
(Cont.)	OPEN	1 TO 8	8	8	R: MULTI ORGAN FAILURE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 多臓器機能不全症候群 L: MULTI ORGAN FAILURE	E: 15 L: 8 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: DISEASE PROGRESSION. C: No reasonable possibility
					R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 16 L: 9 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MULTI ORGAN FAILURE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20719# Age:7[redacted] Sex:Male Race:White Weight:86.3 kg								
(Cont.)	POST	9 TO	4	12	R: MYOCARDIAL INFARCTION S: CARDIAC DISORDERS P: 心筋梗塞 L: MYOCARDIAL INFARCTION	E: 16 L: 5 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, LIFE THREATENING O: MULTI ORGAN FAILURE C: No reasonable possibility
			5	13	R: ADULT RESPIRATORY DISTRESS SYNDROME S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 急性呼吸窮迫症候群 L: ADULT RESPIRATORY DISTRESS SYNDROME	E: 16 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: SUPPLEMENTAL OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20721# Age:8[redacted] Sex:Female Race:White Weight:61.9 kg								
	OPEN	1 TO 209	43	43	R: HIP FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 股関節部骨折 L: HIP FRACTURE	E: 49 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PATIENT HAD A FALL AT HOME EARLY THIS MORNING. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20722# Age:7[redacted] Sex:Male Race:White Weight:97.3 kg									
	OPEN	1 TO 161	6	6		R:CHRONIC SINUS DISEASE S: INFECTIONS AND INFESTATIONS P: 慢性副鼻腔炎 L: CHRONIC SINUSITIS	E: 7 L: 2 Days I: No	G: Grade 1 R1: No reasonable possibility R3: No reasonable possibility O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW WHITE BLOOD CELL COUNT C: No reasonable possibility
			109	109		R:ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L:MENTAL STATUS CHANGES	E: 112 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O:OTHER: DIAGNOSTIC PROCEDURES. HOLDING CONCOMITANT MEDICATION-MORPHINE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MORPHINE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:Venetocla 400 mg + AZA 20722# Age:7[redacted] Sex:Male Race:White Weight:97.3 kg								
(Cont.)	OPEN	1 TO 161	109	109	R: CONSTIPATION S: GASTROINTESTINAL DISORDERS P: 便秘 L: CONSTIPATION	E: 117 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOLDING CONCOMITANT MEDICATION-MORPHINE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			114	114	R: SUB-ACUTE STROKE S: NERVOUS SYSTEM DISORDERS P: 脳血管発作 L: STROKE	E: 114 L: 1 Day I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: REPEAT CTA SCAN, ECHOCARDIOGRAM	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NARCOTICS USED FOR BACK PAIN-MORPHINE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20723# Age:6[redacted] Sex:Male Race:White Weight:101.9 kg								
	OPEN	1 TO 622	535	535	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 542 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20724# Age:7[redacted] Sex:Male Race:White Weight:97.4 kg								
	OPEN	1 TO 951	670	670	R: SMALL BOWEL OBSTRUCTION S: GASTROINTESTINAL DISORDERS P: 小腸閉塞 L: SMALL BOWEL OBSTRUCTION	E: 676 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMISSION, NG TUBE PLACEMENT, AND LAPAROSCOPIC SURGERY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ADHESIVE BANDS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20724# Age:7[redacted] Sex:Male Race:White Weight:97.4 kg								
(Cont.)	OPEN	1 TO 951	686	686	R: SMALL BOWEL OBSTRUCTION S: GASTROINTESTINAL DISORDERS P: 小腸閉塞 L: SMALL BOWEL OBSTRUCTION	E: 699 L: 14 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SURGICAL INTERVENTION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PRIOR AE OF SMALL BOWEL OBSTRUCTION C: No reasonable possibility
			917	917	R: SHORTNESS OF BREATH S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: SHORTNESS OF BREATH	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF ONGOING COUGH C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20724# Age:7[redacted] Sex:Male Race:White Weight:97.4 kg								
(Cont.)	OPEN	1 TO 951	940	940	R: ALLERGIC TRANSFUSION REACTION S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: アレルギー性輸血反応 L: ALLERGIC TRANSFUSION REACTION	E: 941 L: 2 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMISSION OVERNIGHT FOR OBSERVATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRBC TRANSFUSION REACTION C: No reasonable possibility
	POST	952 TO	18	969	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 992 L: 24 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20731# Age:7[redacted] Sex:Female Race: Weight:59.1 kg								
	OPEN	1 TO 469	362	362	R: WORSENING INTERMITTENT CARDIAC CHEST PAIN S: CARDIAC DISORDERS P: 狭心症 L: ANGINA PECTORIS AGGRAVATED	O: Yes I: Yes	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: S/P 2 VESSEL CABG 7/2015. HAS HAD RARE INTERMITTENT CHEST PAIN/TIGHTNESS SINCE. C: No reasonable possibility
			396	396	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 399 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](50868) TRT:Venetocla 400 mg + AZA 20731# Age:7[redacted] Sex:Female Race: Weight:59.1 kg								
(Cont.)	OPEN	1 TO 469	405	405	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	O: Yes I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
	POST	470 TO	26	495	R: HYPOXIA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 低酸素症 L: HYPOXIA	E: 496 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PULMONARY FIBROSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 800 mg + AZA 20720# Age:7[redacted] Sex:Female Race:White Weight:65.6 kg								
	OPEN	1 TO 59	56	56	R: STREPTOCOCCUS MITIS BLOOD INFECTION S: INFECTIONS AND INFESTATIONS P: レンサ球菌性菌血症 L: STREPTOCOCCAL BACTEREMIA	E: 60 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SUBJECT WAS ADMITTED.	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WHITE BLOOD CELL COUNT DECREASED. C: No reasonable possibility
	POST	60 TO	7	66	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 89 L: 24 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OTHER INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20933# Age:8[redacted] Sex:Male Race:White Weight:84.9 kg								
	OPEN	1 TO 114	4	4	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 9 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMMUNITY ACQUIRED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20933# Age:8[redacted] Sex:Male Race:White Weight:84.9 kg									
	(Cont.)	OPEN	1 TO 114	17	17	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 18 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: DISCHARGED HOME ON SUPPLEMENTAL OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALIZTION FOR CONTINUATION OF PNEUMONIA PREVIOUSLY REPORTED C: No reasonable possibility
				62	62	R: EPIGASTRIC PAIN S: GASTROINTESTINAL DISORDERS P: 上腹部痛 L: EPIGASTRIC PAIN	E: 63 L: 2 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CHEST X-RAY, ULTRASOUND	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20933# Age:8[redacted] Sex:Male Race:White Weight:84.9 kg								
	(Cont.)	OPEN	1 TO 114	97	97	R: HIP FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 股関節部骨折 L: HIP FRACTURE	E: 102 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: ORTHOPEDIC SURGERY, 2 UNITS OF PLATELETS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WHEEL CHAIR BOUND C: No reasonable possibility
20936# Age:9[redacted] Sex:Female Race:White Weight:116.6 kg								
		OPEN	1 TO 242	5	5	R: FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE	E: 5 L: 1 Day I: No	G: Grade 2 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: OTHER: PATIENT KEPT INPATIENT FOR OBSERVATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20936# Age:9[redacted] Sex:Female Race:White Weight:116.6 kg								
(Cont.)	OPEN	1 TO 242	96	96	R: HYPOXIA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 低酸素症 L: HYPOXIA	E: 97 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility O: OTHER: CT AND HOME OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT STOPPED TAKING OXYGEN PRESCRIBED BY PRIMARY CARE PHYSICIAN C: No reasonable possibility
20939# Age:8[redacted] Sex:Female Race:White Weight:60.0 kg								
	OPEN	1 TO 309	8	8	R: SKIN INFECTION S: INFECTIONS AND INFESTATIONS P: 皮膚感染 L: SKIN INFECTION	E: 323 L: 316 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE PLACEMENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20939# Age:8[redacted] Sex:Female Race:White Weight:60.0 kg								
(Cont.)	OPEN	1 TO 309	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: 31 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: NASAL WASH, CHEST X RAY, BLOOD CULTURE, URINE ANALYSIS.	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE LINE INFECTION. C: No reasonable possibility
			303	303	R: EPISTAXIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻出血 L: EPISTAXIS	E: 304 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: TRANSFUSIONS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOCYTOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20939# Age:8[redacted] Sex:Female Race:White Weight:60.0 kg								
(Cont.)	OPEN	1 TO 309	304	304	R: FEVERS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 323 L: 20 Days I: Yes	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: BLOOD CULTURES, CXR	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20942# Age:7[redacted] Sex:Male Race:White Weight:84.3 kg								
	OPEN	1 TO 198	24	24	R: NEUTROPENIC FEVERS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 29 L: 6 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20942# Age:7[redacted] Sex:Male Race:White Weight:84.3 kg								
(Cont.)	OPEN	1 TO 198	110	110	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 113 L: 4 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
20943# Age:7[redacted] Sex:Female Race:White Weight:72.4 kg								
	OPEN	1 TO 785	3	3	R: NEUTROPENIC FEVERS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 5 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT SCAN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20943# Age:7[redacted] Sex:Female Race:White Weight:72.4 kg								
(Cont.)	OPEN	1 TO 785	333	333	R: ORAL ULCER S: GASTROINTESTINAL DISORDERS P: 口腔内潰瘍形成 L: ORAL ULCERATION	E: 353 L: 21 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20944# Age:7[redacted] Sex:Male Race:White Weight:95.3 kg								
	POST	227 TO	25	251	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 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20945#	Age:7[redacted]	Sex:Female	Race:White	Weight:135.8 kg				
	OPEN	1 TO 3	3	3	R: PERFORATED SIGMOID DIVERTICULITIS S: GASTROINTESTINAL DISORDERS P: 憩室穿孔 L: DIVERTICULAR PERFORATION	E: 12 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT SCAN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20946#	Age:7[redacted]	Sex:Male	Race:White	Weight:65.6 kg				
	OPEN	1 TO 809	809	809	R: MESSENTERIC ISCHEMIA S: GASTROINTESTINAL DISORDERS P: 腸管虚血 L: MESENTERIC ISCHEMIA	E: 810 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONSTIPATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20946# Age:7[redacted] Sex:Male Race:White Weight:65.6 kg								
(Cont.)	POST	810 TO	1	810	R: CARDIAC ARREST S: CARDIAC DISORDERS P: 心停止 L: CARDIAC ARREST	E: 810 L: 1 Day I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: INTUBATED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: SYNCOPAL EPISODE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:Venetocla 400 mg + AZA 20946# Age:7[redacted] Sex:Male Race:White Weight:65.6 kg								
(Cont.)	POST	810 TO	1	810	R: SMALL BOWEL NECROSIS S: GASTROINTESTINAL DISORDERS P: 消化管壊死 L: NECROSIS BOWEL	E: 811 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: SMALL BOWEL RESECTION	S: Yes, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MESSENTERIC ISCHEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20946# Age:7[redacted] Sex:Male Race:White Weight:65.6 kg								
(Cont.)	POST	810 TO	1	810	R: MULTISYSTEM ORGAN FAILURE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 多臓器機能不全症候群 L: MULTI ORGAN FAILURE	E: 811 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MESSENTERIC ISCHEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20947# Age:7[redacted] Sex:Female Race:White Weight:100.6 kg								
	OPEN	1 TO 225	3	3	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 7 L: 5 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			20	20	R: DYSPNEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: DYSPNEA	E: 23 L: 4 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MED HX GRADE 2 DYSPNEA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:Venetocla 400 mg + AZA 20947# Age:7[redacted] Sex:Female Race:White Weight:100.6 kg								
(Cont.)	OPEN	1 TO 225	41	41	R: WORSENED JOINT INFECTION (RIGHT GREAT TOE) S: INFECTIONS AND INFESTATIONS P: 感染性関節炎 L: JOINT INFECTION	E: 46 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF GOUT C: No reasonable possibility
20948 Age:6[redacted] Sex:Female Race:White Weight:73.2 kg								
	OPEN	1 TO 849	2	2	R: RIGORS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 悪寒 L: RIGORS	E: 7 L: 6 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 1200 mg + DEC 13102# Age:6[redacted] Sex:Female Race:White Weight:67.2 kg								
	POST	51 TO	3	53	R: HYPONATREMIA S: METABOLISM AND NUTRITION DISORDERS P: 低ナトリウム血症 L: HYPONATREMIA	O: Yes I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: USING FLUID RESTRICTION AND INCREASING SODIUM INTAKE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HAD GRADE 1 HYPONATEMIA ON 18NOV2015. INCREASED IN GRADE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53503) TRT:Venetocla 1200 mg + DEC 13102# Age:6[redacted] Sex:Female Race:White Weight:67.2 kg								
(Cont.)	POST	51 TO	3	53	R: HEPATIC CANDIDIASIS S: INFECTIONS AND INFESTATIONS P: 肝カンジダ症 L: HEPATIC CANDIDIASIS	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CT SCAN SHOWED MULTIPLE NODULAR LESION IN THE LIVER WHICH IS CONSISTENT WITH THE BIOPSY OF CANDIDA SPECIES. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 1200 mg + DEC 13102# Age:6[redacted] Sex:Female Race:White Weight:67.2 kg								
(Cont.)	POST	51 TO	3	53	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 62 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + DEC 13510# Age:7[redacted] Sex:Female Race:White Weight:61.0 kg								
	OPEN	1 TO 134	35	35	R: MYOCARDIAL INFARCTION S: CARDIAC DISORDERS P: 心筋梗塞 L: MYOCARDIAL INFARCTION	E: 136 L: 102 Days I: No	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS A MEDICAL HISTORY OF CORONARY ARTERY DISEASE. C: No reasonable possibility
	POST	135 TO	1	135	R: FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE	E: 136 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WEAKNESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 400 mg + DEC 13510# Age:7[redacted] Sex:Female Race:White Weight:61.0 kg								
(Cont.)	POST	135 TO	2	136	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 136 L: 1 Day I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
					R: SEPTIC SHOCK S: INFECTIONS AND INFESTATIONS P: 敗血症性ショック L: SEPTIC SHOCK	E: 136 L: 1 Day I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
13516# Age:6[redacted] Sex:Male Race:White Weight:82.8 kg								
	OPEN	1 TO 968	42	42	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 46 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 400 mg + DEC 13516# Age:6[redacted] Sex:Male Race:White Weight:82.8 kg									
	(Cont.)	OPEN	1 TO 968	448	448	R: SYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神 L: SYNCOPE	E: 448 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FECAL IMPACTION C: No reasonable possibility
TRT:Venetoclax 800 mg + DEC 13504# Age:8[redacted] Sex:Male Race:White Weight:79.4 kg									
		POST	179 TO	10	188	R: FALL S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 転倒 L: FALL	E: 188 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FATIGUE AND CONFUSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 800 mg + DEC 13504# Age:8[redacted] Sex:Male Race:White Weight:79.4 kg								
(Cont.)	POST	179 TO	12	190	R: SEPTIC SHOCK S: INFECTIONS AND INFESTATIONS P: 敗血症性ショック L: SEPTIC SHOCK	E: 191 L: 2 Days I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PULMONARY EDEMA C: No reasonable possibility
					R: ACUTE HYPOXEMIC RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 急性呼吸不全 L: ACUTE RESPIRATORY FAILURE	E: 205 L: 16 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: INTUBATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PULMONARY EDEMA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13504# Age:8[redacted] Sex:Male Race:White Weight:79.4 kg								
(Cont.)	POST	179 TO	16	194	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 205 L: 12 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: NONE	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
13505# Age:6[redacted] Sex:Female Race:White Weight:62.5 kg								
	OPEN	1 TO 45	22	22	R: LEUKOCYTOSIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 白血球増加症 L: LEUKOCYTOSIS	E: 34 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF ELEVATED WBC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 800 mg + DEC 13505# Age:6[redacted] Sex:Female Race:White Weight:62.5 kg								
(Cont.)	OPEN	1 TO 45	45	45	R: LEUKOCYTOSIS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 白血球増加症 L: LEUKOCYTOSIS	E: 48 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY OF EVELATED WBC. C: No reasonable possibility
13506# Age:8[redacted] Sex:Male Race:White Weight:90.9 kg								
	OPEN	1 TO 355	26	26	R: SUPRAVENTRICULAR TACHYCARDIA S: CARDIAC DISORDERS P: 上室性頻脈 L: SUPRAVENTRICULAR TACHYCARDIA	O: Yes I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ATRIAL FIBRILLATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13506# Age:8[redacted] Sex:Male Race:White Weight:90.9 kg								
(Cont.)	OPEN	1 TO 355	71	71	R: PANCYTOPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 汎血球減少症 L: PANCYTOPENIA	E: 121 L: 51 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: TRANSFUSIONAL SUPPORT	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHEMOTHERAPY RELATED C: No reasonable possibility
			121	121	R: PANCYTOPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 汎血球減少症 L: PANCYTOPENIA	E: 280 L: 160 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: RBC AND PLATELET TRANSFUSION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER MD NOTE ON 07/09, PANCYTOPENIA SECONDARY TO CHEMOTHERAPY C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 800 mg + DEC 13506# Age:8[redacted] Sex:Male Race:White Weight:90.9 kg								
(Cont.)	OPEN	1 TO 355	241	241	R: CLOSTRIDIUM DIFFICILE INFECTION S: INFECTIONS AND INFESTATIONS P: クロストリジウム・ディフィシレ感染 L: CLOSTRIDIUM DIFFICILE INFECTION	E: 269 L: 29 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC C: No reasonable possibility
			281	281	R: PANCYTOPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 汎血球減少症 L: PANCYTOPENIA	O: Yes I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO TREATMENT FOR AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13508# Age:6[redacted] Sex:Female Race:White Weight:75.1 kg								
	OPEN	1 TO 422	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: 138 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
					R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 138 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UTI C: No reasonable possibility
			330	330	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 331 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13508# Age:6[redacted] Sex:Female Race:White Weight:75.1 kg								
	(Cont.)	OPEN	1 TO 422	330	330	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 334 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
						R: SEPSIS (CORNYEBACTERIUM) S: INFECTIONS AND INFESTATIONS P: コリネバクテリウム性敗血症 L: CORYNEBACTERIUM SEPSIS	E: 334 L: 5 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
				422	422	R: SEPSIS (KLEBSIELLA) S: INFECTIONS AND INFESTATIONS P: クレブシエラ性敗血症 L: KLEBSIELLA SEPSIS	E: 427 L: 6 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13508# Age:6[redacted] Sex:Female Race:White Weight:75.1 kg								
(Cont.)	OPEN	1 TO 422	422	422	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 429 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS C: No reasonable possibility
13511# Age:6[redacted] Sex:Male Race:White Weight:85.7 kg								
	OPEN	1 TO 465	69	69	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 254 L: 186 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DENTAL NECROSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13511# Age:6[redacted] Sex:Male Race:White Weight:85.7 kg								
	(Cont.)	OPEN	1 TO 465	176	176	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 176 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFUSION RELATED REACTION - DEVELOPED FEVER AFTER RECEIVING DECITABINE C: No reasonable possibility
				366	366	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 367 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 800 mg + DEC 13511# Age:6[redacted] Sex:Male Race:White Weight:85.7 kg								
(Cont.)	OPEN	1 TO 465	366	366	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 367 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: IV FLUID HYDRATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEBRILE NEUTROPENIA C: No reasonable possibility
			407	407	R: BACTEREMIA (FUSOBACTERIUM) S: INFECTIONS AND INFESTATIONS P: フソバクテリウム感染 L: FUSOBACTERIUM INFECTION	E: 421 L: 15 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
			414	414	R: PNEUMONIA (GRAM POSITIVE COCCI) S: INFECTIONS AND INFESTATIONS P: 細菌性肺炎 L: PNEUMONIA GRAM-POSITIVE BACTERIAL	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF PNEUMONIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13511# Age:6[redacted] Sex:Male Race:White Weight:85.7 kg								
(Cont.)	OPEN	1 TO 465	433	433	R: SWELLING IN LOWER EXTREMITIES S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 末梢腫脹 L: SWELLING OF LEGS	O: Yes I: No	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS EDEMA C: No reasonable possibility
			447	447	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 447 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
	POST	466 TO	9	474	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 477 L: 4 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: RECEIVED IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POOR PO INTAKE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13511# Age:6[redacted] Sex:Male Race:White Weight:85.7 kg								
(Cont.)	POST	466 TO	9	474	R: ACUTE RENAL FAILURE S: RENAL AND URINARY DISORDERS P: 急性腎障害 L: ACUTE RENAL FAILURE	E: 477 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POOR PO INTAKE C: No reasonable possibility
13513# Age:8[redacted] Sex:Male Race:White Weight:123.1 kg								
	POST	135 TO	8	142	R: PERIANAL INFECTION S: INFECTIONS AND INFESTATIONS P: 肛門感染 L: ANAL INFECTION	E: 146 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53503) TRT:Venetocla 800 mg + DEC 13513# Age:8[redacted] Sex:Male Race:White Weight:123.1 kg								
(Cont.)	POST	135 TO	20	154	R: CARDIAC CHEST PAIN S: CARDIAC DISORDERS P: 狭心症 L: CHEST PAIN - CARDIAC	E: 155 L: 2 Days I: No	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CARDIAC ARRHYTHMIA C: No reasonable possibility
			21	155	R: CHEST PAIN - CARDIAC S: CARDIAC DISORDERS P: 狭心症 L: CHEST PAIN - CARDIAC	E: 162 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELAPSED AML C: No reasonable possibility
			22	156	R: DEHYDRATION S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 157 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELAPSED AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13513# Age:8[redacted] Sex:Male Race:White Weight:123.1 kg								
(Cont.)	POST	135 TO	22	156	R: FATIGUE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疲労 L: FATIGUE	E: 162 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELAPSED AML C: No reasonable possibility
13515# Age:7[redacted] Sex:Female Race:White Weight:67.5 kg								
	OPEN	1 TO 310	70	70	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 121 L: 52 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEVER C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 800 mg + DEC 13515# Age:7[redacted] Sex:Female Race:White Weight:67.5 kg								
(Cont.)	OPEN	1 TO 310	109	109	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 110 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTEREMIA C: No reasonable possibility
			228	228	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 228 L: 1 Day I: Yes	G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
			230	230	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 233 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS PNEUMONIA ON 17AUG2016. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 800 mg + DEC 13515# Age:7[redacted] Sex:Female Race:White Weight:67.5 kg								
(Cont.)	OPEN	1 TO 310	230	230	R: E. COLI URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 大腸菌性尿路感染 L: ESCHERICHIA URINARY TRACT INFECTION	E: 247 L: 18 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS UTI ON 24SEP2016. C: No reasonable possibility
			263	263	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	O: Yes I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13920# Age:8[redacted] Sex:Male Race:White Weight:76.5 kg								
	OPEN	1 TO 383	6	6	R: DIZZINESS S: NERVOUS SYSTEM DISORDERS P: 浮動性めまい L: DIZZINESS	E: 41 L: 36 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW BLOOD COUNTS C: No reasonable possibility
			12	12	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 13 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HOLD ALL ANTIHYPERTENSIVE MEDICATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW BLOOD COUNTS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 400 mg + AZA 13920# Age:8[redacted] Sex:Male Race:White Weight:76.5 kg								
(Cont.)	OPEN	1 TO 383	41	41	R: DEHYDRATION S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 43 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: IV FLUIDS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DECREASE IN PO INTAKE C: No reasonable possibility
					R: DIZZINESS S: NERVOUS SYSTEM DISORDERS P: 浮動性めまい L: DIZZINESS	E: 64 L: 24 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION C: No reasonable possibility
					R: DYSPNEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: DYSPNEA	E: 64 L: 24 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53503) TRT:Venetocla 400 mg + AZA 13920# Age:8[redacted] Sex:Male Race:White Weight:76.5 kg								
(Cont.)	OPEN	1 TO 383	329	329	R: RIGOR S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 悪寒 L: RIGORS	E: 330 L: 2 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOOD POISONING C: No reasonable possibility
					R: DIAPHORETIC S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 多汗症 L: DIAPHORESIS	E: 330 L: 2 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOOD POISONING C: No reasonable possibility
					R: NAUSEA S: GASTROINTESTINAL DISORDERS P: 悪心 L: NAUSEA	E: 330 L: 2 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOOD POISONING C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13920# Age:8[redacted] Sex:Male Race:White Weight:76.5 kg								
(Cont.)	OPEN	1 TO 383	377	377	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 380 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			380	380	R: SWEETS SYNDROME S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 急性熱性好中球性皮膚症 L: SWEET'S SYNDROME	E: 388 L: 9 Days I: No	G: Grade 1 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 400 mg + AZA 13921# Age:7[redacted] Sex:Male Race:White Weight:96.6 kg								
	OPEN	1 TO 104	36	36	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 43 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
			64	64	R: BACTEREMIA (CLOSTRIDIUM SEPTICUM) S: INFECTIONS AND INFESTATIONS P: クロストリジウム性菌血症 L: CLOSTRIDIUM BACTEREMIA	E: 81 L: 18 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PANCYTOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13921# Age:7[redacted] Sex:Male Race:White Weight:96.6 kg								
(Cont.)	POST	105 TO	1	105	R: CORYNEBACTERIUM BACTEREMIA S: INFECTIONS AND INFESTATIONS P: コリネバクテリウム性菌血症 L: CORYNEBACTERIUM BACTEREMIA	E: 107 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
			9	113	R: KLEBSIELLA BACTEREMIA S: INFECTIONS AND INFESTATIONS P: クレブシエラ性菌血症 L: KLEBSIELLA BACTEREMIA	E: 126 L: 14 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53503) TRT:Venetocla 400 mg + AZA 13922# Age:8[redacted] Sex:Male Race:White Weight:81.5 kg								
	OPEN	1 TO 25	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: 28 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW ANC C: No reasonable possibility
	POST	26 TO	9	34	R: CEREBROVASCULAR ACCIDENT S: NERVOUS SYSTEM DISORDERS P: 脳血管発作 L: CEREBROVASCULAR ACCIDENT	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: RECEIVING PHYSICAL AND SPEECH THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ATRIAL FIBRILLATION AND PACEMAKER C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13922# Age:8[redacted] Sex:Male Race:White Weight:81.5 kg								
(Cont.)	POST	26 TO	25	50	R: ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L: MENTAL STATUS CHANGES	E: 54 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CEREBROVASCULAR ACCIDENT C: No reasonable possibility
					R: ACUTE RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 急性呼吸不全 L: ACUTE RESPIRATORY FAILURE	E: 62 L: 13 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: INTUBATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLUID OVERLOADED STATUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13924# Age:8[redacted] Sex:Female Race:Asian Weight:50.4 kg								
	OPEN	1 TO 482	18	18	R: BACTEREMIA (VIRIDANS STREPTOCOCCI) S: INFECTIONS AND INFESTATIONS P: レンサ球菌性菌血症 L: STREPTOCOCCAL BACTEREMIA	E: 32 L: 15 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE C: No reasonable possibility
			328	328	R: GRAM POSITIVE BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: GRAM-POSITIVE BACTEREMIA	E: 331 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53503) TRT:Venetocla 400 mg + AZA 13924# Age:8[redacted] Sex:Female Race:Asian Weight:50.4 kg								
	(Cont.)	OPEN	1 TO 482	480	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 485 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility
				480	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 485 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13924# Age:8[redacted] Sex:Female Race:Asian Weight:50.4 kg								
(Cont.)	POST	483 TO	1	483	R: RIGHT PARIETO-OCCIPITAL PARENCHYMAL HEMORRHAGIC STROKE S: NERVOUS SYSTEM DISORDERS P: 出血性卒中 L: HEMORRHAGIC STROKE	E: 485 L: 3 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: 1 UNIT OF PRBCS TO INCREASE PLATELETS TO 100,000 AND INR CORRECTED TO LESS THAN 1.2	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: LONG-STANDING PANCYTOPENIA WITH SEVERE THROMBOCYTOPENIA AND PLATELET DYSFUNCTION. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53503) TRT:Venetocla 400 mg + AZA 13924# Age:8[redacted] Sex:Female Race:Asian Weight:50.4 kg								
(Cont.)	POST	483 TO	2	484	R: ISCHEMIC STROKE S: NERVOUS SYSTEM DISORDERS P: 虚血性脳卒中 L: ISCHEMIC STROKE	E: 485 L: 2 Days I: Yes	G: Grade 4 R1: No reasonable possibility R3: 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 PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (80921) TRT:Venetocla 800 mg + DEC 63501# Age:7[redacted] Sex:Male Race:White Weight:77.9 kg								
	OPEN	1 TO 486	5	5	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 7 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GOUT C: No reasonable possibility
	POST	487 TO	15	501	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 506 L: 6 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INDUCTION CHEMOTHERAPY FOR DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (80921) TRT:Venetocla 800 mg + DEC 63501# Age:7[redacted] Sex:Male Race:White Weight:77.9 kg								
(Cont.)		POST	487 TO	20	506	R: FEBRILE NEUTROPAENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 523 L: 18 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO RECENT CHEMOTHERAPY C: No reasonable possibility
TRT:Venetocl x 400 mg + AZA 63902 Age:7[redacted] Sex:Female Race:White Weight:64.5 kg								
		OPEN	1 TO	3	3	R: ACUTE LEFT PAROTITIS S: INFECTIONS AND INFESTATIONS P: 耳下腺炎 L: PAROTITIS	E: 9 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: BACTERIAL INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (80921) TRT:Venetocl x 400 mg + AZA 63902 Age:7[redacted] Sex:Female Race:White Weight:64.5 kg								
(Cont.)	OPEN	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: 40 L: 9 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			507	507	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 512 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			635	635	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 642 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43703# Age:6[redacted] Sex:Female Race: Weight:76.0 kg								
	OPEN	1 TO 117	2	2	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 9 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELATED C: No reasonable possibility
			26	26	R: PULMONARY NOCARDIOSIS S: INFECTIONS AND INFESTATIONS P: 肺ノカルジア症 L: PULMONARY NOCARDIOSIS	E: 73 L: 48 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588)								
TRT:Venetocla 400 mg + AZA								
43703#	Age:6[redacted]	Sex:Female	Race:	Weight:76.0 kg				
(Cont.)	OPEN	1 TO 117	113	113	R: ASTHENIA S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: ASTHENIA	E: 115 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
43704#	Age:7[redacted]	Sex:Female	Race:	Weight:77.0 kg				
	OPEN	1 TO 585	7	7	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 9 L: 3 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			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: 28 L: 12 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43704# Age:7[redacted] Sex:Female Race: Weight:77.0 kg								
(Cont.)	OPEN	1 TO 585	112	112	R: ANAL FISSURE S: GASTROINTESTINAL DISORDERS P: 裂肛 L: ANAL FISSURE	E: 174 L: 63 Days I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SURGERY PERFORMED THE 23NOV2016	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	586 TO	9	594	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 600 L: 7 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43704# Age:7[redacted] Sex:Female Race: Weight:77.0 kg								
(Cont.)	POST	586 TO	27	612	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 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
TRT:Venetocla 800 mg + AZA 43701# Age:7[redacted] Sex:Male Race: Weight:66.0 kg								
	OPEN	1 TO 527	87	87	R: MYOCARDIAL INFARCTION S: CARDIAC DISORDERS P: 心筋梗塞 L: MYOCARDIAL INFARCTION	E: 96 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility O: OTHER: SEE PROCEDURE IN SAE FORM	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE RELATION WITH THROMBOCYTOSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 800 mg + AZA 43701# Age:7[redacted] Sex:Male Race: Weight:66.0 kg								
(Cont.)	POST	528 TO	2	529	R: RIGHT LOWER LOBAR PLEUROPNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 548 L: 20 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			24	551	R: RIGHT LOWER LOBAR PLEUROPNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 575 L: 25 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TUMORAL PROGRESSIVE DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 800 mg + AZA 43702#	Age:7[redacted] Sex:Male	Race:	Weight:81.0 kg					
	OPEN	1 TO 61	50	50	R: SEPTICEMIA TO PSEUDOMONAS AERUGINOSA S: INFECTIONS AND INFESTATIONS P: シュードモナス性敗血症 L: SEPTICEMIA DUE TO PSEUDOMONAS	E: 81 L: 32 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43905#	Age:7[redacted]	Sex:Male	Race:	Weight:74.0 kg				
	OPEN	1 TO 150	24	24	R: MUCOSITIS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 粘膜の炎症 L: MUCOSITIS	E: 33 L: 10 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: /[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43905# Age:7[redacted] Sex:Male Race: Weight:74.0 kg								
(Cont.)	OPEN	1 TO 150	150	150	R: MULTI-ORGAN FAILURE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 多臓器機能不全症候群 L: MULTI-ORGAN FAILURE	E: 162 L: 13 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 A: OTHER: AZACITIDINE AND ANT-199 DRUGS WITHDRAWN RELATED TO PROGRESSIVE DISEASE PER PROTOCOL O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (83588) TRT:Venetocla 400 mg + AZA 43906# Age:7[redacted] Sex:Male Race: Weight:85.0 kg								
	OPEN	1 TO 226	116	116	R: FEBRILE NEUTROPHILIC DERMATOSIS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 急性熱性好中球性皮膚症 L: ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	E: 126 L: 11 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			175	175	R: JAW ABSCESS S: INFECTIONS AND INFESTATIONS P: 顎膿瘍 L: ABSCESS JAW	E: 185 L: 11 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83588) TRT:Venetocla 400 mg + AZA 43906# Age:7[redacted] Sex:Male Race: Weight:85.0 kg								
(Cont.)	OPEN	1 TO 226	186	186	R: PUBIS NEUTROPHILIC DERMATOSIS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 好中球性皮膚症 L: NEUTROPHILIC DERMATOSIS	E: 219 L: 34 Days I: Yes	G: Grade 2 R1: Reasonable possibility R3: No reasonable possibility O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
INV:[redacted] (53187) TRT:Venetocla 400 mg + DEC 22502# Age:6[redacted] Sex:Male Race:White Weight:99.9 kg								
	POST	85 TO	5	89	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 95 L: 7 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53187) TRT:Venetocla 800 mg + DEC 22503# Age:8[redacted] Sex:Male Race:White Weight:77.2 kg								
	OPEN	1 TO 181	39	39	R: UROSEPSIS S: INFECTIONS AND INFESTATIONS P: 尿路性敗血症 L: UROSEPSIS	E: 46 L: 8 Days I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53187) TRT:Venetocla 400 mg + AZA 22905# Age:7[redacted] Sex:Female Race:White Weight:53.1 kg								
	OPEN	1 TO 51	48	48	R: INVASIVE FUNGAL SINUSITIS S: INFECTIONS AND INFESTATIONS P: 真菌性副鼻腔炎 L: SINUSITIS FUNGAL	E: 52 L: 5 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	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: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53187) TRT:Venetocla 400 mg + AZA 22906# Age:6[redacted] Sex:Female Race:White Weight:49.8 kg								
	OPEN	1 TO 529	29	29	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 35 L: 7 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	530 TO	1	530	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 537 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60701# Age:6[redacted] Sex:Male Race:White Weight:86.9 kg								
	OPEN	1 TO 150	4	4	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 6 L: 3 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SEPTIC WORKUP	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED OR INFECTION. EXACT REASON UNKNOWN. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60701# Age:6[redacted] Sex:Male Race:White Weight:86.9 kg								
(Cont.)	OPEN	1 TO 150	140	140	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 154 L: 15 Days I: Yes	G: Grade 2 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITAL ADMISSION	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
					R: LEFT SIDE HIP AREA PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 関節痛 L: PAIN IN HIP	E: 154 L: 15 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION CONFIRMED VIA PET SCAN AND BONE MARROW C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 800 mg + AZA 60703#	Age:7[redacted]	Sex:Male	Race:White	Weight:82.1 kg				
	OPEN	1 TO 113	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: 6 L: 6 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA IN THE BACKGROUND OF AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (35916) TRT:Venetocla 800 mg + AZA 60703# Age:7[redacted] Sex:Male Race:White Weight:82.1 kg								
(Cont.)	OPEN	1 TO 113	11	11	R: CONGESTIVE CARDIAC FAILURE S: CARDIAC DISORDERS P: うっ血性心不全 L: CONGESTIVE CARDIAC FAILURE	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FINAL DIAGNOSIS AS CARDIAC FAILURE. PATIENT HAS HISTORY OF ISCHEMIC HEART DISEASE AND MITRAL VALVE PROLAPSE. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 800 mg + AZA 60703# Age:7[redacted] Sex:Male Race:White Weight:82.1 kg								
(Cont.)	OPEN	1 TO 113	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: 27 L: 7 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: OTHER: COMMENCED CYCLE 2 WITHOUT AZACITIDINE. CURRENTLY RECEIVING ABT 199 ONLY O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLY DISEASE RELATED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 800 mg + AZA 60703# Age:7[redacted] Sex:Male Race:White Weight:82.1 kg								
	(Cont.)	OPEN	1 TO 113	22	22	R: PERSISTENT HYPOTENSION REFRACTORY TO FLUID RESUSCITATION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 27 L: 6 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: FEBRILE NEUTROPENIC SHOCK C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60905# Age:8[redacted] Sex:Male Race:White Weight:106.6 kg								
	OPEN	1 TO 770	260	260	R: LARGE HIATUS HERNIA S: GASTROINTESTINAL DISORDERS P: 裂孔ヘルニア L: HIATUS HERNIA	E: 330 L: 71 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: SURGICAL INTERVENTION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: THE RISK OF HIATUS HERNIA DOES INCREASE WITH AGE. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60905# Age:8[redacted] Sex:Male Race:White Weight:106.6 kg								
(Cont.)	OPEN	1 TO 770	302	302	R: DIVERTICULOSIS S: GASTROINTESTINAL DISORDERS P: 憩室 L: DIVERTICULOSIS	O: Yes I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO PRESSURE FROM HERNIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code:[redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60905# Age:8[redacted] Sex:Male Race:White Weight:106.6 kg								
(Cont.)	OPEN	1 TO 770	313	313	R: DYSPNOEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: DYSPNOEA	E: 391 & L: 79 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HERNIA PUSHING ON THORACIC DIAPHRAGM C: No reasonable possibility

Subject prematurely discontinued ABT-199.
& Date is estimated.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60905# Age:8[redacted] Sex:Male Race:White Weight:106.6 kg								
(Cont.)	OPEN	1 TO 770	363	363	R: CONSTIPATION S: GASTROINTESTINAL DISORDERS P: 便秘 L: CONSTIPATION	E: 368 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: MANUAL EVACUATION BY SURGICAL TEAM	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POST HERNIA REPAIR SURGERY COMPLICATION. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (35916) TRT:Venetocla 400 mg + AZA 60905# Age:8[redacted] Sex:Male Race:White Weight:106.6 kg								
(Cont.)	OPEN	1 TO 770	729	729	R: SKIN INFECTION AT PORT-A-CATH ACCESS SITE S: INFECTIONS AND INFESTATIONS P: カテーテル留置部位感染 L: CATHETER SITE INFECTION	E: 749 L: 21 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTION FROM SKIN BREACH WHILE PORT-A-CATH NEEDLE INSERTION FOR BLOOD COLLECTION OR AZACITIDINE ADMINISTRATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21202# Age:6[redacted] Sex:Male Race:White Weight:79.6 kg								
	OPEN	1 TO 84	3	3	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 7 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (979679) TRT:Venetocla 400 mg + AZA 21202# Age:6[redacted] Sex:Male Race:White Weight:79.6 kg								
(Cont.)	OPEN	1 TO 84	27	27	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 38 L: 12 Days I: Yes	G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
TRT:Venetoclax 800 mg + AZA 21203# Age:7[redacted] Sex:Female Race:White Weight:67.1 kg								
	OPEN	1 TO 148	29	29	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 32 L: 4 Days I: Yes	G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21203# Age:7[redacted] Sex:Female Race:White Weight:67.1 kg								
(Cont.)	OPEN	1 TO 148	134	134	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 134 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE EARLY BRONCHIOLITIS CT SCANS SHOWED OTHERWISE C: No reasonable possibility
21204# Age:7[redacted] Sex:Male Race:Asian Weight:58.9 kg								
	OPEN	1 TO 88	23	23	R: NEUTROPENIC FEVERS S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 26 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility R3: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21204# Age:7[redacted] Sex:Male Race:Asian Weight:58.9 kg								
(Cont.)	OPEN	1 TO 88	59	59	R: SYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神 L: SYNCOPE	E: 59 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOOD PATIENT HAD A RATHER HEAVY MEAL WHICH CAUSED DIARRHEA CAUSING THE PATINET TO LOSE CONSCIOUSNESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21207# Age:7[redacted] Sex:Male Race:Black Weight:105.7 kg								
	OPEN	1 TO 78	8	8	R: BONE PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨痛 L: BONE PAIN	O: Yes I: Yes	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LIKEY AML REALTED BONE PAIN C: No reasonable possibility
	POST	79 TO	25	103	R: FALL S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 転倒 L: FALL	E: 103 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW PLATELETS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21207# Age:7[redacted] Sex:Male Race:Black Weight:105.7 kg								
(Cont.)	POST	79 TO	25	103	R: SUBDURAL HEMATOMA S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 硬膜下血腫 L: SUBDURAL HEMATOMA	E: 113 L: 11 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL DUE TO LOW PLATELET COUNT C: No reasonable possibility
TRT:Venetocla 400 mg + AZA 21721# Age:7[redacted] Sex:Male Race:White Weight:77.7 kg								
	OPEN	1 TO 692	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: 24 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21721# Age:7[redacted] Sex:Male Race:White Weight:77.7 kg									
(Cont.)	OPEN	1 TO 692	74	74		R: RHINOVIRUS S: INFECTIONS AND INFESTATIONS P: ライノウイルス感染 L: RHINOVIRUS INFECTION	E: 77 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOGENOUS LEUKEMIA C: No reasonable possibility
21722# Age:7[redacted] Sex:Male Race:White Weight:105.1 kg									
	OPEN	1 TO 128	31	31		R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 31 L: 1 Day I: No	G: Grade 3 R1: No reasonable possibility R3: Reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21722# Age:7[redacted] Sex:Male Race:White Weight:105.1 kg								
	(Cont.)	OPEN	1 TO 128	84	84	R: ACUTE CHOLECYSTITIS S: HEPATOBILIARY DISORDERS P: 急性胆嚢炎 L: ACUTE CHOLECYSTITIS	E: 141 L: 58 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CHOLECYSTOSTOMY TUBE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CHOLELITHIASIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21722# Age:7[redacted] Sex:Male Race:White Weight:105.1 kg								
(Cont.)	OPEN	1 TO 128	94	94	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RATE S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	E: 96 L: 3 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: CONMED CONTINUED/HOSPITALIZATION	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PAST MEDICAL HISTORY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21722# Age:7[redacted] Sex:Male Race:White Weight:105.1 kg								
(Cont.)	POST	129 TO	8	136	R: ACUTE CHOLECYSTITIS S: HEPATOBILIARY DISORDERS P: 急性胆嚢炎 L: ACUTE CHOLECYSTITIS	E: 141 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: CHOLECYSTECTOMY, ABDOMINAL ULTRASOUND	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CHOLELITHIASIS C: No reasonable possibility
21727# Age:6[redacted] Sex:Male Race:White Weight:108.6 kg								
	POST	132 TO	7	138	R: INFECTION OF UNKNOWN ETIOLOGY S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 144 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE MYELOID LEUKEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocla 400 mg + AZA 21731# Age:6[redacted] Sex:Male Race:Black Weight:86.4 kg								
	OPEN	1 TO 112	72	72	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 73 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PICC CULTURED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			88	88	R: GASTROENTERITIS S: INFECTIONS AND INFESTATIONS P: 胃腸炎 L: GASTROENTERITIS	E: 92 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VIRAL EXPOSURE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocla 400 mg + AZA 21731# Age:6[redacted] Sex:Male Race:Black Weight:86.4 kg								
(Cont.)	POST	113 TO	26	138	R: GRAM NEGATIVE SEPSIS S: INFECTIONS AND INFESTATIONS P: 細菌性敗血症 L: BACTERIAL SEPSIS	E: 161 L: 24 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	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: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21713# Age:7[redacted] Sex:Male Race:Black Weight:102.3 kg									
	OPEN	1 TO 28	27	27		R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 38 L: 12 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: OTHER: CYCLE 2 WILL BE DELAYED. O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocla 800 mg + AZA 21713# Age:7[redacted] Sex:Male Race:Black Weight:102.3 kg								
(Cont.)	POST	29 TO	2	30	R: INTRACRANIAL HEMMORHAGE S: NERVOUS SYSTEM DISORDERS P: 頭蓋内出血 L: INTRACRANIAL HEMORRHAGE	E: 42 L: 13 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: PLATLETS TRANSFUSED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PATIENT HAD BEEN PRESECRIBED LOW MOLECULAR WEIGHT HEPARIN AT OUTSIDE HOSPITAL WITH PLATELET COUNT OF LESS THAN 30. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocl x 800 mg + AZA 21714 Age:8[redacted] Sex:Female Race:Black Weight:74.6 kg									
	OPEN	1 TO		262	262	R: GRAM NEGATIVE INFECTION S: INFECTIONS AND INFESTATIONS P: 細菌感染 L: GRAM-NEGATIVE ROD INFECTION	E: 268 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HICKMAN REMOVED AND REPLACED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
				323	323	R: INFLUENZA S: INFECTIONS AND INFESTATIONS P: インフルエンザ L: INFLUENZA	E: 327 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VIRAL EXPOSURE C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocl x 800 mg + AZA 21714 Age:8[redacted] Sex:Female Race:Black Weight:74.6 kg							
(Cont.)	OPEN	1 TO	479	R: GRAM NEGATIVE BACILLI BACTEREMIA S: INFECTIONS AND INFESTATIONS P: バチルス性菌血症 L: BACILLUS BACTEREMIA	E: 483 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			691	R: ENDOMETRITIS S: INFECTIONS AND INFESTATIONS P: 子宮内膜炎 L: ENDOMETRITIS	E: 707 L: 17 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PESSARY C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted](979679) TRT:Venetocl x 800 mg + AZA 21714 Age:8[redacted] Sex:Female Race:Black Weight:74.6 kg								
	(Cont.)	OPEN	1 TO	949	949	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 969 L: 21 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTIOUS PROCESS C: No reasonable possibility
			1138	1138	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility

OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocl x 800 mg + AZA 21714 Age:8[redacted] Sex:Female Race:Black Weight:74.6 kg								
(Cont.)	OPEN	1 TO	1179	1179	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 1193 L: 15 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility
21715# Age:7[redacted] Sex:Male Race:American Indian/Alaska Native Weight:85.7 kg								
	OPEN	1 TO 1221	31	31	R: PSEUDO GOUT S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: ピロリン酸カルシウム結晶性軟骨石灰化症 L: PSEUDOGOUT	E: 141 L: 111 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21715# Age:7[redacted] Sex:Male Race:American Indian/Alaska Native Weight:85.7 kg								
	(Cont.)	OPEN	1 TO 1221	890	R: GRAM NEGATIVE BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: GRAM-NEGATIVE BACTEREMIA	E: 903 L: 14 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTIOUS PROCESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocla 800 mg + AZA 21715# Age:7[redacted] Sex:Male Race:American Indian/Alaska Native Weight:85.7 kg								
(Cont.)	OPEN	1 TO 1221	914	914	R: CELLULITIS LEFT HAND S: INFECTIONS AND INFESTATIONS P: 蜂巣炎 L: CELLULITIS OF HAND	E: 921 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: XR WRIST AND HAND	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CAT BITE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21715# Age:7[redacted] Sex:Male Race:American Indian/Alaska Native Weight:85.7 kg								
(Cont.)	OPEN	1 TO 1221	1000	1000	R: PSEUDOGOUT S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: ピロリン酸カルシウム結晶性軟骨石灰化症 L: PSEUDOGOUT	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: FALL C: No reasonable possibility
21717# Age:7[redacted] Sex:Female Race:White Weight:50.9 kg								
	OPEN	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: 151 L: 16 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21717# Age:7[redacted] Sex:Female Race:White Weight:50.9 kg								
(Cont.)	OPEN	1 TO 166	141	141	R: PROGRESSIVE INFECTION OF UNKNOWN ETIOLOGY S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION AGGRAVATED	E: 168 L: 28 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: CONTINUED ON CONMEDS FROM ANTIBIOTIC/ANTIFUNGAL/ANTIVIRAL PROPHYLAXIS	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: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21717# Age:7[redacted] Sex:Female Race:White Weight:50.9 kg								
(Cont.)	OPEN	1 TO 166	156	156	R: INTERMITTENT NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 168 L: 13 Days I: Yes	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (979679) TRT:Venetocla 800 mg + AZA 21717# Age:7[redacted] Sex:Female Race:White Weight:50.9 kg								
(Cont.)	POST	167 TO	1	167	R: LIVER ABSCESS S: INFECTIONS AND INFESTATIONS P: 肝膿瘍 L: LIVER ABSCESS	E: 168 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	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: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day Day	of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21719# Age:6[redacted] Sex:Male Race:White Weight:100.8 kg								
	OPEN	1 TO 188	120	120	R: BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 123 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	189 TO	15	203	R: DISSEMINATED FUNGAL INFECTION S: INFECTIONS AND INFESTATIONS P: 真菌感染 L: FUNGAL INFECTION	O: Yes I: No	G: Grade 3 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ENDOSCOPIC SINUS SURGERY, NASAL DEBRIDEMENT, SEPTECTOMY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21725# Age:7[redacted] Sex:Male Race:White Weight:129.4 kg								
	OPEN	1 TO 119	65	65	R: NEUTROPENIC SEPSIS S: INFECTIONS AND INFESTATIONS P: 好中球減少性敗血症 L: NEUTROPENIC SEPSIS	E: 66 L: 2 Days I: No	G: Grade 4 R1: Reasonable possibility R3: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
					R: ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L: MENTAL STATUS CHANGES	E: 71 L: 7 Days I: No	G: Grade 2 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC SEPSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21725# Age:7[redacted] Sex:Male Race:White Weight:129.4 kg								
(Cont.)	OPEN	1 TO 119	67	67	R: VOLUME OVERLOAD S: METABOLISM AND NUTRITION DISORDERS P: 水分過負荷 L: VOLUME OVERLOAD	E: 79 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HISTORY OF CHRONIC HEART FALURE C: No reasonable possibility
	POST	120 TO	16	135	R: FAILURE TO THRIVE S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	E: 141 L: 7 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21728# Age:7[redacted] Sex:Female Race:White Weight:57.0 kg								
		OPEN	1 TO 827	270	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 282 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIAL EXPOSURE C: No reasonable possibility
21730# Age:7[redacted] Sex:Male Race:White Weight:79.0 kg								
		OPEN	1 TO 713	470	R: RESPIRATORY SYNCYTIAL VIRUS S: INFECTIONS AND INFESTATIONS P: RSウイルス感染 L: RESPIRATORY SYNCYTIAL VIRUS INFECTION	E: 479 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VIRAL INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21730# Age:7[redacted] Sex:Male Race:White Weight:79.0 kg								
(Cont.)	OPEN	1 TO 713	470	470	R: GRAM NEGATIVE BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: GRAM-NEGATIVE BACTEREMIA	E: 479 L: 10 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA C: No reasonable possibility
			539	539	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 543 L: 5 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21730# Age:7[redacted] Sex:Male Race:White Weight:79.0 kg								
(Cont.)	OPEN	1 TO 713	713	713	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RATE S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	E: 714 L: 2 Days I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ADMITTED, CHEST XRAY, OXYGEN	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 800 mg + AZA 21730# Age:7[redacted] Sex:Male Race:White Weight:79.0 kg								
	(Cont.)	OPEN	1 TO 713	713	713	R: SEPTIC SHOCK S: INFECTIONS AND INFESTATIONS P: 敗血症性ショック L: SEPTIC SHOCK	E: 714 L: 2 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POSSIBLE BILIARY INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (979679) TRT:Venetocla 400 mg + AZA 21933# Age:7[redacted] Sex:Male Race:White Weight:108.6 kg								
	OPEN	1 TO 74	24	24	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 27 L: 4 Days I: No	G: Grade 4 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility
	POST	75 TO	15	89	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 104 L: 16 Days I: No	G: Grade 3 R1: Reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (979679) TRT:Venetocla 400 mg + AZA 21933# Age:7[redacted] Sex:Male Race:White Weight:108.6 kg								
(Cont.)	POST	75 TO	22	96	R: HYPOXEMIC RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: HYPOXIC RESPIRATORY FAILURE	E: 104 L: 9 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: GIVEN OXYGEN. NASAL CANNULA O2 RATE (L/MIN): 6	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PNEUMONIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](979679) TRT:Venetocla 400 mg + AZA 21936# Age:6[redacted] Sex:Female Race:White Weight:52.1 kg									
	OPEN	1 TO 50	37	37		R: PERIPHERAL NEUROPATHY S: NERVOUS SYSTEM DISORDERS P: 末梢性ニューロパチー L: PERIPHERAL NEUROPATHY	O: Yes I: Yes	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: OTHER: MRI	S: Yes, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: PARKINSONS DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (48886) TRT:Venetocla 400 mg + DEC 26101# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
	OPEN	1 TO 37	9	9	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 9 L: 1 Day I: No	D: No G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch Interval	RX Day ---- Day	of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (48886) TRT:Venetocla 400 mg + DEC 26101# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
	(Cont.)	OPEN	1 TO 37	31	31	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 32 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MOST LIKELY CAUSE OF EVENT: DISEASE UNDER STUDY C: No reasonable possibility
				37	37	R: ACUTE EMBOLIC STROKE S: NERVOUS SYSTEM DISORDERS P: 塞栓性脳卒中 L: EMBOLIC STROKE	E: 38 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - 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: RIGHT VERTEBRAL ARTERY STENOSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (48886) TRT:Venetocla 800 mg + DEC 26102# Age:7[redacted] Sex:Male Race:Asian Weight:80.4 kg								
	OPEN	1 TO 113	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: 33 L: 6 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](48886) TRT:Venetocla 800 mg + DEC 26102# Age:7[redacted] Sex:Male Race:Asian Weight:80.4 kg								
(Cont.)	OPEN	1 TO 113	53	53	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 53 L: 1 Day I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility
			107	107	R: RIGHT INNER UPPER THIGH CELLULITIS S: INFECTIONS AND INFESTATIONS P: 蜂巣炎 L: CELLULITIS	E: 112 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ETIOLOGY UNCLEAR. INFECTION THOUGHT TO HAVE OCCURRED DUE TO FACT THAT PT WAS NEUTROPENIC AT TIME OF EVENT ONSET C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (48886) TRT:Venetocla 800 mg + DEC 26102# Age:7[redacted] Sex:Male Race:Asian Weight:80.4 kg								
(Cont.)		POST	114 TO	1	114	R: FUNGAL INFECTION OF LUNG S: INFECTIONS AND INFESTATIONS P: 真菌性気道感染 L: RESPIRATORY TRACT INFECTION FUNGAL	O: Yes I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: OTHER: PATIENT TAKEN OFF TREATMENT DUE TO NEED TO TAKE POSACONAZOLE FOR THIS FUNGAL INFECTION. STUDY DRUG WITHDRAWN PERMANENTLY O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED STATE DUE TO DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (48886) TRT:Venetocla 800 mg + DEC 26102# Age:7[redacted] Sex:Male Race:Asian Weight:80.4 kg								
(Cont.)	POST	114 TO	1	114	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 125 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY C: No reasonable possibility
TRT:Venetocla 800 mg + DEC 26506# Age:7[redacted] Sex:Female Race:White Weight:55.5 kg								
	OPEN	1 TO 273	95	95	R: PYELONEPHRITIS S: INFECTIONS AND INFESTATIONS P: 腎盂腎炎 L: PYELONEPHRITIS	E: 107 L: 13 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65103# Age:8[redacted] Sex:Male Race:White Weight:81.1 kg								
	OPEN	1 TO 308	9	9	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 10 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 800 mg + DEC 65103# Age:8[redacted] Sex:Male Race:White Weight:81.1 kg								
(Cont.)	OPEN	1 TO 308	71	71	R: HYPOVOLAEMIC SHOCK S: VASCULAR DISORDERS P: 血液量減少性ショック L: HYPOVOLAEMIC SHOCK	E: 77 L: 7 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: TRANSFUSED AND ILIAC STENT INSERTED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PROCEDURE RELATED. BONE MARROW BIOPSY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65103# Age:8[redacted] Sex:Male Race:White Weight:81.1 kg								
(Cont.)	OPEN	1 TO 308	306	306	R: E. COLI BACTERAEMIA S: INFECTIONS AND INFESTATIONS P: 大腸菌性菌血症 L: ESCHERICHIA COLI BACTEREMIA	E: 313 L: 8 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BACTERIA INFECTION ? BILIRARY SOURCE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65103# Age:8[redacted] Sex:Male Race:White Weight:81.1 kg								
(Cont.)	POST	309 TO	12	320	R: E.COLI BACTEREMIA SEPSIS S: INFECTIONS AND INFESTATIONS P: 大腸菌性敗血症 L: SEPTICEMIA DUE TO ESCHERICHIA COLI (E. COLI)	E: 330 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS OF UNKNOWN SOURCE IN CONTEXT OF RECENT E. COLI SEPSIS OR POSSIBLE SOURCE IS SECONDARY TO INFECTED HAEMATOMA ANTERIOR TO LEFT PSOAS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 800 mg + DEC 65104# Age:7[redacted] Sex:Male Race:White Weight:81.0 kg								
	OPEN	1 TO 40	40	40	R: ELEVATED LFTS S: INVESTIGATIONS P: 肝機能検査値上昇 L: LIVER FUNCTION TESTS RAISED	E: 80 L: 41 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GRADE 3 LIVER FUNCTION TEST DERANGEMENT FOR INVESTIGATION. MOST LIKELY CAUSE OF EVENT IS AMBISONE INFUSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65104# Age:7[redacted] Sex:Male Race:White Weight:81.0 kg								
(Cont.)	POST	41 TO	9	49	R: LETHARGY S: NERVOUS SYSTEM DISORDERS P: 嗜眠 L: LETHARGY	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: OTHER: ADMITTED TO HOSPITAL	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE AND GENERAL CONDITION OF PATIENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 1200 mg + DEC 65106# Age:7[redacted] Sex:Female Race:White Weight:57.6 kg								
	OPEN	1 TO 686	596	596	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 604 L: 9 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 1200 mg + DEC 65106# Age:7[redacted] Sex:Female Race:White Weight:57.6 kg								
(Cont.)	POST	687 TO	3	689	R: STREPTOCOCCUS SALIVARIUS BACTEREMIA S: INFECTIONS AND INFESTATIONS P: レンサ球菌性菌血症 L: STREPTOCOCCAL BACTEREMIA	E: 704 L: 16 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ONGOING CYTOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 400 mg + DEC 65507# Age:7[redacted] Sex:Female Race:Native Hawaiian Or Pacific Islander Weight:59.4 kg									
	OPEN	1 TO 256	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: 44 L: 12 Days I: Yes	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOW NEUTROPHIL COUNT, ALLERGIC REACTION TO PLATELET TRANSFUSION C: No reasonable possibility
			222	222		R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 225 L: 4 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53332) TRT:Venetocla 400 mg + DEC 65507# Age:7[redacted] Sex:Female Race:Native Hawaiian Or Pacific Islander Weight:59.4 kg								
(Cont.)	POST	257 TO	9	265	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 275 L: 11 Days I: No	G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: OTHER: PATIENT NOT TAKING STUDY DRUG AT TIME OF EVENT ONSET (CURRENTLY TAKES ABT-199 DAYS 1-14) O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING ACUTE MYELOID LEUKAEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	---- Name	Epoch	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 400 mg + DEC 65508# Age:6[redacted] Sex:Female Race:White Weight:77.0 kg								
	OPEN	1 TO 749	43	43	R: FEVERS UNKNOWN ORIGIN, CHILLS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 悪寒 L: CHILLS	E: 45 L: 3 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPTIC SCREENING, POSSIBLE UNDERLYING INFECTIVE PROCESS & NEUTROPENIA C: No reasonable possibility
					R: FEVERS UNKNOWN ORIGIN, CHILLS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER OF UNKNOWN ORIGIN		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 800 mg + DEC 65509# Age:7[redacted] Sex:Female Race:White Weight:99.8 kg								
	OPEN	1 TO 645	17	17	R: EPISTAXIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻出血 L: EPISTAXIS	E: 20 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PLATELET TRANSFUSION, TRANEXAMIC ACID AND RAPID RHINO TAMPONADE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO THROMBOCYTOPENIA WHICH IS CAUSED BY PTS DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted](53332) TRT:Venetocla 800 mg + DEC 65509# Age:7[redacted] Sex:Female Race:White Weight:99.8 kg								
(Cont.)	OPEN	1 TO 645	102	102	R: STREPTOCOCCUS MITIS BACTERAEMIA S: INFECTIONS AND INFESTATIONS P: レンサ球菌性菌血症 L: STREPTOCOCCAL BACTEREMIA	E: 112 L: 11 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PICC LINE WAS REMOVED AS POSSIBLE SOURCE OF INFECTION C: No reasonable possibility
			308	308	R: HEADACHE S: NERVOUS SYSTEM DISORDERS P: 頭痛 L: HEADACHE	E: 315 L: 8 Days I: No	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: HOSPITALIZED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION, ANAEMIA & POSSIBLE OCCIPITAL COMPONENT & INFECTION RELATED TO NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65509# Age:7[redacted] Sex:Female Race:White Weight:99.8 kg								
(Cont.)	OPEN	1 TO 645	309	309	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 315 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: Reasonable possibility
			435	435	R: ESCHERICHIA E COLI BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 大腸菌性菌血症 L: ESCHERICHIA COLI BACTEREMIA	E: 440 L: 6 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65509# Age:7[redacted] Sex:Female Race:White Weight:99.8 kg								
(Cont.)	OPEN	1 TO 645	603	603	R: ESCHERICHIA COLI-SECONDARY INFECTION S: INFECTIONS AND INFESTATIONS P: 大腸菌感染 L: ESCHERICHIA COLI INFECTION	E: 610 L: 8 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SOFT TISSUE INJURY OTHER- LACERATION TO RIGHT LEG SECONDARY TO FALL C: No reasonable possibility
	POST	646 TO	12	657	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 674 L: 18 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPHILS 0.01. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65509# Age:7[redacted] Sex:Female Race:White Weight:99.8 kg								
(Cont.)	POST	646 TO	21	666	R: VOCAL CORD PALSY S: NERVOUS SYSTEM DISORDERS P: 声帯麻痺 L: VOCAL CORD PALSY	E: 668 L: 3 Days I: No	G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: NASOGASTRIC FEEDING TUBE INSERTED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CEREBRAL VASCULAR ACCIDENT DISCOUNTED, ORAL CANDIDIASIS OR ACUTE MUCOSAL OEDEMA C: No reasonable possibility
65511# Age:7[redacted] Sex:Male Race:White Weight:82.0 kg								
	OPEN	1 TO 863	15	15	R: PARAINFLUENZA 3 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: 19 L: 5 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: BLOOD CULTURES	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML DISEASE RELATED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 800 mg + DEC 65511# Age:7[redacted] Sex:Male Race:White Weight:82.0 kg								
(Cont.)	OPEN	1 TO 863	311	311	R: DIARRHOEA S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHOEA	E: 314 L: 4 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT ATE FISH & CHIPS WITH BOWL OF RAW SEAFOOD WHICH COULD BE CAUSE OF EVENT. C: No reasonable possibility
TRT:Venetocla 400 mg + AZA 65913# Age:8[redacted] Sex:Female Race:White Weight:84.0 kg								
	OPEN	1 TO 28	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: 32 L: 13 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabine + Dosaconzaole.

Program Source Code: [redacted]

TABLE 1__11.3

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-358)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:Venetocla 400 mg + AZA 65913# Age:8[redacted] Sex:Female Race:White Weight:84.0 kg								
(Cont.)	POST	29 TO	13	41	R: ENTEROCOCCUS FAECIUM VAN B (VRE). S: INFECTIONS AND INFESTATIONS P: 腸球菌感染 L: VANCOMYCIN-RESISTANT ENTEROCOCCAL INFECTION	O: Yes I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE PROGRESSION C: No reasonable possibility
65915# Age:8[redacted] Sex:Female Race:White Weight:72.5 kg								
	OPEN	1 TO 61	47	47	R: LEFT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 73 L: 27 Days I: No	G: Grade 3 R1: No reasonable possibility R3: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE AND NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.
AZA = Azacitidine. DEC = Decitabine. DDI = Drug Drug Interaction: Venetoclax 400 MG + Decitabline + Dosaconzaole.

Program Source Code: [redacted]

表 2.7.4-100.　　重篤な有害事象を発現した被験者一覧（M13-834 試験）

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER / NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
TRT:VENETOCLAX - ARM A - COHORT 1							
INV:[redacted] (53098)							
1401 AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:50.6 KG							
	CYCLE 72 1511 TO	7	1517				
				R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:肺炎 L:PNEUMONIA	I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE DELAYED - VENETOCLAX O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:FLU A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM A - COHORT 2							
INV:[redacted] (92761)							
2202 AGE:8[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:66.1 KG							
	POST 96 TO	1	96				
				R:HEART FAILURE S:CARDIAC DISORDERS P:心不全 L:HEART FAILURE	E:128 L:33 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX O:CONCOMITANT MEDICATION PRESCRIBED O:CONCOMITANT MEDICATION DISCONTINUED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:DISCONTINUATION OF AMLODIPINE A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM A - COHORT 3							
INV:[redacted] (978954)							
3303 AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:63.9 KG							

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
	POST	43 TO	8	50	R:DLBCL AGGRAVATED S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:びまん性大細胞型Ｂ細胞性リンパ腫 L:DIFFUSE LARGE B-CELL LYMPHOMA	E:86 L:37 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:TUMOR RELATED A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM A - COHORT 4 INV:[redacted] (978954) 4305 AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:58.7 KG								
	CYCLE 11	225 TO 231	7	231	R:DISEASE PROGRESSION S:GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P:疾患進行 L:DISEASE PROGRESSION	O:YES I:NO	G:GRADE 1 R1:NO REASONABLE POSSIBILITY A:DRUG WITHDRAWN - VENETOCLAX - RELATED TO PROGRESSION O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PRIMARY DISEASE A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM B INV:[redacted] (96133) 5702 AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:78.3 KG								
	OPEN	1 TO	87	87	R:DISSEMINATED HERPES ZOSTER S:INFECTIONS AND INFESTATIONS P:播種性帯状疱疹 L:HERPES ZOSTER DISSEMINATED	E:99 L:13 DAYS I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:REASONABLE POSSIBILITY

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
			107	107	R:COLON ULCER S:GASTROINTESTINAL DISORDERS P:大腸潰瘍 L:COLON ULCER	E:128 L:22 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THERE IS NO EVIDENCE TO SUGGEST A CAUSAL RELATIONSHIP BETWEEN ABT199 AND THIS EVENT. IT WAS CONSIDERED THAT THIS EVENT WAS CAUSED BY THE BACKGROUND OF THE SUBJECT AND THE CONCOMITANT MEDICATIONS. A:NO REASONABLE POSSIBILITY
			295	295	R:SEPSIS S:INFECTIONS AND INFESTATIONS P:敗血症 L:SEPSIS	E:312 L:18 DAYS I:YES	G:GRADE 3 R1:REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:REASONABLE POSSIBILITY

INV:[redacted] (978954)
5304 AGE:7[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.6 KG

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
	OPEN	1 TO 289	289	289	R:MYELODYSPLASTIC SYNDROMES S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:骨髄異形成症候群 L:MYELODYSPLASTIC SYNDROME	O:YES I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY A:DRUG WITHDRAWN - VENETOCLAX - NOT RELATED TO PROGRESSION O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:NO REASONABLE POSSIBILITY
	POST	290 TO	6	295	R:FEBRILE NEUTROPENIA S:BLOOD AND LYMPHATIC SYSTEM DISORDERS P:発熱性好中球減少症 L:FEBRILE NEUTROPENIA	E:298 L:4 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:MYELODYSPLASTIC SYNDROMES A:NO REASONABLE POSSIBILITY
			17	306	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 R1:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:MYELODYSPLASTIC SYNDROMES A:NO REASONABLE POSSIBILITY

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
			22	311	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:肺炎 L:PNEUMONIA	O:YES I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:MYELODYSPLASTIC SYNDROMES A:NO REASONABLE POSSIBILITY
			24	313	R:INFECTIVE SHOCK S:INFECTIONS AND INFESTATIONS P:敗血症性ショック L:SEPTIC SHOCK	E:329 L:17 DAYS I:NO	G:GRADE 4 R1:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PANCYTOPENIA A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM C INV:[redacted] (103235) 6802 AGE:7[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:39.3 KG								
		POST	187 TO	26	212			
					R:CEREBRAL HEMORRHAGE S:NERVOUS SYSTEM DISORDERS P:脳出血 L:CEREBRAL HEMORRHAGE	E:212 L:1 DAY I:NO	G:GRADE 4 R1:NO REASONABLE POSSIBILITY R2:NO REASONABLE POSSIBILITY A:NONE O:NONE	S:YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PRIMARY DISEASE A:NO REASONABLE POSSIBILITY

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
				212				
					R:CEREBRAL HEMORRHAGE S:NERVOUS SYSTEM DISORDERS P:脳出血 L:CEREBRAL HEMORRHAGE	E:212 L:1 DAY I:NO	G:GRADE 5 R1:NO REASONABLE POSSIBILITY R2:NO REASONABLE POSSIBILITY A:NONE O:NONE	S:YES, DEATH OF SUBJECT O:PRIMARY DISEASE A:NO REASONABLE POSSIBILITY
INV:[redacted] (96133)								
6703 AGE:7[redacted]	SEX:FEMALE	RACE:ASIAN	WEIGHT:37.9 KG					
	CYCLE 6	211 TO 259	26	236				
					R:ACUTE GASTRITIS S:GASTROINTESTINAL DISORDERS P:胃炎 L:ACUTE GASTRITIS	E:245 L:10 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY R2:NO REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:GASTRITIS HAS CONTINUED MORE THAN BEFORE. A:NO REASONABLE POSSIBILITY
	CYCLE 7	260 TO 329	28	287				
					R:ACUTE GASTRITIS S:GASTROINTESTINAL DISORDERS P:胃炎 L:ACUTE GASTRITIS	E:311 L:25 DAYS I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY R2:REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:NO REASONABLE POSSIBILITY

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
			52	311	R:GASTRITIS S:GASTROINTESTINAL DISORDERS P:胃炎 L:GASTRITIS	E:327 L:17 DAYS I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY R2:REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:NO REASONABLE POSSIBILITY
	CYCLE 9	379 TO 441	31	409	R:FUNGAL PNEUMONIA S:INFECTIONS AND INFESTATIONS P:真菌性肺炎 L:PNEUMONIA FUNGAL	E:439 L:31 DAYS I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY R2:REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:REASONABLE POSSIBILITY
INV:[redacted] (118344) 61001 AGE:7[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:52.2 KG								
	CYCLE 8	221 TO 268	13	233	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:肺炎 L:PNEUMONIA	I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY R2:NO REASONABLE POSSIBILITY A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:FUNGAL INFECTION A:NO REASONABLE POSSIBILITY

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
	CYCLE 11	329 TO 366	33	361				
					R:SEPSIS S:INFECTIONS AND INFESTATIONS P:敗血症 L:SEPSIS	E:366 L:6 DAYS I:YES	G:GRADE 4 R1:NO REASONABLE POSSIBILITY R2:NO REASONABLE POSSIBILITY A:DOSE DELAYED - AZACITIDINE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CYTOPENIA DUE TO PRIMARY DISEASE A:NO REASONABLE POSSIBILITY
TRT:VENETOCLAX - ARM D INV:[redacted] (105647) 71401 AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:53.8 KG								
	OPEN	1 TO 135	133	133				
					R:CHRONIC LYMPHOCYTIC LEUKEMIA AGGRAVATED S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:慢性リンパ性白血病 L:CHRONIC LYMPHOCYTIC LEUKAEMIA	E:149 L:17 DAYS I:NO	G:GRADE 3 R1:NO REASONABLE POSSIBILITY R3:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PROGRESSIVE DISEASE A:NO REASONABLE POSSIBILITY
INV:[redacted] (92761) 7208 AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.9 KG								

TABLE 14.3__2.1.4
LISTING OF SUBJECTS WITH TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS
(ALL TREATED SUBJECTS)

SUBJECT NUMBER	NAME	--- EPOCH --- INTERVAL	DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 21.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT THE END OF STUDY? L:LENGTH I:INTERMITTENT?	G:NCI TOXICITY R1:RELATIONSHIP TO VENETOCLAX R2: RELATIONSHIP TO AZACITIDINE R3: RELATIONSHIP TO IDEC-C2B8 A:ACTION TAKEN WITH STUDY TREATMENT O:OTHER ACTIONS TAKEN	S:SERIOUS AE? D:DLT EVENT O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
	OPEN	1 TO 114	65	65	R:BACTERIAL PNEUMONIA S:INFECTIONS AND INFESTATIONS P:細菌性肺炎 L:PNEUMONIA BACTERIAL	E:85 L:21 DAYS I:NO	G:GRADE 3 R1:REASONABLE POSSIBILITY R3:REASONABLE POSSIBILITY A:DOSE INTERRUPTED - VENETOCLAX A:DOSE REDUCED - VENETOCLAX O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION D:YES O:IMMUNO COMPROMIZED STATUS ASSOCIATED WITH CLL/SLL A:REASONABLE POSSIBILITY

Program Source Code: [redacted]

表 2.7.4-101.　　重篤な有害事象を発現した被験者一覧（M16-043 試験）

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53898) TRT: Placebo + LDAC								
33003# Age:8[redacted] Sex:Male Race:WHITE Weight:73.5 kg								
	TRT	1 TO 30	3	3	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 16 O: NO L: 14 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53898) TRT: Placebo + LDAC								
33003# Age:8[redacted] Sex:Male Race:WHITE Weight:73.5 kg								
	TRT	1 TO 30	16	16	R: PULMONARY ASPERGILLOSIS S: Infections and infestations P: 気管支肺アスペルギルス症 L: Pulmonary aspergillosis	E: 37 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](53898) TRT: Venetoclax 600 mg QD + LDAC								
33002# Age:8[redacted] Sex:Male Race:WHITE Weight:80.0 kg								
	POST	24 TO 82	1	24	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 50 O: NO L: 27 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53898) TRT: Venetoclax 600 mg QD + LDAC 33004# Age:7[redacted] Sex:Female Race:WHITE Weight:55.0 kg								
	TRT	1 TO 95	3	3	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 9 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](53898) TRT: Venetoclax 600 mg QD + LDAC								
33004# Age:7[redacted] Sex:Female Race:WHITE Weight:55.0 kg								
	TRT	1 TO 95	94	94	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 98 O: NO L: 5 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53898) TRT: Venetoclax 600 mg QD + LDAC 33004# Age:7[redacted] Sex:Female Race:WHITE Weight:55.0 kg								
	POST	96 TO 239	10	105	R: HYPERLEUKOCYTOSIS S: Blood and lymphatic system disorders P: 著明な白血球増多 L: Hyperleukocytosis	E: 108 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: DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](111556) TRT: Placebo + LDAC								
48102# Age:8[redacted] Sex:Male Race:WHITE Weight:80.0 kg								
	TRT	1 TO 49	27	27	R: ESCHERICHIA COLI INFECTION. S: Infections and infestations P: 大腸菌感染 L: Escherichia coli infection	E: 31 O: NO L: 5 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA PRESENT AT BASELINE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (111556) TRT: Venetoclax 600 mg QD + LDAC 48103 Age:7[redacted] Sex:Male Race:WHITE Weight:67.5 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: 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 O: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53332) TRT: Placebo + LDAC 70503# Age:4[redacted] Sex:Female Race:ASIAN Weight:57.7 kg								
	TRT	1 TO 203	203	203	R: INVASIVE PULMONARY MUCORMUCOSIS INFECTION S: Infections and infestations P: ムコール症 L: Pulmonary mucormycosis	E: 241 O: NO L: 39 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED AML PATIENT A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53332) TRT: Venetoclax 600 mg QD + LDAC 70502# Age:6[redacted] Sex:Female Race:WHITE Weight:71.0 kg								
	TRT	1 TO 22	22	22	R: CHEST SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 37 O: NO L: 16 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53332) TRT: Venetoclax 600 mg QD + LDAC									
70502# Age:6[redacted] Sex:Female Race:WHITE Weight:71.0 kg									
	TRT	1 TO 22	22	22		R: HYPOTENSION - SYSTOLIC BP 95-100 S: Vascular disorders P: 低血圧 L: Hypotension	E: 37 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: LOW BLOOD CELL VOLUME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99225) TRT: Placebo + LDAC								
23003# Age:8[redacted] Sex:Female Race:WHITE Weight:77.4 kg								
	TRT	1 TO 92	73	73	R: STAPHYLOCOCCUS EPIDERMIDIS INFECTION S: Infections and infestations P: ブドウ球菌感染 L: Staphylococcus epidermidis infection	E: 79 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: NEUTROPENIA AND AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99225) TRT: Placebo + LDAC								
23003# Age:8[redacted] Sex:Female Race:WHITE Weight:77.4 kg								
	TRT	1 TO 92	73	73	R: FEBRIL NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 84 O: NO L: 12 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STAPHYLOCOCCUS EPIDERMITIS INFECTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99225) TRT: Placebo + LDAC								
23003# Age:8[redacted] Sex:Female Race:WHITE Weight:77.4 kg								
	TRT	1 TO 92	92	92	R: ALTERATED GENERAL STATE S: Investigations P: 全身健康状態異常 L: General physical condition abnormal	E: 109 O: NO L: 18 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPOKALEMIA GRADE 3 + PROGRESSIVE DISEASE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99225) TRT: Venetoclax 600 mg QD + LDAC								
23001# Age:7[redacted] Sex:Male Race:WHITE Weight:68.0 kg								
	TRT	1 TO 101	9	9	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 16 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99225) TRT: Venetoclax 600 mg QD + LDAC								
23001# Age:7[redacted] Sex:Male Race:WHITE Weight:68.0 kg								
	POST	102 TO 151	3	104	R: WORSENING OF GENERAL STATUS S: General disorders and administration site conditions P: 全身健康状態低下 L: General physical health deterioration	E: 114 O: NO L: 11 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: MULTIPLE: MEDICAL PROCEDURE, O2 THERAPY, PALLIATIVE TREATMENT ONGOING (HYDREA), PLATELETS INFUSION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML RELAPSE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26001# Age:7[redacted] Sex:Male Race:WHITE Weight:87.1 kg								
	TRT	1 TO 18	1	1	R: CARDIAC DECOMPENSATION S: Cardiac disorders P: 心不全 L: Decompensation cardiac	E: 8 O: NO L: 8 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: PNEUMONIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26002# Age:6[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	TRT	1 TO 190	14	14	R: ACUTE RESPIRATORY INSUFFICIENCY S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory insufficiency	E: 33 O: NO L: 20 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|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: DETERIORATION OF PLEURAL EFFUSION BOTH SIDES A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26002# Age:6[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	TRT	1 TO 190	14	14	R: PLEURAL EFFUSION BOTH SIDES S: Respiratory, thoracic and mediastinal disorders P: 胸水 L: Bilateral pleural effusion	E: 58 O: NO L: 45 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: YES, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PNEUMONIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26002# Age:6[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	TRT	1 TO 190	14	14	R: TRAUMATIC HAEMATOTHORAX S: Injury, poisoning and procedural complications P: 外傷性血胸 L: Traumatic haemothorax	E: 33 O: NO L: 20 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|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: TRAUMATIC HAEMATOTHORAX AFTER PLEURAL PUNCTURE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26002# Age:6[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	TRT	1 TO 190	114	114	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 115 O: NO L: 2 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: INFECTION A: NO REASONABLE POSSIBILITY R: NO
			188	188	R: LARYNX OEDEMA S: Respiratory, thoracic and mediastinal disorders P: 喉頭浮腫 L: Larynx oedema	E: 221 O: NO L: 34 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POST SURGERY EVENT A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118070) TRT: Placebo + LDAC								
26002# Age:6[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	POST	191 TO 221	11	201	R: SEPSIS WITH STAPHYLOCOCCUS EPIDERMIDIS S: Infections and infestations P: ブドウ球菌性敗血症 L: Staphylococcus epidermidis septicemia	E: 219 O: NO L: 19 DAYS I: YES	G: Grade 4 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: INFECTION OF PICC-LINE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116129) TRT: Venetoclax 600 mg QD + LDAC								
33401# Age:6[redacted] Sex:Male Race:WHITE Weight:61.0 kg								
	TRT	1 TO 51	40	40	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 57 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: UNDERLYING DISEASE-AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120501) TRT: Venetoclax 600 mg QD + LDAC 35202# Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg								
	POST	47 TO 72	7	53	R: CLOSTRIDIUM DIFFICILE INFECTION S: Infections and infestations P:クロストリジウム・ディフィシレ感染 L: Clostridium difficile infection	E: 60 O: NO L: 8 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TEH PATINE HAD DIRRHOEA, DECREASED INCAPACITY. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	5	5	R: INFECTION IN FINGER 2 ON THE LEFT HAND S: Infections and infestations P: 限局性感染 L: Infected finger	E: 6 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, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	6	6	R: INFECTION IN FINGER 2 ON THE LEFT HAND S: Infections and infestations P: 限局性感染 L: Infected finger	E: 12 O: NO L: 7 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED O: MULTIPLE: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	29	29	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 31 O: NO L: 3 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: LDAC|DRUG INTERRUPTED O: MULTIPLE: MEDICAL PROCEDURE, ABDOMINAL CT SCAN C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IT IS ASSUMED THAT ALL SYMPTOMS AND FINDINGS CAN BE EXPLAINED BY PARANEOPLASTIC PHENOMENA A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	57	57	R: SWELLING AT THE RIGHT EYELID. S: Eye disorders P: 眼瞼浮腫 L: Swelling of eyelid	E: 64 O: NO L: 8 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION R: NO
			81	81	R: CLOSTRIDIUM INFECTION S: Infections and infestations P: クロストリジウム感染 L: Clostridial infection	E: 85 O: NO L: 5 DAYS I: YES	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: HOSPITALIZED,	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	142	142	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 148 O: NO L: 7 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: MOST LIKELY EVENT IS ACTIVITY IN HIS SWEET SYNDROME A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99062) TRT: Placebo + LDAC								
10101 Age:7[redacted] Sex:Male Race:WHITE Weight:95.2 kg								
	TRT	1 TO	237	237	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 240 O: NO L: 4 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: A VIRUS A: NO REASONABLE POSSIBILITY R: NO
			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: 270 O: NO L: 4 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122098) TRT: Venetoclax 600 mg QD + LDAC								
13001# Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg								
	TRT	1 TO 80	5	5	R: NEUTROPENIC SEPSIS S: Infections and infestations P: 好中球減少性敗血症 L: Neutropenic sepsis	E: 26 O: NO L: 22 DAYS I: YES	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122098) TRT: Venetoclax 600 mg QD + LDAC								
13001# Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg								
	TRT	1 TO 80	25	25	R: CELLULITIS OF THE HAND S: Infections and infestations P: 蜂巣炎 L: Cellulitis of hand	E: 34 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: CELLULITIS LIKELY CAUSED BY CANNULA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122098) TRT: Venetoclax 600 mg QD + LDAC								
13001# Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg								
	POST	81 TO 140	5	85	R: CLOSTRIDIUM DIFFICILE INFECTION S: Infections and infestations P:クロストリジウム・ディフィシレ感染 L: Clostridium difficile infection	E: 94 O: NO L: 10 DAYS I: NO	G: Grade 4 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: AML DISEASE RELATED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122098) TRT: Venetoclax 600 mg QD + LDAC								
13001# Age:7[redacted] Sex:Female Race:WHITE Weight:66.0 kg								
		POST	81 TO 140	18 98	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 111 O: NO L: 14 DAYS I: YES	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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (121371) TRT: Venetoclax 600 mg QD + LDAC 63701 Age:7[redacted] Sex:Female Race:ASIAN Weight:48.6 kg								
	TRT	1 TO	72	72	R: NEUTROPHIL COUNT DECREASED S: Investigations P: 好中球数減少 L: Neutrophil count decreased	E: 86 O: NO L: 15 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (121371) TRT: Venetoclax 600 mg QD + LDAC 63701 Age:7[redacted] Sex:Female Race:ASIAN Weight:48.6 kg								
	TRT	1 TO	116	116	R: WHITE BLOOD CELL DECREASED S: Investigations P: 白血球数減少 L: White blood cell decreased	E: 130 O: NO L: 15 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO
			72	72	R: WHITE BLOOD CELL DECREASED S: Investigations P: 白血球数減少 L: White blood cell decreased	E: 86 O: NO L: 15 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (121371) TRT: Venetoclax 600 mg QD + LDAC 63701 Age:7[redacted] Sex:Female Race:ASIAN Weight:48.6 kg								
	TRT	1 TO	116	116	R: NEUTROPHIL COUNT DECREASED S: Investigations P: 好中球数減少 L: Neutrophil count decreased	E: 130 O: NO L: 15 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO
			200	200	R: WHITE BLOOD CELL DECREASED S: Investigations P: 白血球数減少 L: White blood cell decreased	E: 219 O: NO L: 20 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (121371) TRT: Venetoclax 600 mg QD + LDAC 63701 Age:7[redacted] Sex:Female Race:ASIAN Weight:48.6 kg								
	TRT	1 TO	200	200	R: NEUTROPHIL COUNT DECREASED S: Investigations P: 好中球数減少 L: Neutrophil count decreased	E: 219 O: NO L: 20 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			296	296	R: WHITE BLOOD CELL DECREASED S: Investigations P: 白血球数減少 L: White blood cell decreased	E: 324 O: NO L: 29 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (121371) TRT: Venetoclax 600 mg QD + LDAC 63701 Age:7[redacted] Sex:Female Race:ASIAN Weight:48.6 kg								
	TRT	1 TO	296	296	R: NEUTROPHIL COUNT DECREASED S: Investigations P: 好中球数減少 L: Neutrophil count decreased	E: 324 O: NO L: 29 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Placebo + LDAC								
84002# Age:7[redacted] Sex:Male Race:WHITE Weight:93.4 kg								
	TRT	1 TO 46	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: 32 O: NO L: 5 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLY RELATED TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Placebo + LDAC								
84002# Age:7[redacted] Sex:Male Race:WHITE Weight:93.4 kg								
	TRT	1 TO 46	39	39	R: GENERALIZED MUSCLE WEAKNESS S: Musculoskeletal and connective tissue disorders P: 筋力低下 L: Generalized muscle weakness	E: 49 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: PER PI, RELATED TO MYELODYSPLASTIC SYNDROME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Placebo + LDAC								
84006# Age:8[redacted] Sex:Male Race:WHITE Weight:78.1 kg								
	TRT	1 TO 35	29	29	R: RIGHT LEG CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 43 O: NO L: 15 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HIT RIGHT LEG WHILE OPENING FRIDGE, WOUND NOT HEALED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Placebo + LDAC								
84006# Age:8[redacted] Sex:Male Race:WHITE Weight:78.1 kg								
	POST	36 TO 141	1	36	R: LEUKOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 41 O: NO L: 6 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: POSSIBLY SKIN INFECTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC								
84004# Age:7[redacted] Sex:Male Race:WHITE Weight:79.3 kg								
	TRT	1 TO 61	47	47	R: SEIZURE S: Nervous system disorders P: 痙攣発作 L: Seizure	E: 48 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: MEDICAL HISTORY OF CEREBRAL VASCULAR ACCIDENT A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC								
84004# Age:7[redacted] Sex:Male Race:WHITE Weight:79.3 kg								
	POST	62 TO 149	4	65	R: LEFT FACIAL CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of face	E: 79 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: PROGRESSION OF AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC								
84005# Age:8[redacted] Sex:Female Race:WHITE Weight:100.3 kg								
	TRT	1 TO 54	31	31	R: PRESYNCOPE S: Nervous system disorders P: 失神寸前の状態 L: Presyncope	E: 32 O: NO L: 2 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: MAYBE ANEMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC 84005# Age:8[redacted] Sex:Female Race:WHITE Weight:100.3 kg								
	TRT	1 TO 54	39	39	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 57 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: ACUTE MYELOBLASTIC LEUKEMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC 84005# Age:8[redacted] Sex:Female Race:WHITE Weight:100.3 kg								
	POST	55 TO 195	19	73	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 110 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: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC 84007# Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg								
	TRT	1 TO 67	4	4	R: HYPONATREMIA S: Metabolism and nutrition disorders P: 低ナトリウム血症 L: Hyponatremia	E: 83 O: NO L: 80 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: CHRONIC SIADH, CHRONIC RENAL INSUFFICIENCY CAUSING DEBILITATION AND PATIENT INABILITY TO SELF CARE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (52791) TRT: Venetoclax 600 mg QD + LDAC								
84007# Age:7[redacted] Sex:Female Race:WHITE Weight:64.1 kg								
	TRT	1 TO 67	65	65	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: 10 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 LUNG INFECTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53159) TRT: Venetoclax 600 mg QD + LDAC 75102 Age:7[redacted] Sex:Female Race:WHITE Weight:79.0 kg								
	TRT	1 TO	8	8	R: INFLUENZA A S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 19 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: AEROSOL TRANSMISSION OF THE INFLUENZA A FROM ANOTHER PERSON/PATIENT A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Placebo + LDAC								
84303# Age:7[redacted] Sex:Male Race:WHITE Weight:72.1 kg								
	TRT	1 TO 25	18	18	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 32 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: COMPROMISED IMMUNE SYSTEM R/T AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC 84301# Age:7[redacted] Sex:Female Race:WHITE Weight:64.9 kg								
	POST	127 TO 413	14	140	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 152 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: CHEMOTHERAPY (MYLOTARG) A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC								
84302# Age:7[redacted] Sex:Female Race:BLACK OR AFRICAN AMERICAN Weight:63.5 kg								
	POST	217 TO 416	6	222	R: SMALL BOWEL OBSTRUCTION S: Gastrointestinal disorders P: 小腸閉塞 L: Small bowel obstruction	E: 225 O: NO L: 4 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: ADHESIONS FROM PRIOR SURGERY A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC								
84302# Age:7[redacted] Sex:Female Race:BLACK OR AFRICAN AMERICAN Weight:63.5 kg								
	POST	217 TO 416	11	227	R: SMALL BOWEL OBSTRUCTION S: Gastrointestinal disorders P: 小腸閉塞 L: Small bowel obstruction	E: 238 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: PREVIOUS SMALL BOWEL OBSTRUCTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC 84304# Age:7[redacted] Sex:Female Race:WHITE Weight:61.7 kg								
	TRT	1 TO 72	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: 15 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: COMPROMISED IMMUNE SYSTEM RELATED TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC 84304# Age:7[redacted] Sex:Female Race:WHITE Weight:61.7 kg								
	TRT	1 TO 72	44	44	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 49 O: NO L: 6 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC 84304# Age:7[redacted] Sex:Female Race:WHITE Weight:61.7 kg								
	TRT	1 TO 72	70	70	R: GRAM POSITIVE COCCI BACTEREMIA S: Infections and infestations P: 菌血症 L: Gram-positive bacteremia	E: 91 O: NO L: 22 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: CHEST XRAY C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMPROMISED IMMUNE SYSTEM RELATED TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103450) TRT: Venetoclax 600 mg QD + LDAC								
84307 Age:7[redacted] Sex:Male Race:WHITE Weight:67.6 kg								
	TRT	1 TO	18	18	R: URINARY RETENTION S: Renal and urinary disorders P: 尿閉 L: Urinary retention	E: 20 O: NO L: 3 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: CONSTIPATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112437) TRT: Venetoclax 600 mg QD + LDAC								
70001# Age:7[redacted] Sex:Male Race:WHITE Weight:109.8 kg								
	TRT	1 TO 423	31	31	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: 46 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112437) TRT: Venetoclax 600 mg QD + LDAC								
70001# Age:7[redacted] Sex:Male Race:WHITE Weight:109.8 kg								
	TRT	1 TO 423	255	255	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 262 O: NO L: 8 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90301# Age:8[redacted] Sex:Male Race:WHITE Weight:64.9 kg								
	TRT	1 TO 19	3	3	R: LEFT LEG INFECTION SKIN S: Infections and infestations P: 皮膚感染 L: Skin infection	E: 15 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: INFECTION BY NEUTROPENIA AND DISEASE CO NDITION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90301# Age:8[redacted] Sex:Male Race:WHITE Weight:64.9 kg								
	TRT	1 TO 19	14	14	R: BLOOD INFECTION(PSEUDOMONAS AERUGINOSA) S: Infections and infestations P: シュードモナス性菌血症 L: Pseudomonal bacteraemia	E: 38 O: NO L: 25 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90301# Age:8[redacted] Sex:Male Race:WHITE Weight:64.9 kg								
	TRT	1 TO 19	19	19	R: RESPIRATORY INSUFICIENCE S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Respiratory insufficiency	E: 38 O: NO L: 20 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, LIFE THREATENING, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90301# Age:8[redacted] Sex:Male Race:WHITE Weight:64.9 kg								
		POST	20 TO 38	21	R: ATRIAL FIBRILATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 24 O: NO L: 4 DAYS I: YES	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, LIFE THREATENING A: NO REASONABLE POSSIBILITY R: NO
90302# Age:7[redacted] Sex:Female Race:WHITE Weight:87.3 kg								
		TRT	1 TO 29	1	R: INFECTION URINARY TRACT TREATMENT BY KLEBSIELLA PNEUMONIAE S: Infections and infestations P: クレブシエラ感染 L: Klebsiella pneumoniae infection	E: 39 O: NO L: 39 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90302# Age:7[redacted] Sex:Female Race:WHITE Weight:87.3 kg								
	TRT	1 TO 29	22	22	R: NEUTROPENIA FEBRIL S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 40 O: NO L: 19 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			4	4	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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC 90302# Age:7[redacted] Sex:Female Race:WHITE Weight:87.3 kg								
	TRT	1 TO 29	22	22	R: THROMBOCYTOPENIA 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 O: PLATELET TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC								
90302# Age:7[redacted] Sex:Female Race:WHITE Weight:87.3 kg								
	TRT	1 TO 29	26	26	R: CUTANEOUS ABSCESS CERVICAL REGION / LEFT NECK S: Infections and infestations P: 頚部膿瘍 L: Cervical abscess	E: 80 O: NO L: 55 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122547) TRT: Venetoclax 600 mg QD + LDAC 90302# Age:7[redacted] Sex:Female Race:WHITE Weight:87.3 kg								
	TRT	1 TO 29	28	28	R: INSUFFICIENCY RESPIRATORY S: Respiratory, thoracic and mediastinal disorders P: 呼吸不全 L: Respiratory insufficiency	E: 43 O: NO L: 16 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: MULTIPLE: MEDICAL PROCEDURE, O2 MASK AND NO INVASIVE VENTILATION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110036) TRT: Venetoclax 600 mg QD + LDAC								
35402# Age:6[redacted] Sex:Male Race:WHITE Weight:99.0 kg								
	POST	303 TO 333	18	320	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 333 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, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (124018) TRT: Venetoclax 600 mg QD + LDAC								
23501# Age:6[redacted] Sex:Male Race:WHITE Weight:81.0 kg								
	TRT	1 TO 29	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: 36 O: NO L: 12 DAYS I: YES	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117094) TRT: Venetoclax 600 mg QD + LDAC								
60201# Age:7[redacted] Sex:Male Race:ASIAN Weight:58.2 kg								
	TRT	1 TO 241	19	19	R: TONSILLITIS S: Infections and infestations P: 扁桃炎 L: Tonsillitis	E: 43 O: NO L: 25 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117094) TRT: Venetoclax 600 mg QD + LDAC									
60201# Age:7[redacted] Sex:Male Race:ASIAN Weight:58.2 kg									
	TRT	1 TO 241	19	19		R: ORAL CANDIDIASIS S: Infections and infestations P: 口腔カンジダ症 L: Oral candidiasis	E: 100 O: NO L: 82 DAYS I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114975) TRT: Placebo + LDAC								
58102# Age:6[redacted] Sex:Male Race:ASIAN Weight:48.6 kg								
	POST	58 TO 61	4	61	R: ACUTE RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 61 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 O: SUSPECT SEPTIC SHOCK RELATED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114975) TRT: Placebo + LDAC								
58103# Age:6[redacted] Sex:Male Race:ASIAN Weight:79.4 kg								
	POST	42 TO 51	5	46	R: HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	E: 51 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, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ARRHYTHMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114975) TRT: Placebo + LDAC								
58103# Age:6[redacted] Sex:Male Race:ASIAN Weight:79.4 kg								
	POST	42 TO 51	8	49	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 51 O: NO L: 3 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: HYPOKALEMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122071) TRT: Venetoclax 600 mg QD + LDAC								
35701# Age:7[redacted] Sex:Male Race:WHITE Weight:66.0 kg								
	TRT	1 TO 15	15	15	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 23 O: NO L: 9 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION O: INJ. MERONEM, INJ, VANCOMYCIN,INJ.KLION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PNEUMONIA AS COMPLICATION OF UNDERLYING DISORDER A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99205) TRT: Placebo + LDAC								
40101# Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg								
	TRT	1 TO 2	2	2	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 31 O: NO L: 30 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: VIRUS INFECTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117095) TRT: Venetoclax 600 mg QD + LDAC 60301# Age:7[redacted] Sex:Female Race:ASIAN Weight:50.2 kg								
	TRT	1 TO 122	51	51	R: PNEUMONIA, FUNGAL S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 161 O: NO L: 111 DAYS I: NO	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117095) TRT: Venetoclax 600 mg QD + LDAC								
60302# Age:6[redacted] Sex:Male Race:ASIAN Weight:64.4 kg								
	TRT	1 TO 227	188	188	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 342 O: NO L: 155 DAYS I: YES	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (49508) TRT: Venetoclax 600 mg QD + LDAC 80202 Age:7[redacted] Sex:Male Race:WHITE Weight:63.6 kg								
	TRT	1 TO	1	1	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 57 O: NO L: 57 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: RECIDIVE OF PNEUMONIA THAT WAS PRESENT BEFORE THE STUDY. A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116128) TRT: Venetoclax 600 mg QD + LDAC 33101# Age:7[redacted] Sex:Male Race:WHITE Weight:89.0 kg								
	POST	27 TO 29	1	27	R: RESPIRATORY TRACK INFECTION S: Infections and infestations P: 気道感染 L: Respiratory tract infection	E: 29 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, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE EVENT WAS A CONSEQUENCE/COMPLICATION DUE TO THE IMMUNE COMPROMISED STATE. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (46783) TRT: Placebo + LDAC								
62802# Age:8[redacted] Sex:Female Race:ASIAN Weight:27.1 kg								
	TRT	1 TO 10	7	7	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 21 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: PNEUMOMIA AFTER INDUCTION CHEMOTHERAPY FOR ACUTE MYELOID LEUKEMIA IS AMONG THE MOST COMMON OF THE INFECTIOUS COMPLICATIONS. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122750) TRT: Placebo + LDAC								
90001# Age:7[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 64	5	5	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: 10 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122750) TRT: Placebo + LDAC								
90001# Age:7[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 64	32	32	R: FEBRILE NEUROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 33 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122750) TRT: Placebo + LDAC								
90001# Age:7[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 64	51	51	R: DIZZINESS S: Nervous system disorders P: 浮動性めまい L: Dizziness	E: 59 O: NO L: 9 DAYS I: YES	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DIZZINESS INTENSIFICATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122750) TRT: Placebo + LDAC								
90001# Age:7[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	POST	65 TO 95 1		65	R: BLOODSTREAM INFECTION S: Infections and infestations P: 敗血症 L: Hematological infection	E: 69 O: NO L: 5 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNESUPRESSION A: NO REASONABLE POSSIBILITY R: NO
				65	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 69 O: NO L: 5 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNESUPRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (72970) TRT: Venetoclax 600 mg QD + LDAC								
38008# Age:7[redacted] Sex:Female Race:WHITE Weight:85.6 kg								
	TRT	1 TO 5	4	4	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 12 O: NO L: 9 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, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: WORSENING OF MEDICAL HISTORY OF ATRIAL FIBRILLATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (115036) TRT: Placebo + LDAC								
50202# Age:6[redacted] Sex:Female Race:ASIAN Weight:56.0 kg								
	TRT	1 TO 156	15	15	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, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Placebo + LDAC								
84102# Age:8[redacted] Sex:Male Race:WHITE Weight:96.5 kg								
	TRT	1 TO 19	19	19	R: LEUKOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 23 O: NO L: 5 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION, NOT RESPONDING TO TREATMENT. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Placebo + LDAC								
84103# Age:8[redacted] Sex:Male Race:WHITE Weight:83.4 kg								
	TRT	1 TO 15	15	15	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: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUBJECT HAS AML AND THIS IS COMMON IN THIS PATIENT POPULATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Placebo + LDAC								
84103# Age:8[redacted] Sex:Male Race:WHITE Weight:83.4 kg								
	TRT	1 TO 15	15	15	R: HYPERBILIRUBINEMIA S: Hepatobiliary disorders P: 高ビリルビン血症 L: Hyperbilirubinemia	E: 21 O: NO L: 7 DAYS I: YES	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84101 Age:7[redacted] Sex:Female Race:WHITE Weight:94.6 kg								
	TRT	1 TO	10	10	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 25 O: NO L: 16 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 A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84101 Age:7[redacted] Sex:Female Race:WHITE Weight:94.6 kg								
	TRT	1 TO	10	10	R: RIGHT EAR CELLULITIS S: Infections and infestations P: 外耳蜂巣炎 L: External ear cellulitis	E: 25 O: NO L: 16 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 A: NO REASONABLE POSSIBILITY R: NO
			312	312	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 337 O: NO L: 26 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC									
84101 Age:7[redacted] Sex:Female Race:WHITE Weight:94.6 kg									
	TRT	1 TO		372	372	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	O: NO I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED O: TRANSFUSION OF BLOOD PRODUCT	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
				472	472	R: PNEUMONIA (LUNG INFECTION) S: Infections and infestations P: 肺炎 L: Pneumonia	E: 486 O: NO L: 15 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 A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84101 Age:7[redacted] Sex:Female Race:WHITE Weight:94.6 kg								
	TRT	1 TO	608	608	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 611 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 A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84104# Age:8[redacted] Sex:Female Race:WHITE Weight:67.1 kg								
	TRT	1 TO 199	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: 20 O: NO L: 4 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84104# Age:8[redacted] Sex:Female Race:WHITE Weight:67.1 kg								
	TRT	1 TO 199	147	147	R: CELLULITIS OF LOWER EXTREMITY S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 153 O: NO L: 7 DAYS I: YES	G: Grade 2 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			154	154	R: FALL S: Injury, poisoning and procedural complications P: 転倒 L: Fall	E: 154 O: NO L: 1 DAY I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84104# Age:8[redacted] Sex:Female Race:WHITE Weight:67.1 kg								
		POST	200 TO 306	17	216	R: LETHARGY S: Nervous system disorders P: 嗜眠 L: Lethargy	O: YES I: NO	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
		TRT	1 TO 199	165	165	R: ANOREXIA S: Metabolism and nutrition disorders P: 食欲減退 L: Anorexia	O: YES I: YES	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (50863) TRT: Venetoclax 600 mg QD + LDAC								
84104# Age:8[redacted] Sex:Female Race:WHITE Weight:67.1 kg								
		POST	200 TO 306	17	216	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 220 O: NO L: 5 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
				19	218	R: DVT LEFT LOWER EXTREMITY S: Vascular disorders P: 深部静脈血栓症 L: DVT of legs	O: YES I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STUDY DISEASE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118170) TRT: Venetoclax 600 mg QD + LDAC								
80401# Age:7[redacted] Sex:Male Race:WHITE Weight:124.7 kg								
	TRT	1 TO 49	26	26	R: METAPNEUMOVIRUS PNEUMONIA LEFT LUNG S: Infections and infestations P: メタニューモウイルス感染 L: Metapneumovirus infection	E: 30 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: DISEASE UNDER TREATMENT(ACUTE MYELOID LEUKEMIA) A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118170) TRT: Venetoclax 600 mg QD + LDAC 80401# Age:7[redacted] Sex:Male Race:WHITE Weight:124.7 kg								
	TRT	1 TO 49	39	39	R: RIGHT LUNG LOWER LOBE PNEUMONIA S: Infections and infestations P: 肺炎 L: Lobar pneumonia	E: 51 O: NO L: 13 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|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: DISEASE UNDER TREATMENT(ACUTE MYELOID LEUKEMIA) A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118170) TRT: Venetoclax 600 mg QD + LDAC 80401# Age:7[redacted] Sex:Male Race:WHITE Weight:124.7 kg								
	TRT	1 TO 49	47	47	R: PULMONARY HEMORRHAGE S: Respiratory, thoracic and mediastinal disorders P: 肺出血 L: Pulmonary hemorrhage	E: 52 O: NO L: 6 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, LIFE THREATENING O: FUNGAL PNEUMONIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118170) TRT: Venetoclax 600 mg QD + LDAC 80402# Age:7[redacted] Sex:Female Race:WHITE Weight:67.5 kg								
	TRT	1 TO 238	11	11	R: E COLI URINARY TRACT INFECTION S: Infections and infestations P: 大腸菌性尿路感染 L: Escherichia urinary tract infection	E: 16 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: CHEMOTHERAPY INDUCED CYTOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Placebo + LDAC								
80001# Age:7[redacted] Sex:Female Race:WHITE Weight:70.6 kg								
	TRT	1 TO 74	18	18	R: BACTEREMIA, SERRATIA MARCESCENS S: Infections and infestations P: セラチア性菌血症 L: Serratia bacteremia	E: 33 O: NO L: 16 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONTAMINATION FROM BACTERIA ALREADY PRESENT IN THE LUNGS A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Placebo + LDAC								
80001# Age:7[redacted] Sex:Female Race:WHITE Weight:70.6 kg								
	POST	75 TO 489	1	75	R: DYSPNEA S: Respiratory, thoracic and mediastinal disorders P: 呼吸困難 L: Dyspnea	E: 103 O: NO L: 29 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Placebo + LDAC								
80001# Age:7[redacted] Sex:Female Race:WHITE Weight:70.6 kg								
	POST	75 TO 489	1	75	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 95 O: NO L: 21 DAYS I: NO	G: Grade 1 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Placebo + LDAC								
80001# Age:7[redacted] Sex:Female Race:WHITE Weight:70.6 kg								
	POST	75 TO 489	2	76	R: LIVER ABSCESS - NO BACTERIA IDENTIFIED S: Infections and infestations P: 肝膿瘍 L: Liver abscess	O: YES I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANTECEDENT OF LONG LASTING NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Venetoclax 600 mg QD + LDAC								
80002 Age:7[redacted] Sex:Male Race:WHITE Weight:76.3 kg								
	TRT	1 TO 672	478	478	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 482 O: NO L: 5 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Venetoclax 600 mg QD + LDAC								
80004# Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg								
	TRT	1 TO 190	135	135	R: MEDICATION ERROR S: Injury, poisoning and procedural complications P: 投薬過誤 L: Medication error	E: 155 O: NO L: 21 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED, LDAC|DOSE REDUCED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: MEDICATION ERROR A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Venetoclax 600 mg QD + LDAC 80004# Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg								
	TRT	1 TO 190	167	167	R: LEUKOCYTOSIS S: Blood and lymphatic system disorders P: 白血球増加症 L: Leukocytosis	E: 170 O: NO L: 4 DAYS I: NO	G: Grade 2 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: THE MEDICATION ERROR IS SUSPECTED TO BE THE CAUSE OF THE SAE OF LEUKOCYTOSIS. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118376) TRT: Venetoclax 600 mg QD + LDAC								
80004# Age:7[redacted] Sex:Female Race:WHITE Weight:53.0 kg								
	POST	191 TO 366	10	200	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 225 O: NO L: 26 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 A: NO REASONABLE POSSIBILITY R: NO
	TRT	1 TO 190	190	190	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 219 O: NO L: 30 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 OR LEUKEMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (115029) TRT: Venetoclax 600 mg QD + LDAC 50501# Age:7[redacted] Sex:Female Race:ASIAN Weight:50.0 kg								
	TRT	1 TO 28	15	15	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 33 O: NO L: 19 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DOSE REDUCED C: YES	S: YES, LIFE THREATENING A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118509) TRT: Venetoclax 600 mg QD + LDAC								
62701# Age:7[redacted] Sex:Female Race:ASIAN Weight:44.7 kg								
	POST	54 TO 60 3		56	R: GASTROINTESTINAL HEMORRHAGE S: Gastrointestinal disorders P: 胃腸出血 L: Gastrointestinal hemorrhage	E: 60 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: THROMBOCYTOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC									
23201# Age:7[redacted] Sex:Male Race:WHITE Weight:84.5 kg									
	TRT	1 TO 307	17	17		R: RIGHT AXILLARY ABSCESS S: Infections and infestations P: 皮下組織膿瘍 L: Axillary abscess	E: 29 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: KLEBSIELLA PNEUMONIAE INFECTIOUS A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg								
	TRT	1 TO	67	67	R: FEBRIL NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 73 O: NO L: 7 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg								
	TRT	1 TO	119	119	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 126 O: NO L: 8 DAYS I: YES	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			94	94	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 98 O: NO L: 5 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg								
	TRT	1 TO	145	145	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 155 O: NO L: 11 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 A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg								
	TRT	1 TO	483	483	R: SEVERE SEPSIS KLEBSIELLA INFECTION S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	E: 495 O: NO L: 13 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|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: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg								
	TRT	1 TO	514	514	R: KLEBSIELLA OXYTOCA INFECTION OF IMPLANTABLE PORT S: Infections and infestations P: クレブシエラ感染 L: Klebsiella oxytoca infection	E: 521 O: NO L: 8 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: INFECTION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC							
23202 Age:8[redacted] Sex:Male Race:WHITE Weight:76.6 kg							
	TRT	1 TO	514	R: KLEBSIELLA OXYTOCA INFECTION OF IMPLANTABLE PORT S: Infections and infestations P: 血管デバイス感染 L: Vascular device infection		--Same as Above--	

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23204# Age:8[redacted] Sex:Female Race:WHITE Weight:68.6 kg								
	TRT	1 TO 303	227	227	R: LEFT BASAL AND RIGHT APICAL PULMONARY LOBULES ALVEOLAR CONDENSATION S: Respiratory, thoracic and mediastinal disorders P: 肺浸潤 L: Lung infiltration	E: 239 O: NO L: 13 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: MULTIPLE: MEDICAL PROCEDURE, BRONCHOALVEOLAR LAVAGE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCURRENT ILLNESS A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Placebo + LDAC								
23204# Age:8[redacted] Sex:Female Race:WHITE Weight:68.6 kg								
	TRT	1 TO 303	279	279	R: CEREBRAL HEMATOMA S: Nervous system disorders P: 脳血腫 L: Cerebral hematoma	O: YES 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: PROGRESSION DISEASE IS POSSIBLE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118246) TRT: Venetoclax 600 mg QD + LDAC 23205 Age:8[redacted] Sex:Female Race:WHITE Weight:60.0 kg								
	TRT	1 TO	18	18	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 41 O: NO L: 24 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: MULTIPLE: MEDICAL PROCEDURE, PROTECTIVE ISOLATION ROOM	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53099) TRT: Venetoclax 600 mg QD + LDAC								
62502# Age:7[redacted] Sex:Male Race:ASIAN Weight:60.3 kg								
	TRT	1 TO 199	162	162	R: ACUTE CHOLECYSTITIS S: Hepatobiliary disorders P: 急性胆嚢炎 L: Acute cholecystitis	E: 210 O: NO L: 49 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED C: YES	S: YES, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118823) TRT: Venetoclax 600 mg QD + LDAC								
63502# Age:6[redacted] Sex:Male Race:ASIAN Weight:53.7 kg								
	POST	29 TO 102	7	35	R: ACUTE PANCREATITIS S: Gastrointestinal disorders P: 急性膵炎 L: Acute pancreatitis	O: YES I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION C: YES	S: YES, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AGGRAVATION OF AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](122548) TRT: Venetoclax 600 mg QD + LDAC								
90101# Age:6[redacted] Sex:Female Race:WHITE Weight:67.0 kg								
	TRT	1 TO 148	15	15	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 167 O: NO L: 153 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122548) TRT: Venetoclax 600 mg QD + LDAC								
90101# Age:6[redacted] Sex:Female Race:WHITE Weight:67.0 kg								
	TRT	1 TO 148	15	15	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 36 O: NO L: 22 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO
			22	22	R: OROPHARYNGEAL CANDIDIASIS S: Infections and infestations P: 中咽頭カンジダ症 L: Oropharyngeal candidiasis	E: 29 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (122548) TRT: Venetoclax 600 mg QD + LDAC								
90101# Age:6[redacted] Sex:Female Race:WHITE Weight:67.0 kg								
	TRT	1 TO 148	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: 29 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 A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Placebo + LDAC								
33205# Age:8[redacted] Sex:Female Race:WHITE Weight:55.0 kg								
	TRT	1 TO 28	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: 17 O: NO L: 3 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Placebo + LDAC								
33207# Age:8[redacted] Sex:Female Race:WHITE Weight:60.0 kg								
	TRT	1 TO 43	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: 44 O: NO L: 2 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|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: STABLE DISEASE - PERSISTENT NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Placebo + LDAC								
33207# Age:8[redacted] Sex:Female Race:WHITE Weight:60.0 kg								
	TRT	1 TO 43	43	43	R: BACTEREMIA - E. COLI S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 44 O: NO L: 2 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: NONE	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC								
33204# Age:8[redacted] Sex:Male Race:WHITE Weight:86.0 kg								
	TRT	1 TO 51	41	41	R: NEUTROPENIC FEVER S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Neutropenic fever	E: 55 O: NO L: 15 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 ASSOCIATED WITH AML. AML STATUS IS STABLE DISEASE. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC								
33204# Age:8[redacted] Sex:Male Race:WHITE Weight:86.0 kg								
	TRT	1 TO 51	46	46	R: LUNG INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 55 O: NO L: 10 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC								
33206# Age:8[redacted] Sex:Male Race:WHITE Weight:109.0 kg								
	TRT	1 TO 113	17	17	R: ACUTE CHOLECYSTITIS S: Hepatobiliary disorders P: 急性胆嚢炎 L: Acute cholecystitis	E: 46 O: NO L: 30 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: BILIARY SLUDGE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC 33206# Age:8[redacted] Sex:Male Race:WHITE Weight:109.0 kg								
	TRT	1 TO 113	60	60	R: SUBCONJUCTIVAL HEMORRHAGE OF LEFT EYE S: Eye disorders P: 結膜出血 L: Conjunctival haemorrhage	E: 69 O: NO L: 10 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: PLATELETS TRANSFUSIONS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: THOMBOCYTOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC								
33206# Age:8[redacted] Sex:Male Race:WHITE Weight:109.0 kg								
	TRT	1 TO 113	60	60	R: UPPER AND LOWER EYELID HEMATOMA OF LEFT EYE S: Eye disorders P: 眼瞼血腫 L: Eyelid hematoma	E: 69 O: NO L: 10 DAYS I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: PLATELETS TRANFUSIONS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THOMBOCYTOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (116130) TRT: Venetoclax 600 mg QD + LDAC								
33208# Age:6[redacted] Sex:Male Race:WHITE Weight:78.0 kg								
	TRT	1 TO 240	32	32	R: GASTRITIS S: Gastrointestinal disorders P: 胃炎 L: Gastritis	E: 39 O: NO L: 8 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (119619) TRT: Venetoclax 600 mg QD + LDAC								
62001# Age:8[redacted] Sex:Male Race:ASIAN Weight:45.8 kg								
	TRT	1 TO 41	41	41	R: CARDIAC FAILURE CONGESTIVE S: Cardiac disorders P: うっ血性心不全 L: Cardiac failure congestive	E: 68 O: NO L: 28 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (97401) TRT: Venetoclax 600 mg QD + LDAC								
40901# Age:5[redacted] Sex:Female Race:WHITE Weight:90.5 kg								
	POST	101 TO 166	2	102	R: ACUTE HEART FAILURE S: Cardiac disorders P: 急性心不全 L: Acute heart failure	E: 106 O: NO L: 5 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: CHRONICA STABLE ANGINA. ARTERIAL HYPERTENSION, PROGRESSIV AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (97401) TRT: Venetoclax 600 mg QD + LDAC								
40902# Age:7[redacted] Sex:Female Race:WHITE Weight:78.0 kg								
	POST	51 TO 59	7	57	R: ACUTE HEART FAILURE S: Cardiac disorders P: 急性心不全 L: Acute heart failure	E: 59 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: LEUKEMIC INFILTRATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (97401) TRT: Venetoclax 600 mg QD + LDAC 40903# Age:7[redacted] Sex:Female Race:WHITE Weight:57.0 kg								
	POST	19 TO 22	1	19	R: HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	E: 22 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, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION O: MULTIPLE: MEDICAL PROCEDURE, TRANSPORTATION TO THE INTENSIVE CARE UNIT C: YES	S: YES, LIFE THREATENING O: DISEASE PROGRESSION - COUNT OF BLASTS IN THE MYELOGRAMMA WAS INCREASED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Placebo + LDAC								
33302# Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg								
	TRT	1 TO 35	7	7	R: HEMATOCHEZIA S: Gastrointestinal disorders P: 血便排泄 L: Hematochezia	E: 11 O: NO L: 5 DAYS I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: TRANSFUSIONS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Placebo + LDAC								
33302# Age:7[redacted] Sex:Male Race:WHITE Weight:85.0 kg								
	TRT	1 TO 35	14	14	R: HEMATOCHEZIA S: Gastrointestinal disorders P: 血便排泄 L: Hematochezia	E: 25 O: NO L: 12 DAYS I: NO	G: Grade 2 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: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Placebo + LDAC								
33313#	Age:7[redacted] Sex:Male Race:WHITE Weight:70.1 kg							
	TRT	1 TO 8	5	5	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 15 O: NO L: 11 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: PLATELET TRANSFUSION	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Placebo + LDAC								
33313# Age:7[redacted] Sex:Male Race:WHITE Weight:70.1 kg								
	POST	9 TO 16	1	9	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 15 O: NO L: 7 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC								
33305# Age:7[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 117	3	3	R: TRANSFUSION DEPENDENT ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Transfusion dependent anemia	E: 28 O: NO L: 26 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC 33306# Age:8[redacted] Sex:Female Race:WHITE Weight:73.0 kg								
	TRT	1 TO 457	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: 34 O: NO L: 15 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC								
33310 Age:8[redacted] Sex:Male Race:WHITE Weight:77.0 kg								
	TRT	1 TO	143	143	R: HIP BONE FRACTURE S: Injury, poisoning and procedural complications P: 股関節部骨折 L: Hip fracture	O: NO I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCIDENTAL FALL A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC 33311# Age:7[redacted] Sex:Female Race:WHITE Weight:55.1 kg								
	TRT	1 TO 132	46	46	R: HEMORRHAGIC GASTRITIS S: Gastrointestinal disorders P: 出血性胃炎 L: Hemorrhagic gastritis	E: 53 O: NO L: 8 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, VENETOCLAX/PLACEBO|DOSE REDUCED, LDAC|DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC								
33315# Age:9[redacted] Sex:Male Race:WHITE Weight:60.1 kg								
	TRT	1 TO 13	5	5	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: 10 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC								
33315# Age:9[redacted] Sex:Male Race:WHITE Weight:60.1 kg								
	TRT	1 TO 13	5	5	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 15 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: SEVERE NEUTROPENIA DUE TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (99259) TRT: Venetoclax 600 mg QD + LDAC 33317 Age:7[redacted] Sex:Female Race:WHITE Weight:70.0 kg								
	TRT	1 TO	5	5	R: DISSEMINATED INTRAVASCULAR COAGULATION S: Blood and lymphatic system disorders P: 播種性血管内凝固 L: Disseminated intravascular coagulation	E: 9 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|DOSE REDUCED, LDAC|DRUG INTERRUPTED O: FFP TRANSFUSION	S: YES, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20103# Age:5[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 28	5	5	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 15 O: NO L: 11 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: DURING HOSPITALIZATION WHILE AML WAS DETECTED DEVELOPED FEVER TREATED WITH IV ANTIBIOTICS. OTHER CAUSE OF EVENT BASELINE ILNESS AML A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20103# Age:5[redacted] Sex:Male Race:WHITE Weight:70.0 kg								
	TRT	1 TO 28	24	24	R: TUMORAL FEVER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 腫瘍熱 L: Tumour associated fever	E: 31 O: NO L: 8 DAYS I: YES	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO SOURCE FOUND AML PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20112# Age:7[redacted] Sex:Female Race:WHITE Weight:50.5 kg								
	TRT	1 TO 65	65	65	R: TUMORAL FEVER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 腫瘍熱 L: Tumour associated fever	E: 79 O: NO L: 15 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF DISEASE AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20113# Age:7[redacted] Sex:Female Race:WHITE Weight:62.5 kg								
	TRT	1 TO 176	58	58	R: LUNG INFECTION (PNEUMONIA) S: Infections and infestations P: 肺炎 L: Pneumonia	E: 63 O: NO L: 6 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY (AML) A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20113# Age:7[redacted] Sex:Female Race:WHITE Weight:62.5 kg								
	TRT	1 TO 176	163	163	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 167 O: NO L: 5 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: PATIENT DEVELOPED FEVER UP TO 38?C AND WAS HOSPITALIZED IN A HOSPITAL NEAR HOME. NO SOURCE WAS FOUND . CHEST RADIOGRAPHY WAS NORMAL A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Placebo + LDAC								
20113# Age:7[redacted] Sex:Female Race:WHITE Weight:62.5 kg								
	TRT	1 TO 176	174	174	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 195 O: NO L: 22 DAYS I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO SOURCE OF INFECTION HAS BEEN IDENTIFIED PATIENTIN AML PROGRESSION ANOTHER THERAPY HAS BEEN STARTED A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC								
20102# Age:8[redacted] Sex:Female Race:WHITE Weight:65.5 kg								
	TRT	1 TO 133	21	21	R: FEBRILE NUETROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 30 O: NO L: 10 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: FEVER OF UNKNOWN ORIGIN. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC								
20102# Age:8[redacted] Sex:Female Race:WHITE Weight:65.5 kg								
	TRT	1 TO 133	21	21	R: DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 30 O: NO L: 10 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: GASTROINTESTINAL DESORDER OF UNKNOWN ORIGIN A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC								
20102# Age:8[redacted] Sex:Female Race:WHITE Weight:65.5 kg								
	POST	134 TO 135	1	134	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 134 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: AML PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC 20105# Age:7[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	TRT	1 TO 142	38	38	R: RETINAL HEMORRHAGE S: Eye disorders P: 網膜出血 L: Retinal hemorrhage	E: 41 O: NO L: 4 DAYS I: YES	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: PLATELET TRANSFUSIONS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLY RELATED WITH THROMBOCITOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC 20105# Age:7[redacted] Sex:Female Race:WHITE Weight:64.5 kg								
	POST	143 TO 180	5	147	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 153 O: NO L: 7 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT DEVELOPED FEVER UP TO 38.3C AND NEUTROPHIL COUNT 0.41MIL/MM3. DECREASE IN NUMBER OF NEUTROPHILS, AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC								
20109 Age:6[redacted] Sex:Male Race:WHITE Weight:61.0 kg								
	TRT	1 TO	156	156	R: GASTRIC HEMORRHAGE S: Gastrointestinal disorders P: 胃出血 L: Gastric hemorrhage	E: 161 O: NO L: 6 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (110902) TRT: Venetoclax 600 mg QD + LDAC								
20111# Age:7[redacted] Sex:Male Race:WHITE Weight:80.0 kg								
	POST	194 TO 390	18	211	R: STROKE S: Nervous system disorders P: 脳血管発作 L: Stroke	E: 235 O: NO L: 25 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: OTHER: UNKNOWN O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WAS HOSPITALIZATED NEAR HOME ON 01/10/2018 DUE TO STROKE . CAUSE FOR THE STROKE PROBABLY CARDIO-EMBOLIC IN RELATION TO CARDIOVASCULAR RISK FACTORS: HYPERTENSION, DYSLIPIDEMIA. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103582) TRT: Placebo + LDAC								
80301# Age:6[redacted] Sex:Male Race:WHITE Weight:101.1 kg								
	TRT	1 TO 223	21	21	R: LEFT HEEL CELLULITIS S: Infections and infestations P: 蜂巣炎 L: Cellulitis of foot	E: 125 O: NO L: 105 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103582) TRT: Placebo + LDAC								
80301# Age:6[redacted] Sex:Male Race:WHITE Weight:101.1 kg								
	TRT	1 TO 223	181	181	R: CALCIFIC TENDINITIS OF THE LEFT KNEE S: Musculoskeletal and connective tissue disorders P: 腱炎 L: Calcific tendinitis	E: 221 O: NO L: 41 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (103582) TRT: Placebo + LDAC								
80301# Age:6[redacted] Sex:Male Race:WHITE Weight:101.1 kg								
	POST	224 TO 435	14	237	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 251 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: NEW CHEMOTHERAPY STARTED ON 24 AUGUST 2018 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118511) TRT: Venetoclax 600 mg QD + LDAC								
75002# Age:7[redacted] Sex:Female Race:WHITE Weight:54.0 kg								
	TRT	1 TO 10	9	9	R: CELLULITIS LEFT LOWER LEG S: Infections and infestations P: 蜂巣炎 L: Cellulitis of leg	E: 14 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: WORSENING CELLULITIS A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53435) TRT: Venetoclax 600 mg QD + LDAC								
38101 Age:7[redacted] Sex:Female Race:WHITE Weight:76.0 kg								
	TRT	1 TO	9	9	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 15 O: NO L: 7 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53435) TRT: Venetoclax 600 mg QD + LDAC								
38101 Age:7[redacted] Sex:Female Race:WHITE Weight:76.0 kg								
	TRT	1 TO	19	19	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 23 O: NO L: 5 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 A: REASONABLE POSSIBILITY R: NO
			22	22	R: ACUTE APENDICITIS S: Infections and infestations P: 虫垂炎 L: Acute appendicitis	E: 34 O: NO L: 13 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE O: MEDICAL PROCEDURE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53054) TRT: Venetoclax 600 mg QD + LDAC 58305# Age:7[redacted] Sex:Female Race:ASIAN Weight:62.5 kg								
	TRT	1 TO 291	6	6	R: E.COLI BACTEREMIA S: Infections and infestations P: 大腸菌性菌血症 L: Escherichia coli bacteremia	E: 36 O: NO L: 31 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53054) TRT: Venetoclax 600 mg QD + LDAC 58305# Age:7[redacted] Sex:Female Race:ASIAN Weight:62.5 kg								
	TRT	1 TO 291	42	42	R: MULTIFOCAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	O: NO I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BRONCHIAL INFECTION RELATED & MYCOPLASMA PNEUMONIA IGG POSITIVE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53054) TRT: Venetoclax 600 mg QD + LDAC 58305# Age:7[redacted] Sex:Female Race:ASIAN Weight:62.5 kg								
	TRT	1 TO 291	196	196	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 207 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: THE CAUSE OF THE URINARY TRACT INFECTION IS "OLD AGE" AND "WOMAN"AND "PREVIOUS UTI MEDICAL HISTORY". A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC 70401# Age:9[redacted] Sex:Female Race:WHITE Weight:63.5 kg								
	TRT	1 TO 287	19	19	R: LEFT SIDED PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 36 O: NO L: 18 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC 70401# Age:9[redacted] Sex:Female Race:WHITE Weight:63.5 kg								
	TRT	1 TO 287	47	47	R: FUNGAL PNEUMONIA S: Infections and infestations P: 真菌性肺炎 L: Pneumonia fungal	E: 62 O: NO L: 16 DAYS I: YES	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC									
70402# Age:8[redacted] Sex:Male Race:WHITE Weight:85.0 kg									
	TRT	1 TO 424	22	22		R: RIGHT CONGESTIVE HEART FAILURE S: Cardiac disorders P: 右室不全 L: Right ventricular failure	O: YES 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 OVERLOAD A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC									
70402# Age:8[redacted] Sex:Male Race:WHITE Weight:85.0 kg									
	TRT	1 TO 424	63	63		R: EXACERBATION OF GOUT S: Metabolism and nutrition disorders P: 痛風 L: Gout aggravated	E: 64 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: PRE-EXISTING GOUT A: NO REASONABLE POSSIBILITY R: NO
			79	79		R: POLYARTICULAR GOUT S: Metabolism and nutrition disorders P: 痛風 L: Articular gout	E: 87 O: NO L: 9 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: MEDICAL HISTORY OF GOUT A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC								
70402# Age:8[redacted] Sex:Male Race:WHITE Weight:85.0 kg								
	TRT	1 TO 424	142	142	R: FEBRILE ILLNESS S: General disorders and administration site conditions P: 発熱 L: Fever	E: 146 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: OPPORTUNISTIC INFECTION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (112452) TRT: Venetoclax 600 mg QD + LDAC								
70402# Age:8[redacted] Sex:Male Race:WHITE Weight:85.0 kg								
	TRT	1 TO 424	400	400	R: DEEP VEIN THROMBOSIS LEFT ARM S: Vascular disorders P: 深部静脈血栓症 L: Deep vein thrombosis	O: NO 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: PRESENCE OF PERIPHERALLY INSERTED CENTRAL CATHETER A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130298) TRT: Placebo + LDAC								
50901# Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO 14	2	2	R: PLATELET COUNT DECREASED S: Investigations P: 血小板数減少 L: Platelet count decreased	O: YES I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130298) TRT: Placebo + LDAC 50901# Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO 14	14	14	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: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: LOW-FLOW NASAL CATHETER OXYGEN ABSORPTION 3L/MIN STARTS ON NOV 6, 2018 C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IT'S ASSOCIATED WITH PRIMARY DISEASE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118344) TRT: Placebo + LDAC								
63602# Age:8[redacted] Sex:Female Race:ASIAN Weight:49.6 kg								
	POST	20 TO 250	19	38	R: ENTEROCOCCUS FAECIUM INFECTION S: Infections and infestations P: 腸球菌感染 L: Enterococcus faecium infection	E: 245 O: NO L: 208 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: DUE TO INFECTION FROM THE CENTRAL VENOUS CATHETER INSERT PART. A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118344) TRT: Placebo + LDAC								
63602# Age:8[redacted] Sex:Female Race:ASIAN Weight:49.6 kg								
	POST	20 TO 250	26	45	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 245 O: NO L: 201 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 WAS EASILY INFECTIBLE DUE TO AML. AND THE LAST PRESCRIPTION OF CLINICAL TRIAL MEDICINE IS 23JUN2017. TIMING OF THE EVENT INDICATES IT IS CONSIDERED "NOT RELATED". A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118344) TRT: Venetoclax 600 mg QD + LDAC								
63601# Age:8[redacted] Sex:Female Race:ASIAN Weight:44.0 kg								
	TRT	1 TO 5	5	5	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 69 O: NO L: 65 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118344) TRT: Venetoclax 600 mg QD + LDAC								
63603# Age:8[redacted] Sex:Female Race:ASIAN Weight:32.6 kg								
	POST	107 TO 207	1	107	R: INTRACRANIAL HEMORRHAGE S: Nervous system disorders P: 頭蓋内出血 L: Intracranial hemorrhage	E: 125 O: NO L: 19 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63301# Age:8[redacted] Sex:Male Race:ASIAN Weight:57.2 kg								
	TRT	1 TO 133	73	73	R: UPPER GASTROINTESTION HEMORRHAGE S: Gastrointestinal disorders P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 83 O: NO L: 11 DAYS I: NO	G: Grade 2 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: OTHER: UNABLE TO ADMINISTER DUE TO FASTING O: MULTIPLE: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, MEDICAL PROCEDURE, FASTING C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63301# Age:8[redacted] Sex:Male Race:ASIAN Weight:57.2 kg								
	POST	134 TO 374	1	134	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 171 O: NO L: 38 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63302# Age:7[redacted] Sex:Male Race:ASIAN Weight:62.4 kg								
	TRT	1 TO 566	15	15	R: UPPER GASTROINTESTINAL HEMORRHAGE S: Gastrointestinal disorders P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 20 O: NO L: 6 DAYS I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED O: FASTING C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63302# Age:7[redacted] Sex:Male Race:ASIAN Weight:62.4 kg								
	TRT	1 TO 566	182	182	R: UPPER GASTROINTESTINAL HEMORRHAGE S: Gastrointestinal disorders P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 202 O: NO L: 21 DAYS I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: VENETOCLAX/PLACEBO|DRUG INTERRUPTED A: OTHER: UNABLE TO ADMINISTTER DUE TO FASTING O: FASTING C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63302# Age:7[redacted] Sex:Male Race:ASIAN Weight:62.4 kg								
	POST	567 TO 607	9	575	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	O: YES I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: BECAUSE MOROHOLOGIC RELAPSE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (118749) TRT: Venetoclax 600 mg QD + LDAC								
63302# Age:7[redacted] Sex:Male Race:ASIAN Weight:62.4 kg								
	POST	567 TO 607	10	576	R: UPPRE GASTROINTESTINAL HEMORRHAGE S: Gastrointestinal disorders P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 583 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: THROMBOCYTOPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117216) TRT: Venetoclax 600 mg QD + LDAC								
13303 Age:7[redacted] Sex:Male Race:WHITE Weight:72.1 kg								
	TRT	1 TO	93	93	R: DISCOLOURATION OF RIGHT INDEX FINGER S: Skin and subcutaneous tissue disorders P: 皮膚変色 L: Skin discoloration	E: 114 O: NO L: 22 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: MEDICAL HISTORY OF LEFT FOREFINGER ISCHAEMIA A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117216) TRT: Venetoclax 600 mg QD + LDAC								
13303 Age:7[redacted] Sex:Male Race:WHITE Weight:72.1 kg								
	TRT	1 TO	390	390	R: PAROTITIS S: Infections and infestations P: 耳下腺炎 L: Parotitis	E: 392 O: NO L: 3 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			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: 96 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 A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (117216) TRT: Venetoclax 600 mg QD + LDAC								
13303 Age:7[redacted] Sex:Male Race:WHITE Weight:72.1 kg								
	TRT	1 TO	509	509	R: NEUTROPENIC SEPSIS S: Infections and infestations P: 好中球減少性敗血症 L: Neutropenic sepsis	E: 513 O: NO L: 5 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: NONE C: YES	S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (109760) TRT: Venetoclax 600 mg QD + LDAC								
18101# Age:7[redacted] Sex:Male Race:WHITE Weight:94.0 kg								
	TRT	1 TO 56	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: 5 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (109760) TRT: Venetoclax 600 mg QD + LDAC									
18101# Age:7[redacted] Sex:Male Race:WHITE Weight:94.0 kg									
	TRT	1 TO 56	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: 18 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 A: NO REASONABLE POSSIBILITY R: NO
			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: 33 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (109760) TRT: Venetoclax 600 mg QD + LDAC								
18101# Age:7[redacted] Sex:Male Race:WHITE Weight:94.0 kg								
	TRT	1 TO 56	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: 47 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 A: NO REASONABLE POSSIBILITY R: NO
			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: 65 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (109760) TRT: Venetoclax 600 mg QD + LDAC								
18102# Age:6[redacted] Sex:Male Race:WHITE Weight:92.7 kg								
	TRT	1 TO 83	7	7	R: GRAM + SEPTICEMIA S: Infections and infestations P: 細菌性敗血症 L: Septicemia gram-positive	E: 28 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 A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (109760) TRT: Venetoclax 600 mg QD + LDAC								
18102# Age:6[redacted] Sex:Male Race:WHITE Weight:92.7 kg								
	TRT	1 TO 83	28	28	R: STAPHYLOCOCCUS EPIDERMITIS BACTERIEMIA S: Infections and infestations P: ブドウ球菌性菌血症 L: Staphylococcal bacteremia	E: 35 O: NO L: 8 DAYS I: NO	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PORT-A-CATH INFECTION DUE TO STAPHYLOCOCCUS EPIDERMIDIS A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120899) TRT: Placebo + LDAC								
40302# Age:7[redacted] Sex:Male Race:WHITE Weight:74.2 kg								
	TRT	1 TO 52	52	52	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 57 O: NO L: 6 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, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LEUCEMIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120899) TRT: Placebo + LDAC								
40309# Age:7[redacted] Sex:Female Race:WHITE Weight:64.4 kg								
	TRT	1 TO 30	2	2	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 8 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 O: THE CAUSE OF SEPSIS IS A PRECEDING BACTERIURIA IN A PATIENT WITH REDUCED IMMUNE STATUS (AGE, ACUTE MYELOBLASTIC LEUKEMIA) A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120899) TRT: Venetoclax 600 mg QD + LDAC 40303 Age:6[redacted] Sex:Female Race:WHITE Weight:80.0 kg								
	TRT	1 TO	16	16	R: PNEUMONIA, WORSENING S: Infections and infestations P: 肺炎 L: Pneumonia aggravated	E: 27 O: NO L: 12 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 O: ACUTE RESPIRATORY FAILURE A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120899) TRT: Venetoclax 600 mg QD + LDAC 40310# Age:6[redacted] Sex:Male Race:WHITE Weight:117.5 kg								
	TRT	1 TO 28	24	24	R: INVASIVE MYCOSIS OF THE LUNGS S: Infections and infestations P: 肺真菌症 L: Mycosis pulmonary	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: DEVELOPMENT OF INVASIVE MYCOSIS ON THE BACKGROUND OF PROLONGED CYTOPENIA IN AN IMMUNO-COMPROMISED PATIENT A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114329) TRT: Placebo + LDAC								
41101# Age:7[redacted] Sex:Female Race:WHITE Weight:60.0 kg								
	TRT	1 TO 18	17	17	R: SEPSIS (MULTIDRUG RESISTANT KLEBSIELLA PNEUMONIAE) S: Infections and infestations P: クレブシエラ性敗血症 L: Klebsiella sepsis	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 WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION C: YES	S: YES, LIFE THREATENING O: MYELOTOXIC AGRANULOCYTOSIS A: REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114329) TRT: Venetoclax 600 mg QD + LDAC								
41103# Age:8[redacted] Sex:Female Race:WHITE Weight:75.0 kg								
	TRT	1 TO 76	49	49	R: LEFT-SIDED RADICAL PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 56 O: NO L: 8 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: NEUTROPENIA A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (114329) TRT: Venetoclax 600 mg QD + LDAC								
41103# Age:8[redacted] Sex:Female Race:WHITE Weight:75.0 kg								
	TRT	1 TO 76	76	76	R: LEFT-SIDED LOWER-LOBE PNEUMONIA S: Infections and infestations P: 肺炎 L: Lobar pneumonia	E: 84 O: NO L: 9 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTIOUS COMPLICATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53326) TRT: Venetoclax 600 mg QD + LDAC								
26101# Age:6[redacted] Sex:Male Race:WHITE Weight:56.0 kg								
	TRT	1 TO 227	30	30	R: ACUTE RENAL FAILURE S: Renal and urinary disorders P: 急性腎障害 L: Acute renal failure	E: 62 O: NO L: 33 DAYS I: NO	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](53326) TRT: Venetoclax 600 mg QD + LDAC								
26101# Age:6[redacted] Sex:Male Race:WHITE Weight:56.0 kg								
	POST	228 TO 325	8	235	R: PNEUMONIA INFECTION S: Infections and infestations P: 肺炎 L: Pneumonia	E: 246 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: DUE TO AML A: NO REASONABLE POSSIBILITY R: NO
	TRT	1 TO 227	30	30	R: PNEUMONIA INFECTION S: Infections and infestations P: 肺炎 L: Pneumonia	E: 116 O: NO L: 87 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53326) TRT: Venetoclax 600 mg QD + LDAC								
26104# Age:7[redacted] Sex:Female Race:WHITE Weight:78.0 kg								
	TRT	1 TO 181	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: 42 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: DUE TO AML A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53326) TRT: Venetoclax 600 mg QD + LDAC 26104# Age:7[redacted] Sex:Female Race:WHITE Weight:78.0 kg								
	TRT	1 TO 181	88	88	R: ORTHOSTATIC DYSREGULATION WITH SYNCOPE S: Nervous system disorders P: 起立不耐性 L: Orthostatic dysregulation	E: 92 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: EXSICCOSIS-> LOW BLODD PRESSURE-> SYNCOPE A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (53326) TRT: Venetoclax 600 mg QD + LDAC								
26104# Age:7[redacted] Sex:Female Race:WHITE Weight:78.0 kg								
	TRT	1 TO 181	160	160	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 182 O: NO L: 23 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: DUE TO AML A: NO REASONABLE POSSIBILITY R: NO
			88	88	R: ORTHOSTATIC DYSREGULATION WITH SYNCOPE S: Nervous system disorders P: 失神 L: Syncope		--Same as Above--	

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120275) TRT: Venetoclax 600 mg QD + LDAC 58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	58	58	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 72 O: NO L: 15 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120275) TRT: Venetoclax 600 mg QD + LDAC 58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	58	58	R: THROMBOCYTOPENIA S: Blood and lymphatic system disorders P: 血小板減少症 L: Thrombocytopenia	E: 72 O: NO L: 15 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120275) TRT: Venetoclax 600 mg QD + LDAC								
58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	109	109	R: AST 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: AST increased	E: 115 O: NO L: 7 DAYS I: NO	G: Grade 1 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE: FATTY LIVER RELATED A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120275) TRT: Venetoclax 600 mg QD + LDAC								
58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	109	109	R: ALT INCREASED S: Investigations P: アラニンアミノトランスフェラーゼ増加 L: ALT increased	E: 115 O: NO L: 7 DAYS I: YES	G: Grade 2 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE: FATTY LIVER RELATED A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted](120275) TRT: Venetoclax 600 mg QD + LDAC								
58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	172	172	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: NO I: YES	G: Grade 3 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE O: BLOOD TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE OF EVENT MIGHT BE ABOUT LDAC (TREATMENT DATE FROM 7/31 TO 8/9) A: NO REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (120275) TRT: Venetoclax 600 mg QD + LDAC								
58201 Age:6[redacted] Sex:Female Race:ASIAN Weight:70.0 kg								
	TRT	1 TO	486	486	R: FEBRILE NEUTROPENIA S: Blood and lymphatic system disorders P: 発熱性好中球減少症 L: Febrile neutropenia	E: 489 O: NO L: 4 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY R: NO

LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130308) TRT: Placebo + LDAC								
50104# Age:6[redacted] Sex:Male Race:ASIAN Weight:54.5 kg								
	TRT	1 TO 8	8	8	R: SEPTIC SHOCK S: Infections and infestations P: 敗血症性ショック L: Septic shock	E: 27 O: NO L: 20 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, LIFE THREATENING A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130308) TRT: Placebo + LDAC								
50104# Age:6[redacted] Sex:Male Race:ASIAN Weight:54.5 kg								
	TRT	1 TO 8	8	8	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 27 O: NO L: 20 DAYS I: NO	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG WITHDRAWN - NOT RELATED TO PROGRESSION, LDAC|DRUG INTERRUPTED O: MEDICAL PROCEDURE C: YES	S: YES, LIFE THREATENING A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130308) TRT: Placebo + LDAC								
50106# Age:7[redacted] Sex:Female Race:ASIAN Weight:53.0 kg								
		POST	17 TO 50	26 42	R: HEART FAILURE S: Cardiac disorders P: 心不全 L: Heart failure	O: YES I: NO	G: Grade 4 R: NO REASONABLE POSSIBILITY Z: NO REASONABLE POSSIBILITY A: NONE C: YES	S: YES, LIFE THREATENING O: DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. POST = Post Study Drug Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (130308) TRT: Venetoclax 600 mg QD + LDAC								
50101# Age:6[redacted] Sex:Male Race:ASIAN Weight:83.5 kg								
	TRT	1 TO 58	46	46	R: LEUKOPENIA S: Blood and lymphatic system disorders P: 白血球減少症 L: Leukopenia	E: 71 O: NO L: 26 DAYS I: YES	G: Grade 4 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (93702) TRT: Venetoclax 600 mg QD + LDAC								
51202# Age:7[redacted] Sex:Male Race:ASIAN Weight:58.0 kg								
	TRT	1 TO 230	8	8	R: THROMBOCYTOPENIA 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: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

TABLE 1__11.2

Listing of Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M16-043)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug Z: Relationship to LDAC A: Action Taken O: Other Actions Taken C: Concomitant or Additional TRT Given	S: Serious AE? O: Other Cause of Event A: AbbVie Opinion of Causality R: Related to TLS?
INV: [redacted] (93702) TRT: Venetoclax 600 mg QD + LDAC								
51202# Age:7[redacted] Sex:Male Race:ASIAN Weight:58.0 kg								
	TRT	1 TO 230	120	120	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: VENETOCLAX/PLACEBO|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO
			54	54	R: LUNG INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 68 O: NO L: 15 DAYS I: NO	G: Grade 3 R: REASONABLE POSSIBILITY Z: REASONABLE POSSIBILITY A: MULTIPLE: VENETOCLAX/PLACEBO|DRUG INTERRUPTED, LDAC|DRUG INTERRUPTED C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY R: NO

# Subject prematurely discontinued.
LDAC = Low Dose Cytarabine. TRT = On Study Treatment.
Note: Data included are subject to a cutoff date of 15AUG2019.

Program Source Code: [redacted]

表 2.7.4-102.　　重篤な有害事象を発現した被験者一覧（M14-387 試験）

1881

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (86364) TRT:ABT-199 P 2 PORTION - 600 MG QD 41201# Age:7[redacted] Sex:Female Race:White Weight:70.0 kg							
	OPEN	1 TO 198	16 16	R: RIGHT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 23 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: POSSIBLE COMMUNITY ACQUIRED PNEUMONIA RELATING TO PRE-EXISTING NEUTROPAENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (86364) TRT:ABT-199 P 2 PORTION - 600 MG QD 41201# Age:7[redacted] Sex:Female Race:White Weight:70.0 kg								
(Cont.)	OPEN	1 TO 198	25	25	R: RIGHT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 39 L: 15 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: EXACERBATION OF RIGHT LOWER LOBE PNEUMONIA REQUIRING READMISSION AND ADDITIONAL IV ANTIBIOTICS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (86364) TRT:ABT-199 P 2 PORTION - 600 MG QD 41201# Age:7[redacted] Sex:Female Race:White Weight:70.0 kg							
	(Cont.)	OPEN 1 TO 198	29	R: NSTEMI S: CARDIAC DISORDERS P: 急性心筋梗塞 L: NON STEMI	E: 39 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ANAEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT 2 - 800 MG QD 50101# Age:7[redacted] Sex:Male Race:White Weight:78.0 kg							
	OPEN	1 TO 475	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: 13 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT IS IN APLASIA AND HAS TEMERATUR TILL 38.5?C SINCE 03.07.2015 HE RECEIVES PARACETAMOL 1 G. THE HOSPITALISATION IS NOW PROLONGED. PLANNED DISCHARGING WAS TODAY. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT 2 - 800 MG QD 50101# Age:7[redacted] Sex:Male Race:White Weight:78.0 kg								
	(Cont.)	OPEN	1 TO 475	18	18	R: FEVER OF UNKNOWN ORIGIN S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER OF UNKNOWN ORIGIN	E: 18 L: 1 Day I: Yes	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POTENTIAL INFECTION FOCUS C: No reasonable possibility
						R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 19 L: 2 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: <POTENTIAL INFECT FOCUS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C HORT 2 - 800 MG QD 50101# Age:7[redacted] Sex:Male Race:White Weight:78.0 kg								
(Cont.)	OPEN	1 TO 475	471	471	R: PLEURAL EMPYEMA S: INFECTIONS AND INFESTATIONS P: 感染性胸水 L: PULMONARY EMPYEMA	E: 476 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO STUDY DISEASE C: No reasonable possibility
TRT:ABT-199 OHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
	OPEN	1 TO	19	19	R: PORT INFECTION WITH KLEBSIELLA PNEUMONIA S: INFECTIONS AND INFESTATIONS P: クレブシエラ菌性肺炎 L: KLEBSIELLA PNEUMONIA	E: 24 L: 6 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PORT EXPLANTATION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION OF PORT IMPLANTATION PUNCTURE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg							
(Cont.)	OPEN	1 TO	19	19	R: PORT INFECTION WITH KLEBSIELLA PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 血管デバイス感染 L: VASCULAR DEVICE INFECTION		--Same as Above--	
			81	81	R: ORGANIC PSYCHO SYNDROME S: PSYCHIATRIC DISORDERS P: 身体疾患による精神病性障害 L: ORGANIC PSYCHOSIS	E: 82 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAUSE OF THE EVENT WAS DRONABINOL. C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
(Cont.)	OPEN	1 TO	704	704	R: ACUTE MYOCARDIAL INFARCTION S: CARDIAC DISORDERS P: 急性心筋梗塞 L: ACUTE MYOCARDIAL INFARCTION	E: 718 L: 15 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AGE RELATED C: No reasonable possibility
			706	706	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 718 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
(Cont.)	OPEN	1 TO	1152	1152	R: LACUNAR INFARCTION BRAIN S: NERVOUS SYSTEM DISORDERS P: ラクナ梗塞 L: LACUNAR INFARCTION	E: 1157 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AGE C: No reasonable possibility
			1162	1162	R: FEMURFRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 大腿骨骨折 L: FEMUR FRACTURE	E: 1202 L: 41 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
	(Cont.)	OPEN	1 TO	1166	1166	R: NASOCOMIAL PNEUMONITIS S: INFECTIONS AND INFESTATIONS P: 院内感染 L: NOSOCOMIAL INFECTION	E: 1179 L: 14 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INTENSIVE CARE UNIT STAY C: No reasonable possibility
				1171	1171	R: NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION S: CARDIAC DISORDERS P: 急性心筋梗塞 L: NON ST SEGMENT ELEVATION MYOCARDIAL INFARCTION	E: 1181 L: 11 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AGE C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
(Cont.)	OPEN	1 TO	1214	1214	R: STROKE S: NERVOUS SYSTEM DISORDERS P: 脳血管発作 L: STROKE	E: 1220 L: 7 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PREVIOUS STROKE C: No reasonable possibility
			1250	1250	R: PAIN LEFT FEMUR UNDER STRESS S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨痛 L: PAIN FEMORAL	E: 1251 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: SURGERY FEMUR LEFT	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SURGERY: CLOSED REPOSITION AND FIXATION WITH INTERTAN NAIL C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 COHORT 1 EXPANSION - 600 MG QD 50102 Age:8[redacted] Sex:Male Race:White Weight:77.5 kg								
(Cont.)	OPEN	1 TO	1261	1261	R: PAIN LEFT FEMUR S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨痛 L: PAIN FEMORAL	E: 1265 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FEMUR FRACTURE 2018 C: No reasonable possibility
TRT:ABT-199 P_2 PORTION - 600 MG QD 50201# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
	OPEN	1 TO 76	10	10	R: WORSENING OF PATIENTS GENERAL CONDITION S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 全身健康状態低下 L: REDUCED GENERAL CONDITION	E: 48 L: 39 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50201# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
(Cont.)	OPEN	1 TO 76	49	49	R: CONSTIPATION S: GASTROINTESTINAL DISORDERS P: 便秘 L: CONSTIPATION	E: 53 L: 5 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility
			54	54	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 63 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50201# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
(Cont.)	OPEN	1 TO 76	67	67	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 85 L: 19 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
50202# Age:7[redacted] Sex:Female Race:White Weight:75.0 kg								
	OPEN	1 TO 126	89	89	R: NAUSEA S: GASTROINTESTINAL DISORDERS P: 悪心 L: NAUSEA	E: 100 L: 12 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
			106	106	R: NAUSEA S: GASTROINTESTINAL DISORDERS P: 悪心 L: NAUSEA	O: Yes I: Yes	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50203#	Age:7[redacted]	Sex:Male	Race:White	Weight:80.0 kg				
	OPEN	1 TO 198	2	2	R: CONFUSION, UNCERTAIN GAIT S: PSYCHIATRIC DISORDERS P: 錯乱状態 L: CONFUSION	E: 58 L: 57 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE CEREBRAL PURPURA DOCUMENTED ON MRI FROM 04APR2016 C: No reasonable possibility
					R: CONFUSION, UNCERTAIN GAIT S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 歩行障害 L: UNSTEADY GAIT		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50203# Age:7[redacted] Sex:Male Race:White Weight:80.0 kg								
(Cont.)	OPEN	1 TO 198	52	52	R: SUBARACHNOIDAL BLEEDING S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: くも膜下出血 L: SUBARACHNOID HEMORRHAGE	E: 59 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL C: No reasonable possibility
			82	82	R: CHOLECYSTITIS S: HEPATOBILIARY DISORDERS P: 胆嚢炎 L: CHOLECYSTITIS	E: 91 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: CHOLEYSTECTOMY	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THERE IS NO REASON KNOWN WHICH HACE CONTRIBUTED TO THE EVENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50203# Age:7[redacted] Sex:Male Race:White Weight:80.0 kg								
(Cont.)	OPEN	1 TO 198	95	95	R: VENETOCLAX OVERDOSE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 過量投与 L: DRUG OVERDOSE	E: 121 L: 27 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: CONFUSION OF PATIENT C: No reasonable possibility
50206# Age:8[redacted] Sex:Female Race:White Weight:69.4 kg								
	OPEN	1 TO 45	43	43	R: MUCOSITIS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 粘膜の炎症 L: MUCOSITIS	E: 55 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50207# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
	OPEN	1 TO 411	209	209	R: WORSENING OF ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA AGGRAVATED	E: 211 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: TRANSFUSION AND HOSPITALISATION	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECTED BLEEDING UNKNOWN ORIGIN, OESOPHAGO-GASTRO-DUODENOSCOPY WAS DONE WITHOUT NO FINDIGS OF BLEEDINGS. SO NO CAUSE OF EVENT WAS DETECTED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50207# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
(Cont.)	OPEN	1 TO 411	270	270	R: INTESTINE DIVERTICULAR BLEEDING S: GASTROINTESTINAL DISORDERS P: 出血性腸憩室 L: INTESTINAL DIVERTICULAR BLEEDING	E: 281 L: 12 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DUE TO DIVERTICEL C: No reasonable possibility
			313	313	R: INTESTINE DIVERTICULAR BLEEDING S: GASTROINTESTINAL DISORDERS P: 出血性腸憩室 L: INTESTINAL DIVERTICULAR BLEEDING	E: 321 L: 9 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THROMBOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50207# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
(Cont.)	OPEN	1 TO 411	370	370	R: SYMPTOMATIC ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 378 L: 9 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: TRANSFUSION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
					R: PORT CATHETER INFECTION S: INFECTIONS AND INFESTATIONS P: 医療機器関連感染 L: CATHETER INFECTION	E: 384 L: 15 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, LEUOPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50207# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
	(Cont.)	OPEN	1 TO 411	411	411	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 420 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYIN DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 P 2 PORTION - 600 MG QD 50207# Age:7[redacted] Sex:Male Race:White Weight:85.1 kg								
(Cont.)	POST	412 TO	9	420	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	O: Yes I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNSUPRSSION UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 50208# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
	OPEN	1 TO 344	7	7	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 13 L: 7 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA, LEUCOPENIA C: No reasonable possibility
			80	80	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 84 L: 5 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 50208# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
(Cont.)	OPEN	1 TO 344	117	117	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 121 L: 5 Days I: No	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
			153	153	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 160 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 50208# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
	(Cont.)	OPEN	1 TO 344	182	182	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 190 L: 9 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility
				220	220	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 227 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 50208# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
	(Cont.)	OPEN	1 TO 344	315	315	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 327 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SKIN INFECTION C: No reasonable possibility
				318	318	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 327 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53326) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 50208# Age:8[redacted] Sex:Male Race:White Weight:71.0 kg								
(Cont.)	POST	345 TO	1	345	R: INFECTION OF UNKNOWN ORIGIN S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	E: 353 L: 9 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility
INV:[redacted] (50863) TRT:ABT-199 P_2 PORTION - 600 MG QD 31202# Age:8[redacted] Sex:Female Race:White Weight:55.9 kg								
	OPEN	1 TO 259	64	64	R: TRANSIENT ISCHEMIC ATTACK S: NERVOUS SYSTEM DISORDERS P: 一過性脳虚血発作 L: TRANSIENT ISCHEMIC ATTACK	E: 67 L: 4 Days I: Yes	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AGE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31202# Age:8[redacted] Sex:Female Race:White Weight:55.9 kg								
(Cont.)	OPEN	1 TO 259	90	90	R: EYE DISORDER, OTHER (BINOCULAR DIPLOPIA) S: EYE DISORDERS P: 複視 L: BINOCULAR DIPLOPIA	E: 92 L: 3 Days I: Yes	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUBJECT REPORTED THAT SHE HAS A HISTORY OF THIS SO IT IS ATTRIBUTED TO HER MEDICAL HISTORY C: No reasonable possibility
31203# Age:7[redacted] Sex:Male Race:White Weight:102.9 kg								
	OPEN	1 TO 394	33	33	R: BURSITIS WITH CELLULITIS - RIGHT ELBOW AND RIGHT WRIST S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 滑液包炎 L: BURSITIS	E: 38 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF RUE SWELLING WITH TRAUMATIC PICC PLACEMENT AT BASELINE. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31203# Age:7[redacted] Sex:Male Race:White Weight:102.9 kg								
(Cont.)	OPEN	1 TO 394	33	33	R: BURSITIS WITH CELLULITIS-RIGHT ELBOW AND RIGHT WRIST S: INFECTIONS AND INFESTATIONS P: 蜂巣炎 L: CELLULITIS		--Same as Above--	
31204# Age:7[redacted] Sex:Male Race:White Weight:95.8 kg								
	OPEN	1 TO 154	74	74	R: THROMBOCYTOPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 血小板減少症 L: THROMBOCYTOPENIA	E: 76 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: Reasonable possibility A: NONE O: OTHER: PLATELET TRANSFUSION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31204# Age:7[redacted] Sex:Male Race:White Weight:95.8 kg								
	(Cont.)	POST	155 TO	1	155	R: BLOOD INFECTION (STAPHYLOCOCCUS EPIDERMIDIS, COAGULASE NEGATIVE) S: INFECTIONS AND INFESTATIONS P: ブドウ球菌性敗血症 L: STAPHYLOCOCCUS EPIDERMIDIS SEPTICEMIA	E: 162 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECT SOURCE WAS MOST LIKELY THE PATIENT'S LUE PICC LINE AS HE HAD ERYTHEMA AND TENDERNESS AT THIS SITE PRIOR TO REMOVAL FOR THIS REASON ON 6/7 C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31204# Age:7[redacted] Sex:Male Race:White Weight:95.8 kg							
(Cont.)	POST	155 TO	9	163 R: DYSPNEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: DYSPNEA	E: 173 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS SEVERE PULMONARY HYPERTENSION/CHF. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31206# Age:8[redacted] Sex:Male Race:White Weight:76.3 kg								
	OPEN	1 TO 512	19	19	R: ACUTE ISCHEMIC STROKE S: NERVOUS SYSTEM DISORDERS P: 虚血性脳卒中 L: ISCHEMIC STROKE	E: 24 L: 6 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: RIGHT CAROTID EMBOLECTOMY AND STENT PLACEMENT	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PER MD NOTE: "COULD HAVE OTHER METABOLIC OR INFECTIOUS CASUE, AS WELL, HOWEVER, IN THE SETTING OF CT ANGIOGRAPHY IWHT DEFINITIVE INTRACRANIAL CLOT, THIS IS LESS LIKELY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31206# Age:8[redacted] Sex:Male Race:White Weight:76.3 kg							
(Cont.)	OPEN	1 TO 512	26 26	R: ELEVATED TROPONINS S: INVESTIGATIONS P: トロポニン増加 L: TROPONIN INCREASED	E: 29 L: 4 Days I: No	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PATIENT WAS NOTED TO HAVE GRADE 2 DIASTOLIC DYSFUNCTION AND WAS DISCHARGED TO FOLLOW UP WITH PCP AND CARDIOLOGIST. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31206# Age:8[redacted] Sex:Male Race:White Weight:76.3 kg								
(Cont.)	OPEN	1 TO 512	76	76	R: GENERALIZED WEAKNESS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: WEAKNESS GENERALIZED	E: 78 L: 3 Days I: No	D: No G: Grade 2 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
31208# Age:6[redacted] Sex:Male Race:White Weight:75.8 kg								
	OPEN	1 TO 57	53	53	R: LUNG INFECTION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	E: 66 L: 14 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 H2 PORTION - 600 MG QD 31209 Age:8[redacted] Sex:Male Race:White Weight:81.9 kg								
	OPEN	1 TO	57	57	R: MILD DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 59 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS MEDICAL HISTORY OF DIVERTICULITIS C: No reasonable possibility
31210# Age:7[redacted] Sex:Male Race:White Weight:80.4 kg								
	OPEN	1 TO 35	23	23	R: LUNG INFECTION (FUNGAL) S: INFECTIONS AND INFESTATIONS P: 真菌性気道感染 L: RESPIRATORY TRACT INFECTION FUNGAL	E: 31 L: 9 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 P 2 PORTION - 600 MG QD 31210# Age:7[redacted] Sex:Male Race:White Weight:80.4 kg								
(Cont.)	POST	36 TO	1	36	R: LUNG INFECTION (FUNGAL) S: INFECTIONS AND INFESTATIONS P: 真菌性気道感染 L: RESPIRATORY TRACT INFECTION FUNGAL	E: 44 L: 9 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31211# Age:8[redacted] Sex:Male Race:White Weight:98.3 kg								
	OPEN	1 TO 234	37	37	R: INFECTIOUS COLITIS, DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 41 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HE INITIALLY PRESENTED WITH DIVERTICULITIS AND FEVER. IT RESOLVED ON ANTIBIOTICS. C: No reasonable possibility
					R: INFECTIOUS COLITIS, DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 感染性大腸炎 L: INFECTIOUS COLITIS		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31212# Age:6[redacted] Sex:Male Race:White Weight:99.2 kg								
	OPEN	1 TO 23	16	16	R: HEMATURIA S: RENAL AND URINARY DISORDERS P: 血尿 L: HEMATURIA	E: 20 L: 5 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: OTHER: TRANSUSIONS	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			23	23	R: LUNG INFECTION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	E: 28 L: 6 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: DISC LDAC - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31213# Age:6[redacted] Sex:Male Race:White Weight:58.8 kg								
	OPEN	1 TO 104	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: 22 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PT IS IMMUNE COMPROMISED AND ON CHEMO C: No reasonable possibility
			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: 59 L: 12 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31213# Age:6[redacted] Sex:Male Race:White Weight:58.8 kg								
(Cont.)	OPEN	1 TO 104	70	70	R: PNEUMOTHORAX S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 気胸 L: PNEUMOTHORAX	E: 74 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: RIGHT PIGTAIL CATHETER PLACED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: D/T HIS HISTORY OF SPONTANEOUS RIGHT PNEUMO AND COPD C: No reasonable possibility
	POST	105 TO	9	113	R: DYSPNEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸困難 L: DYSPNEA	E: 126 L: 14 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HIS DYSPNEA IS DUE TO HIS HISTORY OF PNEUMOTHORAX C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31214# Age:8[redacted] Sex:Female Race:White Weight:44.4 kg								
	OPEN	1 TO 171	6	6	R: DEVICE RELATED INFECTION (RIGHT CHEST MED PORT) S: INFECTIONS AND INFESTATIONS P: 医療機器関連感染 L: DEVICE RELATED INFECTION	E: 12 L: 7 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RIGHT CHEST PORT C: No reasonable possibility
			14	14	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 37 L: 24 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			73	73	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 79 L: 7 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31215# Age:9[redacted] Sex:Male Race:White Weight:90.2 kg								
	OPEN	1 TO 117	21	21	R: CATHETER RELATED INFECTION (PERIPHERALLY INSERTED) S: INFECTIONS AND INFESTATIONS P: 医療機器関連感染 L: CATHETER RELATED INFECTION	E: 30 L: 10 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			46	46	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 50 L: 5 Days I: No	D: No G: Grade 1 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31215# Age:9[redacted] Sex:Male Race:White Weight:90.2 kg								
	(Cont.)	OPEN	1 TO 117	57	57	R: DEVICE RELATED INFECTION-PORT S: INFECTIONS AND INFESTATIONS P: 血管デバイス感染 L: VASCULAR DEVICE INFECTION	E: 61 L: 5 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
31216# Age:7[redacted] Sex:Female Race:White Weight:89.1 kg								
		OPEN	1 TO 17	10	10	R: WORSENING HEART FAILURE S: CARDIAC DISORDERS P: 心不全 L: CARDIAC FAILURE AGGRAVATED	E: 18 L: 9 Days I: No	G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31216# Age:7[redacted] Sex:Female Race:White Weight:89.1 kg								
	(Cont.)	POST	18 TO	3	20	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 22 L: 3 Days I: No	D: No G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: OTHER: SUBJECT TOOK HER LAST DOSE OF STUDY DRUG ON 3/16/2017 THEN SHE WITHDREW CONSENT O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
31217# Age:6[redacted] Sex:Male Race:White Weight:76.1 kg								
		OPEN	1 TO 359	106	106	R: BACTEREMIA INFECTION S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 120 L: 15 Days I: No	G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31217# Age:6[redacted] Sex:Male Race:White Weight:76.1 kg								
	(Cont.)	OPEN	1 TO 359	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: 174 L: 14 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
				197	197	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 202 L: 6 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31217# Age:6[redacted] Sex:Male Race:White Weight:76.1 kg								
(Cont.)	OPEN	1 TO 359	257	257	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 262 L: 6 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			325	325	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 327 L: 3 Days I: No	D: No G: Grade 1 R1: Reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 31217# Age:6[redacted] Sex:Male Race:White Weight:76.1 kg								
	(Cont.)	OPEN	1 TO 359	349	349	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 405 L: 57 Days I: No	D: No G: Grade 2 R1: Reasonable possibility R2: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
31218 Age:8[redacted] Sex:Male Race:White Weight:86.2 kg								
		OPEN	1 TO 10	10	10	R: EPISTAXIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻出血 L: EPISTAXIS	E: 12 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 COHORT C - PH2 PORTION - 600 MG QD 31218 Age:8[redacted] Sex:Male Race:White Weight:86.2 kg								
(Cont.)	OPEN	1 TO	104	104	R: GASTROINTESTINAL DISORDERS, DIARRHEA, DEHYDRATION S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 107 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPECT VIRAL ETIOLOGY GIVEN ABRUPT ONSET OF VOMITING AND DIARRHEA ACCOMPANIED BY MALAISE AND LOW GRADE FEVER AND SHORT DURATION OF SYMPTOMS C: No reasonable possibility
					R: GASTROINTESTINAL DISORDERS, DIARRHEA, DEHYDRATION S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHEA		--Same as Above--	

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50863) TRT:ABT-199 COHORT C - PH2 PORTION - 600 MG QD 31218 Age:8[redacted] Sex:Male Race:White Weight:86.2 kg								
	(Cont.)	OPEN	1 TO	104	104	R: GASTROINTESTINAL DISORDERS, DIARRHEA, DEHYDRATION S: GASTROINTESTINAL DISORDERS P: 胃腸障害 L: GASTROINTESTINAL DISORDER		--Same as Above--	
				287	287	R: FRACTURE OF FEMORAL NECK, RIGHT, CLOSED S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 大腿骨頚部骨折 L: FEMORAL NECK FRACTURE	E: 298 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: SUBJECT FELL C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 C HORT 1 EXPANSION - 600 MG QD 32104# Age:8[redacted] Sex:Female Race:White Weight:59.4 kg								
	OPEN	1 TO 119	39	39	R: WEAKNESS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: WEAKNESS	E: 123 L: 85 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANEMIA/HYPOXIA C: No reasonable possibility
					R: HYPONATREMIA S: METABOLISM AND NUTRITION DISORDERS P: 低ナトリウム血症 L: HYPONATREMIA	E: 123 L: 85 Days I: Yes	D: No G: Grade 3 R1: Reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 C_HORT 1 EXPANSION - 600 MG QD 32104# Age:8[redacted] Sex:Female Race:White Weight:59.4 kg								
(Cont.)	OPEN	1 TO 119	39	39	R: HYPOXIA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 低酸素症 L: HYPOXIA	E: 39 L: 1 Day I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: SUPPLEMENTAL O2 PRN TO KEEP O2 SAT >90%	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANEMIA C: No reasonable possibility
			62	62	R: FALL, HIP PAIN FROM FALL (SYMPTOM) S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 転倒 L: FALL	E: 64 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT SCAN OF RIGHT HIP AND RIGHT LOWER EXTREMITY	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ANEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 C HORT 1 EXPANSION - 600 MG QD 32104# Age:8[redacted] Sex:Female Race:White Weight:59.4 kg							
(Cont.)	OPEN	1 TO 119	62	R: FALL, HIP PAIN FROM FALL (SYMPTOM) S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 外傷後疼痛 L: PAIN TRAUMA ACTIVATED		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 P 2 PORTION - 600 MG QD 32202# Age:8[redacted] Sex:Female Race:White Weight:78.5 kg							
	OPEN	1 TO 424	13	R: FLUID VOLUME OVERLOAD S: METABOLISM AND NUTRITION DISORDERS P: 水分過負荷 L: VOLUME OVERLOAD	E: 15 L: 3 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SUPPLEMENTAL OXYGEN ADMINISTERED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT ILLNESS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 P 2 PORTION - 600 MG QD 32202# Age:8[redacted] Sex:Female Race:White Weight:78.5 kg								
	(Cont.)	OPEN	1 TO 424	13	13	R: ACUTE HYPOXIC RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 急性呼吸不全 L: ACUTE RESPIRATORY FAILURE	E: 15 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: PATIENT PUT ON O2	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLUID VOLUME OVERLOAD C: No reasonable possibility
				267	267	R: PAROXYSMAL ATRIAL FIBRILLATION S: CARDIAC DISORDERS P: 心房細動 L: PAROXYSMAL ATRIAL FIBRILLATION	E: 267 L: 1 Day I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 P 2 PORTION - 600 MG QD 32202# Age:8[redacted] Sex:Female Race:White Weight:78.5 kg								
(Cont.)	OPEN	1 TO 424	313	313	R: BONE INFECTION (OSTEOMYELITIS) S: INFECTIONS AND INFESTATIONS P: 骨髄炎 L: OSTEOMYELITIS	E: 314 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: AMPUTATION OF GREAT BIG TOE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING AML C: No reasonable possibility
	POST	425 TO	8	432	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 454 L: 23 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53446) TRT:ABT-199 P 2 PORTION - 600 MG QD 32203# Age:7[redacted] Sex:Male Race:White Weight:119.5 kg								
	OPEN	1 TO 132	52	52	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 59 L: 8 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			132	132	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 141 L: 10 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
	POST	133 TO	22	154	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 156 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60201# Age:7[redacted] Sex:Female Race:White Weight:74.0 kg								
	OPEN	1 TO 69	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: 17 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CHEST X RAY WAS DONE AND WAS NEGATIVE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60201# Age:7[redacted] Sex:Female Race:White Weight:74.0 kg								
(Cont.)	OPEN	1 TO 69	54	54	R: PULMONARY ASPERGILLOSIS S: INFECTIONS AND INFESTATIONS P: 気管支肺アスペルギルス症 L: PULMONARY ASPERGILLOSIS	E: 71 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOR SI THE EVENT IS NOT CORRELATED TO STUDY DRUG. THE SUBJ HAS UNDERLYNIG DISEASE. THE PATIENT HAD INTERMITTENT FEVER FROM APRIL 17 TO MAY 3 C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60201# Age:7[redacted] Sex:Female Race:White Weight:74.0 kg							
(Cont.)	OPEN	1 TO 69	58 58	R: SEPSIS BY E.COLI S: INFECTIONS AND INFESTATIONS P: 大腸菌性敗血症 L: SEPTICAEMIA DUE TO ESCHERICHIA COLI (E. COLI)	E: 71 L: 14 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FOR SI THE EVENT IS NOT CORRELATED TO STUDY DRUG. THE SUBJ HAS UNDERLYNIG DISEASE. THE PATIENT HAD INTERMITTENT FEVER FROM APRIL 17 TO MAY 3 C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60203# Age:7[redacted] Sex:Male Race:White Weight:68.4 kg								
	OPEN	1 TO 88	19	19	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 30 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTIOUS EVENT FOR WHICH HAS NOT BEEN ISOLATED NOTHING. NEUTROPENIA REMAIN GRADE 4, FEVER DISAPPEAR THE DAY AFTER START OF ANTIBIOTIC THERAPY. 22 JUN 2016 A NEW FEVER 38. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P_2 PORTION - 600 MG QD 60203# Age:7[redacted] Sex:Male Race:White Weight:68.4 kg								
(Cont.)	POST	89 TO	12	100	R: PULMONARY OUTBREAK S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺障害 L: PULMONARY DISORDER	E: 115 L: 16 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PULMONARY OUTBRACK WAS CAUSED PROBABLY BY THE NEUTROPENIA LINKED TO THE DISEASE.SUBJECT WAS ADMITTED TO AN OUTSIDE FACILITY AND RECORDS NOT AVAILABLE. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60204# Age:7[redacted] Sex:Male Race:White Weight:87.5 kg								
	POST	88 TO	4	91	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 96 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALIZATION IN OTHER HOSPITAL C: No reasonable possibility
			28	115	R: CONFUSION S: PSYCHIATRIC DISORDERS P: 錯乱状態 L: CONFUSION	E: 126 L: 12 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ISCHEMIC ELECTROCARDIOGRAPHIC CHANGES C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (989332) TRT:ABT-199 P 2 PORTION - 600 MG QD 60204# Age:7[redacted] Sex:Male Race:White Weight:87.5 kg								
(Cont.)	POST	88 TO	28	115	R: HYPERPYREXIA S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 異常高熱 L: HYPERPYREXIA	E: 126 L: 12 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33202# Age:7[redacted] Sex:Female Race:White Weight:84.3 kg								
	OPEN	1 TO 11	11	11	R: SPONTANEOUS SPLENIC RUPTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 脾破裂 L: SPLENIC RUPTURE	E: 20 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: SPLENIC EMBOLIZATION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MOTOR VEHICLE ACCIDENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33202# Age:7[redacted] Sex:Female Race:White Weight:84.3 kg								
(Cont.)	POST	12 TO	26	37	R: PULMONARY EDEMA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺水腫 L: PULMONARY EDEMA	E: 54 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VOLUME OVERLOAD C: No reasonable possibility
33205# Age:7[redacted] Sex:Male Race:White Weight:76.9 kg								
	OPEN	1 TO 57	34	34	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 46 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT SCAN OF CHEST	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33205# Age:7[redacted] Sex:Male Race:White Weight:76.9 kg							
	(Cont.)	OPEN	1 TO 57	50 50	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 84 L: 35 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE PROGRESSION C: No reasonable possibility
					R: PROGRESSION OF DISEASE S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 疾患進行 L: DISEASE PROGRESSION	E: 88 L: 39 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33206# Age:7[redacted] Sex:Male Race:White Weight:86.0 kg								
	OPEN	1 TO 84	11	11	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 13 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER TREATMENT C: No reasonable possibility
	POST	85 TO	30	114	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 115 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33207# Age:7[redacted] Sex:Male Race:Asian Weight:62.9 kg								
	POST	91 TO	19	109	R: LEFT LOWER LOBE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: LOBAR PNEUMONIA	E: 119 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: OTHER: N/A, PATIENT'S LAST DOSE WAS 5/8/2016 AND WAS TAKEN OFF STUDY 5/16/16 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
33209# Age:7[redacted] Sex:Male Race:White Weight:55.0 kg								
	OPEN	1 TO 33	9	9	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 13 L: 5 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33209# Age:7[redacted] Sex:Male Race:White Weight:55.0 kg								
(Cont.)	POST	34 TO	1	34	R: TYPHLITIS INTO INTUSSUSCEPTION S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: TYPHLITIS	E: 35 L: 2 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: TRANSFUSIONS ; PLATELETS, PACKED RED BLOOD CELLS,FRESH FROZEN PLASMA	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TYPHLITIS C: No reasonable possibility
					R: TYPHLITIS INTO INTUSSUSCEPTION S: GASTROINTESTINAL DISORDERS P: 腸重積症 L: INTUSSUSCEPTION		--Same as Above--	

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33209# Age:7[redacted] Sex:Male Race:White Weight:55.0 kg								
(Cont.)	POST	34 TO	1	34	R: GI BLEED S: GASTROINTESTINAL DISORDERS P: 胃腸出血 L: GI BLEED	E: 34 L: 1 Day I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GI BLEED C: No reasonable possibility
					R: E COLI SEPSIS S: INFECTIONS AND INFESTATIONS P: 大腸菌性敗血症 L: SEPTICEMIA DUE TO ESCHERICHIA COLI (E. COLI)	E: 59 L: 26 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33210# Age:6[redacted] Sex:Female Race:White Weight:96.0 kg								
	OPEN	1 TO 124	64	64	R: LACERATED FINGER S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 裂傷 L: LACERATION OF FINGER	E: 76 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: SUTURES APPLIED	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: FELL OFF LOUNGE CHAIR
33214# Age:7[redacted] Sex:Male Race:White Weight:73.7 kg								
	POST	105 TO	2	106	R: NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 好中球減少症 L: NEUTROPENIA	E: 108 L: 3 Days I: Yes	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF AML DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33214# Age:7[redacted] Sex:Male Race:White Weight:73.7 kg								
	(Cont.)	POST	105 TO	9	113	R: RESPIRATORY FAILURE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 呼吸不全 L: RESPIRATORY FAILURE	E: 126 L: 14 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: INTUBATED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF AML DISEASE C: No reasonable possibility
33216# Age:7[redacted] Sex:Female Race:White Weight:83.3 kg								
		POST	456 TO	15	470	R: HEADACHE S: NERVOUS SYSTEM DISORDERS P: 頭痛 L: HEADACHE	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P 2 PORTION - 600 MG QD 33217# Age:6[redacted] Sex:Female Race:White Weight:102.2 kg								
	OPEN	1 TO 84	84	84	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	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION A: OTHER: SUBJECT TAKEN OFF STUDY O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: 7+3	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML (DISEASE UNDER STUDY) C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 P_2 PORTION - 600 MG QD 33217# Age:6[redacted] Sex:Female Race:White Weight:102.2 kg									
(Cont.)		POST	85 TO	9	93	R: HEMORRHAGIC STROKE S: NERVOUS SYSTEM DISORDERS P: 出血性卒中 L: HEMORRHAGIC STROKE	E: 115 L: 23 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: OTHER: PT TAKEN OFF STUDY 7/18/16 O: OTHER: PT TRANSFERRED TO ICU	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSIVE AML C: No reasonable possibility
TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 33218# Age:7[redacted] Sex:Female Race: Weight:65.6 kg									
		POST	230 TO	19	248	R: PNEUMONITIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺臓炎 L: PNEUMONITIS	O: Yes I: Yes	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 COHORT C - PH2 PORTION - 600 MG QD 33220 Age:7[redacted] Sex:Female Race:White Weight:49.2 kg								
	OPEN	1 TO	293	293	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	I: Yes	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility
			420	420	R: ATRIAL FIBRILLATION S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION	E: 435 L: 16 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NONE C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 COHORT C - PH2 PORTION - 600 MG QD 33220 Age:7[redacted] Sex:Female Race:White Weight:49.2 kg								
(Cont.)	OPEN	1 TO	469	469	R: WEAKNESS SECONDARY TO METOPROLOL S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: WEAKNESS	E: 470 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT MEDICATION C: No reasonable possibility
			526	526	R: ATRIAL FIBRILLATION S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION	E: 526 L: 1 Day I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: METOPROLOL DOSE WAS INCREASED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICATION CHANGES, TOPROL WAS REDUCED BEFORE THE EVENT AND THEN THE EVENT HAPPENED C: No reasonable possibility

OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 OHORT C - PH2 PORTION - 600 MG QD 33220 Age:7[redacted] Sex:Female Race:White Weight:49.2 kg								
(Cont.)	OPEN	1 TO	689	689	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	E: 691 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RESPIRATORY SYNCYTIAL VIRUS C: No reasonable possibility
33221# Age:7[redacted] Sex:Male Race: Weight:74.2 kg								
	OPEN	1 TO 55	42	42	R: FAILURE TO THRIVE S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 33221# Age:7[redacted] Sex:Male Race: Weight:74.2 kg								
	(Cont.)	POST	56 TO	6	61	R: PROGRESSION OF PREEXISTING 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: 70 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
33222# Age:7[redacted] Sex:Male Race:White Weight:78.0 kg								
		OPEN	1 TO 42	26	26	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 27 L: 2 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 33222# Age:7[redacted] Sex:Male Race:White Weight:78.0 kg								
(Cont.)	POST	43 TO	1	43	R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎障害 L: ACUTE KIDNEY INJURY	O: Yes I: No	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
33223# Age:7[redacted] Sex:Male Race: Weight:68.3 kg								
	OPEN	1 TO 27	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: 16 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 33223# Age:7[redacted] Sex:Male Race: Weight:68.3 kg								
(Cont.)	OPEN	1 TO 27	27	27	R: LETHARGY S: NERVOUS SYSTEM DISORDERS P: 嗜眠 L: LETHARGY	E: 31 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
33224# Age:6[redacted] Sex:Female Race:White Weight:71.2 kg								
	OPEN	1 TO 26	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: 37 L: 13 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53188) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 33224# Age:6[redacted] Sex:Female Race:White Weight:71.2 kg							
(Cont.)	POST	27 TO	16	42	R: ALTERED MENTAL STATUS S: PSYCHIATRIC DISORDERS P: 精神状態変化 L: MENTAL STATUS CHANGES	E: 59 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 C_HORT 2 - 800 MG QD 34101# Age:6[redacted] Sex:Male Race:White Weight:87.4 kg								
	OPEN	1 TO 35	29	29	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 52 L: 24 Days I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROBABLE RELATIONSHIP TO DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34202# Age:7[redacted] Sex:Male Race:White Weight:78.9 kg								
	OPEN	1 TO 42	7	7	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 10 L: 4 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE OF ACUTE MYELOID LEUKEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P_2 PORTION - 600 MG QD 34202# Age:7[redacted] Sex:Male Race:White Weight:78.9 kg								
	(Cont.)	POST	43 TO	1	43	R: HEPATIC FAILURE S: HEPATOBILIARY DISORDERS P: 肝不全 L: HEPATIC FAILURE	E: 47 L: 5 Days I: No	D: No G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
34203# Age:7[redacted] Sex:Female Race:White Weight:69.9 kg								
		OPEN	1 TO 541	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: 39 L: 19 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EVENT RELATED TO DISEASE. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P_2 PORTION - 600 MG QD 34203# Age:7[redacted] Sex:Female Race:White Weight:69.9 kg								
(Cont.)	OPEN	1 TO 541	120	120	R: BACK PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 背部痛 L: BACK PAIN	E: 134 L: 15 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY C: No reasonable possibility
34204# Age:7[redacted] Sex:Male Race:White Weight:94.0 kg								
	OPEN	1 TO 320	119	119	R: SYMPTOMATIC HYPOTENSION, SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK S: CARDIAC DISORDERS P: 第一度房室ブロック L: AV BLOCK FIRST DEGREE	E: 122 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PT. HAS HISTORY OF TIA'S AND BRADYCARDIA. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34204# Age:7[redacted] Sex:Male Race:White Weight:94.0 kg							
	(Cont.)	OPEN	1 TO 320	119	119	R: SYMPTOMATIC HYPOTENSION, SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK S: CARDIAC DISORDERS P: 洞性徐脈 L: SINUS BRADYCARDIA	--Same as Above--	
						R: SYMPTOMATIC HYPOTENSION, SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34205# Age:7[redacted] Sex:Male Race:White Weight:83.9 kg								
	OPEN	1 TO 659	7	7	R: COLONIC PERFORATION S: GASTROINTESTINAL DISORDERS P: 大腸穿孔 L: COLONIC PERFORATION	E: 7 L: 1 Day I: No	D: No G: Grade 4 R1: No reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
			26	26	R: COLONIC OBSTRUCTION S: GASTROINTESTINAL DISORDERS P: 大腸閉塞 L: COLONIC OBSTRUCTION	E: 34 L: 9 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POST-SURGICAL ADHESIONS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34205# Age:7[redacted] Sex:Male Race:White Weight:83.9 kg								
	(Cont.)	OPEN	1 TO 659	27	27	R: VOMITING S: GASTROINTESTINAL DISORDERS P: 嘔吐 L: VOMITING	E: 29 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HAS HISTORY OF VOMITING AND NAUSEA. C: No reasonable possibility
				53	53	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 54 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML DISEASE UNDER STUDY C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34205# Age:7[redacted] Sex:Male Race:White Weight:83.9 kg								
(Cont.)	POST	660 TO	5	664	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	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: Reasonable possibility
34206# Age:7[redacted] Sex:Male Race:White Weight:122.2 kg								
	OPEN	1 TO 1046	13	13	R: BACTERIAL UPPER RESPIRATORY INFECTION S: INFECTIONS AND INFESTATIONS P: 細菌性上気道感染 L: UPPER RESPIRATORY TRACT INFECTION BACTERIAL	E: 30 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELATED TO AML DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34207# Age:7[redacted] Sex:Male Race:White Weight:91.7 kg								
	OPEN	1 TO 8	8	8	R: DIFFUSE ALVEOLAR HEMORRHAGE S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺胞出血 L: PULMONARY ALVEOLAR HEMORRHAGE	E: 10 L: 3 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: NONE	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELATED TO AML DISEASE PROGRESSION C: No reasonable possibility
34210# Age:8[redacted] Sex:Male Race:White Weight:80.9 kg								
	POST	166 TO	4	169	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 173 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OTHER, NOT KNOWN C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34211# Age:7[redacted] Sex:Male Race:White Weight:93.2 kg								
	OPEN	1 TO 79	30	30	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 43 L: 14 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING ACUTE MYELOID LEUKEMIA C: No reasonable possibility
34212# Age:6[redacted] Sex:Male Race:White Weight:79.0 kg								
	OPEN	1 TO 72	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: 29 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDERSTUDY, ACUTE MYELOID LEUKEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P 2 PORTION - 600 MG QD 34212# Age:6[redacted] Sex:Male Race:White Weight:79.0 kg								
	(Cont.)	OPEN	1 TO 72	40	40	R: GENERALIZED MUSCLE WEAKNESS S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 筋力低下 L: GENERALIZED MUSCLE WEAKNESS	E: 89 L: 50 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: NONE	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELATED TO UNDERLYING ACUTE MYELOID LEUKEMIA DISEASE AND ADRENAL FATIGUE C: No reasonable possibility
				44	44	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 49 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING ACUTE MYELOID LEUKEMIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 P_2 PORTION - 600 MG QD 34212# Age:6[redacted] Sex:Male Race:White Weight:79.0 kg								
(Cont.)	POST	73 TO	1	73	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 89 L: 17 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE RELATIONSHIP TO UNDERLYING ACUTE MYELOID LEUKEMIA C: No reasonable possibility
TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 34214# Age:8[redacted] Sex:Male Race:White Weight:80.9 kg								
	OPEN	1 TO 92	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 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE RELATED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 34214# Age:8[redacted] Sex:Male Race:White Weight:80.9 kg								
(Cont.)	OPEN	1 TO 92	29	29	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 34 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CALCIUM PYROPHOSPHATE DIHYDRATE CRYSTAL DEPOSITION DISEASE (CPPD) WITH SCAPHOLUNATE ADVANCED COLLAPSE (SLAC) WRIST C: No reasonable possibility
			77	77	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 82 L: 6 Days I: No	G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 34215# Age:7[redacted] Sex:Male Race:White Weight:109.1 kg								
	OPEN	1 TO 100	16	16	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 30 L: 15 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPSIS RELATED TO GRAM NEGATIVE RODS IN ADDITION TO AFIB WITH RVR ASSOCIATED WITH PATIENT'S PAST MEDICAL HISTORY. C: No reasonable possibility
			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 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (83690) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 34215# Age:7[redacted] Sex:Male Race:White Weight:109.1 kg								
(Cont.)	POST	101 TO	1	101	R: WHITE BLOOD CELL INCREASED S: INVESTIGATIONS P: 白血球数増加 L: WHITE BLOOD CELL INCREASED	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT ADMITTED DUE TO DISEASE PROGRESSION, WBC AT 63. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53442) TRT:ABT-199 C_HORT 2 - 800 MG QD 35101# Age:7[redacted] Sex:Male Race:White Weight:92.3 kg								
	OPEN	1 TO 131	11	11	R: NEAR SYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神寸前の状態 L: NEAR SYNCOPE	E: 11 L: 1 Day I: No	D: No G: Grade 2 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53442) TRT:ABT-199 C_HORT 2 - 800 MG QD 35101# Age:7[redacted] Sex:Male Race:White Weight:92.3 kg								
(Cont.)	OPEN	1 TO 131	12	12	R: ASPERGILLUS PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 気管支肺アスペルギルス症 L: PNEUMONIA ASPERGILLUS	O: Yes I: Yes	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53442) TRT:ABT-199 C_HORT 2 - 800 MG QD 35101# Age:7[redacted] Sex:Male Race:White Weight:92.3 kg								
(Cont.)	OPEN	1 TO 131	48	48	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 49 L: 2 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: RBC TRANSFUSIONS	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WAS FOUND WAS FOUND TO HAVE VERY LOW BLOOD COUNTS, WAS GIVEN BLOOD PRODUCTS OVER NIGHT IN HOSPITAL AND DISCHARGED THE NEXT MORNING. C: No reasonable possibility
	POST	132 TO	15	146	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 147 L: 2 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE PNEUMONIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53442) TRT:ABT-199 C_HORT 2 - 800 MG QD 35102# Age:7[redacted] Sex:Female Race:White Weight:63.0 kg							
	OPEN	1 TO 37	31	R: CANDIDA ALBICANS PNEUMONIA S: INFECTIONS AND INFESTATIONS P: カンジダ性肺炎 L: CANDIDA PNEUMONIA	E: 59 L: 29 Days I: No	D: No G: Grade 4 R1: Reasonable possibility R2: Reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40101# Age:7[redacted] Sex:Female Race:White Weight:73.7 kg								
	OPEN	1 TO 581	2	2	R: HYPERTENSION S: VASCULAR DISORDERS P: 高血圧 L: HYPERTENSION	E: 4 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: GIVEN ANTIHYPERTENSIVE (ACE-I) DRUG	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PRE-EXISTING ESSENTIAL HYPERTENSION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40101# Age:7[redacted] Sex:Female Race:White Weight:73.7 kg							
(Cont.)	OPEN	1 TO 581	10	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 11 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: URINE AND BLOOD CULTURES	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIA SECONDARY TO AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40101# Age:7[redacted] Sex:Female Race:White Weight:73.7 kg							
(Cont.)	OPEN	1 TO 581	30	R: CENTRAL CHEST PAIN: NON CARDIAC S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 非心臓性胸痛 L: CHEST PAIN (NON-CARDIAC)	E: 32 L: 3 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: LABS PERFORMED (TROPONIN AND CK), CHEST XRAY, LUNG VQ SCAN, ECG	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: G-CSF INJECTIONS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40101# Age:7[redacted] Sex:Female Race:White Weight:73.7 kg								
(Cont.)	OPEN	1 TO 581	232	232	R: FEBRILE ILLNESS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 239 L: 8 Days I: No	D: No G: Grade 1 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMMUNITY ACQUIRED INFECTION C: No reasonable possibility
			375	375	R: PRESYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神寸前の状態 L: PRESYNCOPE	E: 376 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? LOW BLOOD GLUCOSE, ? CARDIAC PRECIPITANT ? EXERCISE PRECIPTANT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40102# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
	OPEN	1 TO 507	4	4	R: PARAINFLUENZA 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: 10 L: 7 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: AML DISEASE ASSOCIATED NEUTROPENIA; C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40102# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
(Cont.)	OPEN	1 TO 507	5	5	R: ACUTE CORONARY SYNDROME S: CARDIAC DISORDERS P: 急性冠動脈症候群 L: ACUTE CORONARY SYNDROME	E: 6 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PARAINFLUENZA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40102# Age:7[redacted] Sex:Male Race:White Weight:69.7 kg								
(Cont.)	OPEN	1 TO 507	42	42	R: SYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神 L: SYNCOPE	E: 43 L: 2 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DEHYDRATION, HOT WEATHER C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40103# Age:7[redacted] Sex:Female Race:White Weight:58.6 kg								
	OPEN	1 TO 7	1	1	R: E.COLI URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 大腸菌性尿路感染 L: ESCHERICHIA URINARY TRACT INFECTION	E: 6 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: INFECTION + SUPPRESSION RELATED TO AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40103# Age:7[redacted] Sex:Female Race:White Weight:58.6 kg								
(Cont.)	OPEN	1 TO 7	3	3	R: WORSENING HYPONATRAEMIA S: METABOLISM AND NUTRITION DISORDERS P: 低ナトリウム血症 L: HYPONATRAEMIA AGGRAVATED	E: 8 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: REDUCTION IN IV FLUIDS	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: RELATED TO A COMBINATION OF AGGRESSIVE FLUID MANAGEMENT WITH TLS PROPHYLAXIS AND DIARRHOEA LEADING TO A FREE WATER EXCESS. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40103# Age:7[redacted] Sex:Female Race:White Weight:58.6 kg								
(Cont.)	OPEN	1 TO 7	7	7	R: SUBDURAL HAEMORRHAGE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 硬膜下出血 L: SUBDURAL HAEMORRHAGE	E: 13 L: 7 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: AGRESSIVE PLATELET TRANSFUSION SUPPORT. NEUROSURGICAL CONSULTATION - UNABLE TO PROCEED WITH SURGERY OWING TO THROMBOCYTOPENIA AND INABILITY TO ADEQUATELY SUPPORT PLATELET COUNTS.	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: THROMBOCYTOPENIA (DISEASE RELATED) C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 - 600 MG QD 40104# Age:6[redacted] Sex:Male Race:White Weight:60.4 kg								
	OPEN	1 TO 28	26	26	R: SERRATIA MARCESCENS SEPSIS S: INFECTIONS AND INFESTATIONS P: セラチア性敗血症 L: SERRATIA SEPSIS	E: 38 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: NEUTROPENIA SECONDARY TO AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40105# Age:7[redacted] Sex:Female Race:White Weight:60.3 kg								
	OPEN	1 TO 28	12	12	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 17 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOSUPPRESSED PATIENT WITH AML C: No reasonable possibility
	POST	29 TO	17	45	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 50 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION AND PROGRESSIVE DISEASE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40106# Age:7[redacted] Sex:Male Race:White Weight:84.0 kg								
	OPEN	1 TO 527	34	34	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 50 L: 17 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: OTHER: PATIENT'S ABT CURRENTLY INTERRUPTED NOT DUE TO THIS EVENT. MORE INFORMATION TO FOLLOW. O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40106# Age:7[redacted] Sex:Male Race:White Weight:84.0 kg								
	(Cont.)	OPEN	1 TO 527	99	99	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 104 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DISEASE RELATED NEUTROPENIA C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40106# Age:7[redacted] Sex:Male Race:White Weight:84.0 kg								
(Cont.)	OPEN	1 TO 527	525	525	R: FEVER SECONDARY TO LUNG INFECTION S: INFECTIONS AND INFESTATIONS P: 肺感染 L: LUNG INFECTION	O: Yes I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: O2 SUPPORT REQUIRED (HIGH FLOW, NP)	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ?FUNGAL LUNG INFECTION; IMMUNOCOMPROMISED PATIENT WITH AML C: No reasonable possibility
					R: FEVER SECONDARY TO LUNG INFECTION S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40107# Age:7[redacted] Sex:Male Race:White Weight:90.9 kg								
	OPEN	1 TO 28	14	14	R: BLEEDING HAEMORRHOIDS + COLONIC POLYP S: GASTROINTESTINAL DISORDERS P: 痔出血 L: HAEMORRHOIDAL BLEEDING	E: 30 L: 17 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PACKED RBC TRANSFUSION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: DISEASE RELATED (AML) C: No reasonable possibility
					R: BLEEDING HAEMORRHOIDS + COLONIC POLYP S: GASTROINTESTINAL DISORDERS P: 大腸ポリープ L: COLONIC POLYP		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40107# Age:7[redacted] Sex:Male Race:White Weight:90.9 kg								
	(Cont.)	OPEN	1 TO 28	20	20	R: E.COLI BACTERAEMIA S: INFECTIONS AND INFESTATIONS P: 大腸菌性菌血症 L: ESCHERICHIA COLI BACTERAEMIA	E: 30 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IMMUNOCOMPROMISED AML PATIENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 2 - 800 MG QD 40107# Age:7[redacted] Sex:Male Race:White Weight:90.9 kg								
(Cont.)	POST	29 TO	12	40	R: ABDOMINAL PAIN (GI DISORDER) S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 43 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ENLARGED SPLEEN IN A PATIENT WITH PRIOR MYELOFIBROSIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT 1 EXPANSION - 600 MG QD 40109# Age:7[redacted] Sex:Male Race:White Weight:75.6 kg								
	OPEN	1 TO 148	148	148	R: RAPIDLY INCREASING WHITE CELL COUNT (WBC) S: INVESTIGATIONS P: 白血球数増加 L: WHITE BLOOD CELL COUNT INCREASED	E: 155 L: 8 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - RELATED TO PROGRESSION A: DISC LDAC - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PROGRESSIVE DISEASE AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40202# Age:6[redacted] Sex:Female Race:White Weight:85.5 kg								
	OPEN	1 TO 523	522	522	R: ACUTE CHOLECYSTITIS S: HEPATOBILIARY DISORDERS P: 急性胆嚢炎 L: ACUTE CHOLECYSTITIS	E: 532 L: 11 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHOLELITHIASIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40203# Age:7[redacted] Sex:Male Race:White Weight:74.3 kg								
	OPEN	1 TO 438	5	5	R: PNEUMONIA - HOSPITAL ACQUIRED S: INFECTIONS AND INFESTATIONS P: 肺炎 L: HOSPITAL ACQUIRED PNEUMONIA	E: 26 L: 22 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO FLUID OVERLOAD C: No reasonable possibility
			40	40	R: INCREASED LIPASE AND AMYLASE S: INVESTIGATIONS P: アミラーゼ増加 L: AMYLASE INCREASED	E: 46 L: 7 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: OTHER: INVESTIGATION - CT SCAN PREDNISOLONE CEASED	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ? STEROID (PREDNISOLONE) INDUCED C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40203# Age:7[redacted] Sex:Male Race:White Weight:74.3 kg								
(Cont.)	OPEN	1 TO 438	40	40	R: INCREASED LIPASE AND AMYLASE S: INVESTIGATIONS P: リパーゼ増加 L: LIPASE INCREASED		--Same as Above--	
			404	404	R: URINARY RETENTION S: RENAL AND URINARY DISORDERS P: 尿閉 L: URINARY RETENTION	O: Yes I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: IN DWELLING CATHETER	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POST-OPERATIVE URINARY RETENTION; PROSTATE C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40205# Age:7[redacted] Sex:Female Race:White Weight:92.6 kg								
	OPEN	1 TO 942	13	13	R: MULTI-PATHOGEN BACTERAEMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTERAEMIA	E: 36 L: 24 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PORTACATH REMOVED, NEW PICC LINE INSERTED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LIKELY SOURCE OF MULTIPATHOGEN BACTERAEMIA = PORTACATH C: No reasonable possibility
			101	101	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 116 L: 16 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEUTROPENIC PATIENT C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40205# Age:7[redacted] Sex:Female Race:White Weight:92.6 kg							
	(Cont.)	OPEN	1 TO 942 167	167	R: HAEMATURIA AND ASSOCIATED DYSURIA S: RENAL AND URINARY DISORDERS P: 排尿困難 L: DYSURIA	E: 172 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC A: ABT-199 DOSE REDUCED O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PLATELET TRANSFUSION	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY TO GRADE 4 THROMBOCYTOPENIA; PATIENT'S RENAL HISTORY C: No reasonable possibility
					R: HAEMATURIA AND ASSOCIATED DYSURIA S: RENAL AND URINARY DISORDERS P: 血尿 L: HAEMATURIA		--Same as Above--	

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40205# Age:7[redacted] Sex:Female Race:White Weight:92.6 kg								
(Cont.)	OPEN	1 TO 942	210	210	R: UPPER RESPIRATORY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 上気道感染 L: UPPER RESPIRATORY TRACT INFECTION	E: 213 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? VIRAL C: No reasonable possibility
			454	454	R: LEFT ARM PICC ASSOCIATED OCCLUSIVE DVT S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 医療機器関連血栓症 L: CATHETER RELATED THROMBOSIS	E: 472 L: 19 Days I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40205# Age:7[redacted] Sex:Female Race:White Weight:92.6 kg								
(Cont.)	OPEN	1 TO 942	938	938	R: SUBACUTE/CHRONIC PULMONARY EMBOLI S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺塞栓症 L: CHRONIC PULMONARY EMBOLISM	O: Yes I: No	D: No G: Grade 2 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NIL OTHER CAUSE AS PER SUB-INVESTIGATOR C: No reasonable possibility
	POST	943 TO 9	9	951	R: UROSEPSIS IN DWELLING CATHETER RELATED CYSTITIS S: INFECTIONS AND INFESTATIONS P: 膀胱炎 L: CYSTITIS	E: 968 L: 18 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NIL OTHER CAUSE AS PER SUB-INVESTIGATOR C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40205# Age:7[redacted] Sex:Female Race:White Weight:92.6 kg							
(Cont.)	POST	943 TO 9	951	R: UROSEPSIS IN DWELLING CATHETER RELATED CYSTITIS S: INFECTIONS AND INFESTATIONS P: 医療機器関連感染 L: CATHETER RELATED INFECTION		--Same as Above--	
				R: UROSEPSIS IN DWELLING CATHETER RELATED CYSTITIS S: INFECTIONS AND INFESTATIONS P: 尿路性敗血症 L: UROSEPSIS		--Same as Above--	

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40206# Age:7[redacted] Sex:Female Race:White Weight:74.2 kg								
	OPEN	1 TO 659	23	23	R: GASTROENTERITIS S: INFECTIONS AND INFESTATIONS P: 胃腸炎 L: GASTROENTERITIS	E: 29 L: 7 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ? INFECTION C: No reasonable possibility
40207# Age:7[redacted] Sex:Male Race:White Weight:74.6 kg								
	OPEN	1 TO 447	5	5	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 10 L: 6 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ? OTHER INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40209# Age:7[redacted] Sex:Female Race:Black Weight:52.2 kg							
	OPEN	1 TO 42	42 42	R: INTENTIONAL OVERDOSE OF DIAZEPAM S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 企図的過量投与 L: INTENTIONAL OVERDOSE	E: 46 L: 5 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: OTHER: HOSPITALIZATION FOR OBSERVATION; PATIENT DECLINED FURTHER TREATMENT; LACK OF RESPONSE TO TRIAL TREATMENT	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DIAGNOSIS OF AML; RESISTANT DISEASE AT END OF CYCLE 1 C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40210# Age:7[redacted] Sex:Female Race:White Weight:60.9 kg								
	OPEN	1 TO 427	328	328	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 331 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LEUKAEMIA C: No reasonable possibility
			421	421	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 424 L: 4 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML DISEASE RELATED FEVER C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40211# Age:6[redacted] Sex:Female Race:White Weight:70.4 kg								
	OPEN	1 TO 293	34	34	R: RIGHT SIDED PLEURITIC CHEST PAIN S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 胸膜痛 L: PLEURITIC PAIN	E: 57 L: 24 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SMALL RIGHT-SIDED PLEURAL EFFUSION TOO SMALL TO TAP C: No reasonable possibility
			98	98	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 107 L: 10 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LIKELY DIVERTICULITIS C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40211# Age:6[redacted] Sex:Female Race:White Weight:70.4 kg								
	(Cont.)	OPEN	1 TO 293	133	133	R: DIVERTICULITIS S: INFECTIONS AND INFESTATIONS P: 憩室炎 L: DIVERTICULITIS	E: 140 L: 8 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION/ ABDO SEPSIS, CONSTIPATION C: No reasonable possibility
				209	209	R: AVASCULAR NECROSIS LEFT HIP S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 骨壊死 L: AVASCULAR NECROSIS	E: 265 L: 57 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SEPTIC ARTHRITIS, HIP C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40211# Age:6[redacted] Sex:Female Race:White Weight:70.4 kg							
	(Cont.)	OPEN 1 TO 293	272	R: PNEUMOCYSTIS PNEUMONIA S: INFECTIONS AND INFESTATIONS P: ニューモシスチス・イロベチイ肺炎 L: PNEUMOCYSTIS PNEUMONIA	E: 286 L: 15 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CHEST INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40211# Age:6[redacted] Sex:Female Race:White Weight:70.4 kg								
(Cont.)	OPEN	1 TO 293	293	293	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 306 L: 14 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40213# Age:7[redacted] Sex:Male Race:White Weight:82.4 kg								
	OPEN	1 TO 28	6	6	R: BACILLUS LICHENIFORMIS SEPTICAEMIA S: INFECTIONS AND INFESTATIONS P: 細菌性敗血症 L: BACTERIAL SEPSIS	E: 18 L: 13 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOSUPPRESSED NEUTROPENIC AML PATIENT C: No reasonable possibility
40214# Age:6[redacted] Sex:Male Race:White Weight:93.7 kg								
	OPEN	1 TO 28	14	14	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 46 L: 33 Days I: No	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: IMMUNOCOMPROMISED PATIENT WITH AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 P 2 PORTION - 600 MG QD 40214# Age:6[redacted] Sex:Male Race:White Weight:93.7 kg							
(Cont.)	OPEN	1 TO 28	17	17	R: HAEMOLYTIC ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 溶血性貧血 L: HEMOLYTIC ANEMIA	O: Yes I: Yes	D: No G: Grade 3 R1: No reasonable possibility R2: No reasonable possibility A: NONE O: OTHER: BLOOD TRANSFUSION AS REQUIRED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RED CELL ALLO ANTIBODY DETECTED - ANTI-LU1. C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 40216# Age:8[redacted] Sex:Female Race:White Weight:62.9 kg								
	OPEN	1 TO 12	9	9	R: CHEST INFECTION - SEPSIS S: INFECTIONS AND INFESTATIONS P: 肺敗血症 L: PULMONARY SEPSIS	E: 15 L: 7 Days I: No	D: No G: Grade 4 R1: No reasonable possibility R2: No reasonable possibility A: DISC ABT-199 - NOT RELATED TO PROGRESSION A: DISC LDAC - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IMMUNOCOMPROMISED ELDERLY PATIENT WITH NEW DIAGNOSIS OF AML C: No reasonable possibility

# Subject prematurely discontinued ABT-199.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 40218# Age:7[redacted] Sex:Male Race:White Weight:80.9 kg								
	POST	49 TO	4	52	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 80 L: 29 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: INTERRUPTION OF ABT-199 A: INTERRUPTION OF LDAC O: CONCOMITANT MEDICATION PRESCRIBED	R: No S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-387)

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 21.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? D: Duration L: Length I: Intermittent?	D: DLT Event G: NCI Toxicity -Relationship to- R1: ABT-199 R2: CYTARABINE A: Action Taken with Study Treatment O: Other Actions Taken	R: Related to TLS? S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (53332) TRT:ABT-199 C_HORT C - PH2 PORTION - 600 MG QD 40219# Age:6[redacted] Sex:Female Race:White Weight:71.2 kg							
	POST	29 TO	13 41	R: EPISTAXIS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻出血 L: EPISTAXIS	E: 44 L: 4 Days I: No	D: No G: Grade 3 R1: Reasonable possibility R2: Reasonable possibility A: NONE O: OTHER: PLATELET TRANSFUSION	R: No S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: Reasonable possibility

# Subject prematurely discontinued ABT-199.
POST = Off.

Program Source Code: [redacted]

表 2.7.4-103.　　重篤な有害事象を発現した被験者一覧（M14-212 試験）

[redacted]
VENETOCLAX (ABT-199)
ADDITIONAL ANALYSIS REPORT FOR JAPAN CTD274-AML JNDA (SAFETY)
R&D/19/0377 - CLINICAL/STATISTICAL

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40001# Age:5[redacted] Sex:Female Race:White Weight:63.1 kg							
	OPEN	1 TO 35	16	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 23 L: 8 Days I: Yes	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING DISEASE (AML) C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40001# Age:5[redacted] Sex:Female Race:White Weight:63.1 kg							
(Cont.)	OPEN	1 TO 35	26	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 33 L: 8 Days I: Yes	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40001# Age:5[redacted] Sex:Female Race:White Weight:63.1 kg							
(Cont.)	OPEN	1 TO 35	34	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 38 L: 5 Days I: Yes	G: Grade 3 R: No reasonable possibility A: DRUG WITHDRAWN - RELATED TO PROGRESSION A: DISCONTINUED STUDY - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: UNDERLYING DISEASE (AML) C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40003#	Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg							
		OPEN	1 TO 127	105	R: INFECTION-OTHER (PSEUDOMONAS BACTEREMIA) S: INFECTIONS AND INFESTATIONS P: シュードモナス性菌血症 L: PSEUDOMONAL BACTEREMIA	E: 110 L: 6 Days I: No	G: Grade 3 R: Reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME C: No reasonable possibility
					R: ACUTE PHARYNGITIS S: INFECTIONS AND INFESTATIONS P: 咽頭炎 L: ACUTE PHARYNGITIS	E: 110 L: 6 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE PHARYNGITIS (PRESUMED VIRAL) C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40003# Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg							
(Cont.)	OPEN	1 TO 127	120	R: ACUTE PHARYNGITIS (VIRAL) S: INFECTIONS AND INFESTATIONS P: ウイルス性咽頭炎 L: VIRAL PHARYNGITIS	E: 128 L: 9 Days I: No	G: Grade 2 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: ADENOVIRUS INFECTION C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50907) TRT:ABT-199 40003# Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg							
(Cont.)	OPEN	1 TO 127	123	R: HERPETIC NEURALGIA S: NERVOUS SYSTEM DISORDERS P: ヘルペス後神経痛 L: POST HERPETIC NEURALGIA	E: 127 L: 5 Days I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HERPES OTICUS C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Day Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40003# Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg							
(Cont.)	POST	128 TO 3	130	R: PSEUDOMONAS CATHETER RELATED INFECTION S: INFECTIONS AND INFESTATIONS P: シュードモナス感染 L: PSEUDOMONAS INFECTION	E: 130 L: 1 Day I: Yes	G: Grade 3 R: No reasonable possibility A: OTHER: PT. OFF TREATMENT WITH STUDY DRUG SINCE 8/1/14 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: PT. IS IMMUNOCOMPROMISED AND HAS RECENT HISTORY OF PSEUDOMONAS BACTEREMIA. C: No reasonable possibility

# Subject prematurely discontinued study.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40003# Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg								
(Cont.)	POST	128 TO	3	130	R: PAIN (RIGHT JAW) S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 顎痛 L: PAIN JAW	E: 137 L: 8 Days I: No	G: Grade 3 R: No reasonable possibility A: OTHER: PATIENT IS OFF STUDY DRUG SINCE 8/1/14 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: HERPES NEURALGIA VERSUS BONE PAIN DUE TO DISEASE PROGRESSION C: No reasonable possibility

# Subject prematurely discontinued study.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50907) TRT:ABT-199 40003# Age:3[redacted] Sex:Female Race:Black Weight:54.5 kg							
(Cont.)	POST	128 TO 145	18	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 149 L: 5 Days I: No	G: Grade 3 R: No reasonable possibility A: OTHER: PATIENT OFF STUDY DRUG SINCE 8/1/14 O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL EVENT REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT SERIOUS OUTCOME O: IMMUNOCOMPROMISED STATE DUE TO UNDERLYING AML; PATIENT ON PALLIATIVE PO CYTARABINE. C: No reasonable possibility

# Subject prematurely discontinued study.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20001# Age:7[redacted] Sex:Male Race:Asian Weight:74.3 kg							
	OPEN	1 TO 21	2	R: ATRIAL FIBRILLATION S: CARDIAC DISORDERS P: 心房細動 L: ATRIAL FIBRILLATION	E: 13 L: 12 Days I: Yes	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ELECTROLYTE IMBALANCE C: No reasonable possibility
20002# Age:8[redacted] Sex:Male Race:White Weight:81.7 kg							
	OPEN	1 TO 106	25	R: HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION	E: 27 L: 3 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SYNCOPE, CHEST PAIN C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20002#	Age:8[redacted]	Sex:Male	Race:White	Weight:81.7 kg				
(Cont.)		POST	107 TO 1	107	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 109 L: 3 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			20	126	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 138 L: 13 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20003#	Age:7[redacted]	Sex:Male	Race:White	Weight:91.9 kg				
		OPEN	1 TO 29	7	7	R: GENERALIZED MUSCLE WEAKNESS S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 筋力低下 L: GENERALIZED MUSCLE WEAKNESS	E: 10 L: 4 Days I: No	G: Grade 2 R: No reasonable possibility A: NONE O: OTHER: PHYSICAL THERAPY	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DECONDITIONED C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20003#	Age:7[redacted] Sex:Male Race:White Weight:91.9 kg							
(Cont.)		OPEN	1 TO 29	24	R: MALIGNANT PLEURAL EFFUSION S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 悪性胸水 L: MALIGNANT PLEURAL EFFUSION	E: 35 L: 12 Days I: No	G: Grade 3 R: No reasonable possibility A: DRUG WITHDRAWN - RELATED TO PROGRESSION A: DISCONTINUED STUDY - RELATED TO PROGRESSION O: OTHER: CT CHEST, CXRAY, THORACENTESIS	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
20004#	Age:5[redacted] Sex:Female Race:White Weight:46.8 kg							
		POST	29 TO	1	R: SINUSITIS, RHINORRHEA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻漏 L: RHINORRHEA	E: 36 L: 8 Days I: Yes	G: Grade 1 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20004# Age:5[redacted] Sex:Female Race:White Weight:46.8 kg							
(Cont.)	POST	29 TO 29	1	R: SINUSITIS, RHINORRHEA S: INFECTIONS AND INFESTATIONS P: 副鼻腔炎 L: SINUSITIS		--Same as Above--	
20006# Age:7[redacted] Sex:Female Race:White Weight:66.0 kg							
	OPEN	1 TO 30	1	R: UTI S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: UTI	E: 8 L: 8 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
20007# Age:6[redacted] Sex:Male Race:Asian Weight:67.4 kg							
	OPEN	1 TO 82	14	R: LEFT SCROTAL CELLULITIS S: INFECTIONS AND INFESTATIONS P: 男性外性器蜂巣炎 L: CELLULITIS GENITAL ORGAN (MALE)	E: 22 L: 9 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20007# Age:6[redacted] Sex:Male Race:Asian Weight:67.4 kg							
(Cont.)	OPEN	1 TO 82	35	R: SCROTAL PAIN S: REPRODUCTIVE SYSTEM AND BREAST DISORDERS P: 陰嚢痛 L: SCROTAL PAIN	E: 41 L: 7 Days I: Yes	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SCROTAL LESION C: No reasonable possibility
			67	R: SCROTAL CELLULITIS S: INFECTIONS AND INFESTATIONS P: 男性外性器蜂巣炎 L: CELLULITIS OF MALE EXTERNAL GENITAL ORGAN	E: 79 L: 13 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20007# Age:6[redacted] Sex:Male Race:Asian Weight:67.4 kg								
(Cont.)	OPEN	1 TO 82	67	67	R: SEPTIC SHOCK S: INFECTIONS AND INFESTATIONS P: 敗血症性ショック L: SEPTIC SHOCK	E: 79 L: 13 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, NEUTROPENIA C: No reasonable possibility
			82	82	R: FAILURE TO THRIVE, WEAKNESS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 無力症 L: WEAKNESS R: FAILURE TO THRIVE, WEAKNESS S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	E: 103 L: 22 Days I: No	G: Grade 2 R: No reasonable possibility A: DRUG WITHDRAWN - RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED --Same as Above--	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20007# Age:6[redacted] Sex:Male Race:Asian Weight:67.4 kg								
(Cont.)		POST	83 TO 105	23	R: SEPTIC SHOCK S: INFECTIONS AND INFESTATIONS P: 敗血症性ショック L: SEPTIC SHOCK	E: 141 L: 37 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20009# Age:7[redacted] Sex:Female Race:White Weight:78.3 kg								
		OPEN	1 TO 144	130	R: LEPTOTRICHIA BUCCALIS BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 菌血症 L: BACTEREMIA	E: 131 L: 2 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION, NEUTROPENIA C: No reasonable possibility
				130	R: LEPTOTRICHIA BUCCALIS BACTEREMIA S: INFECTIONS AND INFESTATIONS P: レプトトリキア感染 L: LEPTOTRICHIA BUCCALIS INFECTION		--Same as Above--	

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term / S: System Organ Class / P: MedDRA ver. 18.1 Preferred Term / L: Lower Level Term	E: RX Day Ended / O: Ongoing at the End of Study / L: Length / I: Intermittent?	G: NCI Toxicity / R: Relationship to Study Drug / A: Action Taken with Study Treatment / O: Other Actions Taken	S: Serious AE? / O: Other Cause of Event / C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20009# Age:7[redacted] Sex:Female Race:White Weight:78.3 kg							
(Cont.)	OPEN	1 TO 144	130	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 133 L: 4 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			138	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 146 L: 9 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility
20010# Age:7[redacted] Sex:Female Race:White Weight:81.0 kg							
	POST	31 TO	9	R: ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 42 L: 4 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20010# Age:7[redacted] Sex:Female Race:White Weight:81.0 kg							
(Cont.)	POST	31 TO 54	24	R: LABIAL CELLULITIS S: INFECTIONS AND INFESTATIONS P: 女性外陰部蜂巣炎 L: VULVAL CELLULITIS	E: 77 L: 24 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20011# Age:6[redacted] Sex:Male Race:White Weight:102.9 kg							
	OPEN	1 TO 66	21	R: LEFT HYDROCELE S: CONGENITAL, FAMILIAL AND GENETIC DISORDERS P: 陰嚢水瘤 L: HYDROCELE	E: 25 L: 5 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING AML C: No reasonable possibility
20012# Age:6[redacted] Sex:Female Race:Black Weight:69.3 kg							
	OPEN	1 TO 103	46	R: VRE BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 腸球菌性菌血症 L: ENTEROCOCCAL BACTEREMIA	E: 52 L: 7 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20012# Age:6[redacted] Sex:Female Race:Black Weight:69.3 kg							
(Cont.)	OPEN	1 TO 103	63	R: LEFT LOWER EXTERMITY CELLULITIS S: INFECTIONS AND INFESTATIONS P: 蜂巣炎 L: CELLULITIS OF LEG	E: 80 L: 18 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
			84	R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎不全 L: ACUTE KIDNEY INJURY	E: 88 L: 5 Days I: No	G: Grade 2 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POOR ORAL INTAKE C: No reasonable possibility
			103	R: CATHETER RELATED BACTEREMIA S: INFECTIONS AND INFESTATIONS P: 医療機器関連感染 L: CATHETER BACTEREMIA	E: 111 L: 9 Days I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20012#	Age:6[redacted] Sex:Female Race:Black Weight:69.3 kg							
(Cont.)		OPEN	1 TO 103	103	R: URINARY TRACT INFECTION S: INFECTIONS AND INFESTATIONS P: 尿路感染 L: URINARY TRACT INFECTION	E: 111 L: 9 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
20013#	Age:7[redacted] Sex:Female Race:Black Weight:71.4 kg							
		OPEN	1 TO 255	29	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 36 L: 8 Days I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
				255	R: MESENTERIC ENTERITIS S: GASTROINTESTINAL DISORDERS P: 腸間膜炎 L: MESENTERITIS	E: 262 L: 8 Days I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50869) TRT:ABT-199 20014# Age:7[redacted] Sex:Female Race:Black Weight:103.5 kg							
	POST	106 TO 117	12	R: MULTIFOCAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 143 L: 27 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION C: No reasonable possibility
				R: ACUTE KIDNEY INJURY S: RENAL AND URINARY DISORDERS P: 急性腎不全 L: ACUTE KIDNEY INJURY	E: 143 L: 27 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NEW AML TREATMENT C: No reasonable possibility
20015# Age:6[redacted] Sex:Male Race:White Weight:72.0 kg							
	OPEN	1 TO 27	3	R: FUNGAL PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 真菌性肺炎 L: PNEUMONIA FUNGAL	E: 13 L: 11 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:ABT-199 30002# Age:4[redacted] Sex:Female Race:White Weight:50.3 kg							
	POST	20 TO 6	25	R: FAILURE TO THRIVE S: METABOLISM AND NUTRITION DISORDERS P: 成長障害 L: FAILURE TO THRIVE	O: Yes I: No	G: Grade 3 R: No reasonable possibility A: OTHER: SUBJECT'S LAST DOSE OF ABT-199 WAS ON 15-FEB-2014. SUBJECT DID NOT RESTART AND DISCONTINUED STUDY ON 18-FEB-2013. O: OTHER: SUBJECT DID NOT RESTART AND DISCONTINUED STUDY ON 18-FEB-2013.	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: RELATED TO AML C: No reasonable possibility

# Subject prematurely discontinued study.
POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50839) TRT:ABT-199 30005#	Age:7[redacted] Sex:Male Race:White Weight:91.0 kg							
		OPEN	1 TO 85	44	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 52 L: 9 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility
		POST	86 TO	4	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: No reasonable possibility A: OTHER: PATIENT HAD ALREADY ENDED TREATMENT PRIOR TO THIS EVENT O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AML C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:ABT-199 10003# Age:7[redacted] Sex:Male Race:White Weight:79.0 kg								
		OPEN	1 TO 246	14	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 22 L: 9 Days I: No	G: Grade 4 R: Reasonable possibility A: DRUG WITHDRAWN - NOT RELATED TO PROGRESSION O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility
10004# Age:7[redacted] Sex:Male Race:White Weight:73.1 kg								
		OPEN	1 TO 246	240	R: PRESYNCOPE S: NERVOUS SYSTEM DISORDERS P: 失神寸前の状態 L: PRESYNCOPE	E: 241 L: 2 Days I: No	G: Grade 2 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HYPONATREMIA; HYPOVOLEMIA C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10007# Age:1[redacted] Sex:Male Race:White Weight:71.0 kg								
		OPEN	1 TO 59	59	R: PROGRESSION OF PRE-EXISTING CANCER, LEFT SIDED ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	O: Yes I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROGRESSION OF UNDERLYING AML C: No reasonable possibility
				59	R: PROGRESSION OF PRE-EXISTING CANCER, LEFT SIDED ABDOMINAL PAIN S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 悪性新生物進行 L: PROGRESSION OF PRE-EXISTING CANCER		--Same as Above--	

# Subject prematurely discontinued study.
OPEN = Open Label.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10008#	Age:5[redacted] Sex:Female Race:White Weight:54.9 kg							
		POST	14 TO 2	15	R: INTRA-ABDOMINAL BLEEDING S: GASTROINTESTINAL DISORDERS P: 腹腔内出血 L: INTRA-ABDOMINAL BLEEDING	O: Yes I: No	G: Grade 4 R: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SPONTANEOUS SPLENIC ARTERIAL BLEED C: No reasonable possibility
10009#	Age:6[redacted] Sex:Female Race:White Weight:125.8 kg							
		OPEN	1 TO 49	18 18	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 40 L: 23 Days I: Yes	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN AT THIS TIME. C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term / S: System Organ Class / P: MedDRA ver. 18.1 Preferred Term / L: Lower Level Term	E: RX Day Ended / O: Ongoing at the End of Study / L: Length / I: Intermittent?	G: NCI Toxicity / R: Relationship to Study Drug / A: Action Taken with Study Treatment / O: Other Actions Taken	S: Serious AE? / O: Other Cause of Event / C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10009# Age:6[redacted] Sex:Female Race:White Weight:125.8 kg							
(Cont.)	OPEN	1 TO 49	44	R: HYPOKALEMIA S: METABOLISM AND NUTRITION DISORDERS P: 低カリウム血症 L: HYPOKALEMIA	O: Yes I: No	G: Grade 4 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN AT THIS TIME. C: No reasonable possibility
	POST	50 TO	7	56	R: DEHYDRATION, HYPOTENSION S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 57 L: 2 Days I: No	G: Grade 3 R: No reasonable possibility A: OTHER: PATIENT WAS DISCONTINUED THE DAY BEFORE THIS EVENT, AND NEXT DAY WAS FOUND TO BE DEHYDRATED AND HYPOTENSIVE. O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE; PATIENT NEGLECT OF SELF C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10009# Age:6[redacted] Sex:Female Race:White Weight:125.8 kg							
(Cont.)	POST	50 TO 7	56	R: DEHYDRATION, HYPOTENSION S: VASCULAR DISORDERS P: 低血圧 L: HYPOTENSION		--Same as Above--	
10010# Age:7[redacted] Sex:Male Race:White Weight:98.2 kg							
	OPEN	1 TO 169	115	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: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: Reasonable possibility
			115	R: DIARRHEA S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHEA	O: Yes I: No	G: Grade 3 R: Reasonable possibility A: DOSE INTERRUPTED O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10010# Age:7[redacted] Sex:Male Race:White Weight:98.2 kg							
(Cont.)	OPEN	1 TO 169	123	R: FEVER S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 124 L: 2 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE. C: No reasonable possibility
	POST	170 TO	24	193	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 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility
10011# Age:8[redacted] Sex:Male Race:White Weight:68.7 kg							
	OPEN	1 TO 142	18	18	R: FEBRILE NEUTROPENIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: FEBRILE NEUTROPENIA	E: 31 L: 14 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV:[redacted] (50868) TRT:ABT-199 10011#	Age:8[redacted]	Sex:Male	Race:White	Weight:68.7 kg				
(Cont.)	OPEN	1 TO 142	136	136	R: SEPSIS S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS	E: 142 L: 7 Days I: No	G: Grade 4 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE. C: No reasonable possibility
					R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 142 L: 7 Days I: No	G: Grade 3 R: No reasonable possibility A: DOSE INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE. C: No reasonable possibility
	POST	143 TO	13	155	R: NEUTROPENIC FEVER S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 発熱性好中球減少症 L: NEUTROPENIC FEVER	E: 162 L: 8 Days I: No	G: Grade 4 R: No reasonable possibility A: NONE O: NONE	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE C: No reasonable possibility

# Subject prematurely discontinued study.
OPEN = Open Label. POST = Off.

Program Source Code: [redacted]

TABLE 1__11.5

Listing of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Death)
(Safety Analysis Set - M14-212)

Subject Number	Epoch Name	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA ver. 18.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	G: NCI Toxicity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event C: Sponsor Opinion of Causality
INV: [redacted] (50868) TRT:ABT-199 10011# Age:8[redacted] Sex:Male Race:White Weight:68.7 kg							
(Cont.)	POST	143 TO 155	13	R: CONGESTIVE HEART FAILURE S: CARDIAC DISORDERS P: うっ血性心不全 L: CONGESTIVE HEART FAILURE	E: 162 L: 8 Days I: No	G: Grade 3 R: No reasonable possibility A: NONE O: OTHER: CONMEDS WERE GIVEN FOR THE HYPOXIA ASSOCIATED WITH CHF.	S: Yes, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN ETIOLOGY C: No reasonable possibility

# Subject prematurely discontinued study.
POST = Off.

Program Source Code: [redacted]

2.7.5 参考文献

参考文献は，各セクションの末尾に記載した。