表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		F	URINARY TRACT INFECTION Infections and infestations Urinary tract infection	01MAR20[redacted] 10MAR20[redacted] 10D 21	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				PNEUMONIA Infections and infestations Pneumonia	01MAR20[redacted] 10MAR20[redacted] 10D 21	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	LUNG CANCER RECURRENCE Neoplasms benign, malignant and unspecified (incl cysts and polyps) Lung carcinoma cell type unspecified recurrent	11APR20[redacted] 42	Grade 2 - HOSP	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study	Not Recovered /Not Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		F	ANEMIA Blood and lymphatic system disorders Anaemia	03MAR20[redacted] 11MAR20[redacted] 9D 43	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	SEPSIS Infections and infestations Sepsis	17MAR20[redacted] 17MAR20[redacted] 1D 31	Grade 5 - DTH	Unlikely - Unlikely	Dose Not Changed - None	Fatal
			F	ACUTE RENAL FAILURE Renal and urinary disorders Acute kidney injury	06APR20[redacted] 11APR20[redacted] 6D 29	Grade 2 - HOSP	Unlikely - Unlikely	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		F	DIABETES Metabolism and nutrition disorders Diabetes mellitus	08APR20[redacted] 12APR20[redacted] 5D 10	Grade 2 - HOSP	Unlikely - Possibly	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved With Sequelae
				ANEMIA AS A RESULT OF BLEEDING FROM GASTROINTESTINAL TRACK Blood and lymphatic system disorders Anaemia	22APR20[redacted] 24	Grade 4 - HOSP	Unlikely - Possibly	Dose Not Changed - Specific Therapy / Medication	Recovering /Resolving
				GASTROINTESTINAL BLEEDING Gastrointestinal disorders Gastrointestinal haemorrhage	22APR20[redacted] 24	Grade 3 - HOSP	Unlikely - Possibly	Dose Not Changed - Specific Therapy / Medication	Recovering /Resolving

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		M	THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	04MAY20[redacted] 9	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - None	Not Recovered /Not Resolved
				GASTRITIS Gastrointestinal disorders Gastritis	04MAY20[redacted] 9	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	06MAY20[redacted] 11	Grade 4 - LT	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		M	NEPHROPATHY Renal and urinary disorders Nephropathy	07MAY20[redacted] 08MAY20[redacted] 2D 12	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Fatal
			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	14JAN20[redacted]/08:58 18JAN20[redacted]/11:09 4D02H11M 16	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	FEMORAL NECK FRACTURE Injury, poisoning and procedural complications Femoral neck fracture	04FEB20[redacted]/11:00 07MAR20[redacted]/07:02 31D20H02M 24	Grade 3 - DI	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		F	THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	11APR20[redacted] 13	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovering /Resolving
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	11APR20[redacted] 17APR20[redacted] 7D 13	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	20JUN20[redacted] 21JUN20[redacted] 2D 69	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Poland	[redacted]		M	ANEMIA Blood and lymphatic system disorders Anaemia	20JUN20[redacted] 21JUN20[redacted] 2D 69	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	SUDDEN DEATH General disorders and administration site conditions Sudden death	19APR20[redacted]/12:15 19APR20[redacted]/12:15 0D00H00M 8	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
			M	INFECTION OF UNKNOWN ORIGIN Infections and infestations Infection	08JUN20[redacted] 15JUN20[redacted] 8D 44	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Serbia	[redacted]		F	SUDDEN DEATH, CAUSE UNKNOWN General disorders and administration site conditions Sudden death	17MAY20[redacted] 17MAY20[redacted] 1D 62	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - Subject Withdrawn From Study	Fatal
			F	SUDDEN DEATH General disorders and administration site conditions Sudden death	25MAY20[redacted] 25MAY20[redacted] 1D 52	Grade 5 - DTH	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study	Fatal
			M	THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	16JUN20[redacted]/08:17 22JUN20[redacted]/11:02 6D02H45M 79	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Serbia	[redacted]		M	THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	02JUN20[redacted]/08:03 04JUN20[redacted]/08:00 1D23H57M 16	Grade 4 - LT	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				ILEUS Gastrointestinal disorders Ileus	28MAY20[redacted] 08JUN20[redacted] 12D 11	Grade 3 - HOSP,LT	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study	Recovered /Resolved
			M	ESOPHAGEAL STENOSIS Gastrointestinal disorders Oesophageal stenosis	17MAY20[redacted] 01JUN20[redacted] 16D 70	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Spain	[redacted]		F	EDEMA LIMBS General disorders and administration site conditions Oedema peripheral	11APR20[redacted] 21APR20[redacted] 11D 43	Grade 5 - LT,DTH	Unlikely - Unlikely	Dose Not Changed - Specific Therapy / Medication	Fatal
				LEFT PLEURAL EFFUSION Respiratory, thoracic and mediastinal disorders Pleural effusion	12APR20[redacted] 44	Grade 2 - HOSP	Not Related - Unlikely	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
				URINE INFECTION Infections and infestations Urinary tract infection	12APR20[redacted] 44	Grade 2 - IME	Unlikely - Unlikely	Dose Not Changed - Specific Therapy / Medication	Recovering /Resolving

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Spain	[redacted]		M	ANURIA Renal and urinary disorders Anuria	14JUL20[redacted]/16:00 19JUL20[redacted] 6D 80	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				ANAEMIA Blood and lymphatic system disorders Anaemia	14JUL20[redacted]/16:00 80	Grade 1 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
				HEMATURIA Renal and urinary disorders Haematuria	14JUL20[redacted]/16:00 19JUL20[redacted] 6D 80	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Spain	[redacted]		M	RENAL FAILURE Renal and urinary disorders Renal failure	15JUN20[redacted] 18JUN20[redacted] 4D 51	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				URINARY TRACT INFECTION Infections and infestations Urinary tract infection	15JUN20[redacted] 23JUN20[redacted] 9D 51	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				ANEMIA Blood and lymphatic system disorders Anaemia	16JUN20[redacted] 23JUN20[redacted] 8D 52	Grade 2 - IME	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Spain	[redacted]		M	HEMATURIA Renal and urinary disorders Haematuria	26APR20[redacted] 04MAY20[redacted] 9D 1	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
Ukraine			M	STROKE Nervous system disorders Cerebrovascular accident	09MAR20[redacted] 22MAR20[redacted] 14D 50	Grade 4 - HOSP,LT	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovered /Resolved
			F	DUODENAL ULCER Gastrointestinal disorders Duodenal ulcer	11APR20[redacted]/08:50 20	Grade 4 - HOSP	Not Related - Possibly	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovering /Resolving

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Ukraine	[redacted]		F	STOMACH BLEEDING, FORREST IA Gastrointestinal disorders Gastric haemorrhage	11APR20[redacted]/08:50 11APR20[redacted]/12:40 0D03H50M 20	Grade 3 - HOSP,LT	Not Related - Possibly	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	01FEB20[redacted]/09:05 04FEB20[redacted]/08:10 2D23H05M 7	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	ACUTE PNEUMONIA Infections and infestations Pneumonia	13JUN20[redacted]/10:00 13JUN20[redacted]/22:52 0D12H52M 27	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Fatal

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
Ukraine	[redacted]		F	DEATH DUE TO UNKNOWN CAUSE General disorders and administration site conditions Death	10MAY20[redacted] 10MAY20[redacted]/05:32 1D 7	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
			M	GASTRIC CANCER PROGRESSION Neoplasms benign, malignant and unspecified (incl cysts and polyps) Malignant neoplasm progression	03JAN20[redacted] 05JAN20[redacted] 3D 14	Grade 5 - DTH	Not Related - Not Related	Drug Withdrawn - None	Fatal
			M	SCLC PROGRESSION Neoplasms benign, malignant and unspecified (incl cysts and polyps) Malignant neoplasm progression	25JAN20[redacted]/19:00 25JAN20[redacted]/19:00 0D00H00M 48	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
United States	[redacted]		F	SYNCOPE Nervous system disorders Syncope	06JUN20[redacted] 06JUN20[redacted] 1D 48	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				GASTRITIS Gastrointestinal disorders Gastritis	14MAY20[redacted]/07:30 18MAY20[redacted]/11:19 4D03H49M 25	Grade 2 - HOSP	Unlikely - Probably	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				BACK PAIN Musculoskeletal and connective tissue disorders Back pain	14MAY20[redacted]/07:30 02JUN20[redacted]/07:30 19D00H00M 25	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved With Sequelae

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）（続き）

Country	Site	Patient ID	Gender	AE Verbatim Term MedDRA SOC Name MedDRA Preferred term	Start Date/Time Stop Date/Time Duration (Days, Hours, Minutes)* Day of Onset	Intensity CTC grade - SAE Criteria	Relationship to Study Drug - Relationship to Dexamethasone	Action Taken with Study Drug - Other Action Taken	Outcome
United States	[redacted]		F	MULTIPLE PULMONARY EMBOLI Respiratory, thoracic and mediastinal disorders Pulmonary embolism	28DEC20[redacted] 02JAN20[redacted] 6D 7	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	MALNUTRITION Metabolism and nutrition disorders Malnutrition	08MAR20[redacted] 09MAR20[redacted] 2D 7	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				PROGRESSIVE DISEASE General disorders and administration site conditions Disease progression	22MAR20[redacted] 22MAR20[redacted] 1D 21	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal

第 5.3.5.1.6 項 NETU-15-18 CSR Listing 16.2.7.3

(19)　海外 NETU-08-18 試験

表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 4[redacted] years, first treated 16JUN20[redacted]							
23JUN20[redacted] / 25JUN20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
Patient: [redacted] female, 4[redacted] years, first treated 09FEB20[redacted]							
24FEB20[redacted] / 25FEB20[redacted]	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ESOPHAGEAL REFLUX DISORDER	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Unlikely	Unlikely
Patient: [redacted] female, 5[redacted] years, first treated 22SEP20[redacted]							
26SEP20[redacted] / 27SEP20[redacted]	Metabolism and nutrition disorders/ Hypokalaemia/ WORSENING HYPOKALEMIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related
06DEC20[redacted] / 07DEC20[redacted]	Metabolism and nutrition disorders/ Hypokalaemia/ WORSENING HYPOKALEMIA	4	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 5[redacted] years, first treated 10JUL20[redacted]							
22JUL20[redacted] / 29JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Unlikely	Unlikely

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 4[redacted] years, first treated 16MAR20[redacted]							
04JUN20[redacted] / 14JUN20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 5[redacted] years, first treated 23MAR20[redacted]							
04APR20[redacted] / 06APR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
05APR20[redacted] / 11APR20[redacted]	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Unlikely
Patient: [redacted] female, 3[redacted] years, first treated 16APR20[redacted]							
19JUN20[redacted] / 22JUN20[redacted]	Infections and infestations/ Device related infection/ CENTROL LINE INFECTION	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Unlikely	Possible

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 4[redacted] years, first treated 01JUN20[redacted]							
19JUL20[redacted] / 27JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 4[redacted] years, first treated 08JUN20[redacted]							
12SEP20[redacted] / 18SEP20[redacted]	Infections and infestations/ Septic shock/ SEPTIC SHOCK	5	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 29MAY20[redacted]							
01JUN20[redacted] / 15JUN20[redacted]	Injury, poisoning and procedural complications/ Femur fracture/ FRACTURE OF FEMORAL BONE	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 7[redacted] years, first treated 13JUL20[redacted]							
20SEP20[redacted] / 26SEP20[redacted]	Infections and infestations/ Pneumonia/ PNEUMONIA FROM LEFT SIDE	3	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 6[redacted] years, first treated 14DEC20[redacted] 27FEB20[redacted] 02MAR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FIBRILE NEUTROPENIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 29NOV20[redacted] 15DEC20[redacted] 16DEC20[redacted]	Reproductive system and breast disorders/ Metrorrhagia/ METRORRHAGIA	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 5[redacted] years, first treated 23NOV20[redacted] 26MAR20[redacted] -	Cardiac disorders/ Cytotoxic cardiomyopathy/ TOXIC CARDIOMYOPATHY	6	Yes/ MILD	NOT RECOVERED/ NOT RESOLVED	None	Unlikely	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 20SEP20[redacted] 30SEP20[redacted] 04OCT20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 5[redacted] years, first treated 16FEB20[redacted]							
02MAY201[redacted] / -	Vascular disorders/ Arterial thrombosis limb/ THROMBOSIS RIGHT ARM	4	Yes/ MODERATE	NOT RECOVERED/ NOT RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Possible
Patient: [redacted] female, 6[redacted] years, first treated 22MAR20[redacted]							
04APR20[redacted] / 06APR20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA (0.9 /NL)	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
06APR20[redacted] / 11APR20[redacted]	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION WITH FEVER	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
10APR20[redacted] / 15APR20[redacted]	Infections and infestations/ Pneumonia/ PNEUMONIA	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 28MAR20[redacted]							
03JUL20[redacted] / 04JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ NEUTROPENIC FEVER	5	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 6[redacted] years, first treated 28MAR20[redacted]							
05JUL20[redacted] / 07JUL20[redacted]	Gastrointestinal disorders/ Anal fissure/ ANAL RHAGADE	5	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 4[redacted] years, first treated 06MAR20[redacted]							
14MAY20[redacted] / 24MAY20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
14MAY20[redacted] / 24MAY20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
04JUN20[redacted] / 14JUN20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
04JUN20[redacted] / 14JUN20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
04JUL20[redacted] / 09JUL20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	6	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
04JUL20[redacted] / 09JUL20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	6	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted], male, 6[redacted] years, first treated 10MAY20[redacted]							
15SEP20[redacted] / 21SEP20[redacted]	Infections and infestations/ Appendicitis/ APPENDICITIS	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 07JUN20[redacted]							
16AUG20[redacted] / 17AUG20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPAENIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 31AUG20[redacted]							
30NOV20[redacted] / 02DEC20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA GRADE 4	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related
30NOV20[redacted] / 12DEC20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
30NOV20[redacted] / 12DEC20[redacted]	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA IV GRADE	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted], female, 5[redacted] years, first treated 01DEC20[redacted]							
28DEC20[redacted] 30DEC20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
29DEC20[redacted] 30DEC20[redacted]	General disorders and administration site conditions/ General physical health deterioration/ POOR GENERAL CONDITION	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
29DEC20[redacted] 09JAN20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 7[redacted] years, first treated 17DEC20[redacted]							
24JAN20[redacted] 01FEB20[redacted]	Infections and infestations/ Skin infection/ SUBCUTANEOUS INFECTION OF THE RIGHT HAND	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted], female, 7[redacted] years, first treated 09JAN20[redacted]							
16FEB20[redacted] / 26FEB20[redacted]	General disorders and administration site conditions/ Pyrexia/ FEVER	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 7[redacted] years, first treated 21MAR20[redacted]							
24APR20[redacted] / 26APR20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA G IV	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 15MAY20[redacted]							
12JUN20[redacted] / 21JUN20[redacted]	General disorders and administration site conditions/ Mucosal inflammation/ MUCOSITIS GRADE 1 - ORAL	2	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
15JUN20[redacted] / 21JUN20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA GIV	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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表 2.7.4.8.4.2-5　重篤な有害事象一覧（NETU-08-18）（続き）

Actual treatment: Netu/Palo FDC

Start/Stop date	System organ class/ Preferred term/ Reported term	Cycle of onset	Serious/ Intensity	Outcome	Action taken?	Relationship to Study drug	Relationship to Additional study drug
Patient: [redacted] female, 6[redacted] years, first treated 15MAY20[redacted]							
04JUL20[redacted] / 05JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ NEUTROPENIC FEVER	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
05JUL20[redacted] / 10JUL20[redacted]	General disorders and administration site conditions/ Mucosal inflammation/ MUCOSITIS	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 07MAR20[redacted]							
MAR20[redacted] / 21MAR20[redacted]	Gastrointestinal disorders/ Mouth ulceration/ ULCERATIVE STOMATITIS	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
20MAR20[redacted] / 22MAR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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