表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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, 7[redacted] years, first treated 15MAR20[redacted] 04APR20[redacted] 06APR20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ PNEUMOTHORAX	1	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], male, 5[redacted] years, first treated 28NOV20[redacted] 04FEB20[redacted] 11FEB20[redacted]	Gastrointestinal disorders/ Gastric perforation/ GASTRIC PERFORATION	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Probable

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 24APR20[redacted]							
16JUL20[redacted] 18JUL20[redacted]	General disorders and administration site conditions/ Asthenia/ WEAKNESS	4	Yes/ SEVERE	FATAL	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
16JUL20[redacted] 18JUL20[redacted]	Metabolism and nutrition disorders/ Electrolyte imbalance/ ELECTROLYTE IMBALANCE	4	Yes/ SEVERE	FATAL	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

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 24APR20[redacted]							
18JUL20[redacted] 18JUL20[redacted]	Cardiac disorders/ Cardiac arrest/ CARDIAC ARREST	4	Yes/ SEVERE	FATAL	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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, 5[redacted] years, first treated 23NOV20[redacted]							
19DEC20[redacted] / 27DEC20[redacted]	Infections and infestations/ Urinary tract infection/ URINARY INFECTION	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 18JAN20[redacted]							
18FEB20[redacted] / 24FEB20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
18FEB20[redacted] / 24FEB20[redacted]	Infections and infestations/ Pneumonia/ PNEUMONIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 16FEB20[redacted]							
11APR20[redacted] / 17APR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	3	Yes/ MODERATE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication	Not Related	Not Related
11APR20[redacted] / 17APR20[redacted]	Gastrointestinal disorders/ Stomatitis/ STOMATITIS	3	Yes/ MODERATE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

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 13MAR20[redacted]							
02APR20[redacted] / 02APR20[redacted]	Metabolism and nutrition disorders/ Acidosis/ ACIDOSIS	1	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization	Not Related	Not Related
02APR20[redacted] / 02APR20[redacted]	Cardiac disorders/ Cardiopulmonary failure/ CARDIOPULMONARY FAILURE	1	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 05OCT20[redacted]							
01JAN20[redacted] 17JAN20[redacted]	Gastrointestinal disorders/ Diverticulum intestinal/ DIVERTICULITITS COLI	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
01JAN20[redacted] 17JAN20[redacted]	Gastrointestinal disorders/ Subileus/ SUBILEUS	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related

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 14DEC20[redacted]							
10MAR20[redacted] 16MAR20[redacted]	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	7	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
12MAR20[redacted] 13MAR20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPHIL COUNT DECREASED (NEUTROPENIA GR 4)	7	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 02FEB20[redacted]							
10MAY20[redacted] / 14MAY20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] male, 6[redacted] years, first treated 28NOV20[redacted]							
22DEC20[redacted] / 28DEC20[redacted]	Infections and infestations/ Pneumonia/ PNEUMONIA	2	Yes/ SEVERE	FATAL	Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] female, 5[redacted] years, first treated 29NOV20[redacted]							
21MAR20[redacted] / 21MAR20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ LUNG EMBOLISM	6	Yes/ SEVERE	FATAL	None	Not Related	Unlikely

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, 7[redacted] years, first treated 18JAN20[redacted]							
22FEB20[redacted] / 24FEB20[redacted]	Cardiac disorders/ Cardiopulmonary failure/ ACUTE CARDIOPULMONARY INSUFFICIENCY		Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related
22FEB20[redacted] / 16MAR20[redacted]	Gastrointestinal disorders/ Duodenal ulcer perforation/ ULCUS DUODENI PERFORANS		Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Possible
22FEB20[redacted] / 16MAR20[redacted]	Gastrointestinal disorders/ Peritonitis/ ACUTE PERITONITIS		Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 03APR20[redacted] 05JUL20[redacted] 12JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Not Related
Patient: [redacted] male, 7[redacted] years, first treated 03OCT20[redacted] 28NOV20[redacted] 29NOV20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

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 10OCT20[redacted] 25OCT20[redacted] 31OCT20[redacted]	Infections and infestations/ Infection/ INFECTION	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] male, 6[redacted] years, first treated 03JAN20[redacted] 15FEB20[redacted] 15FEB20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	3	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 06FEB20[redacted]							
27FEB20[redacted] / 09MAR20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm progression/ ENDOMETRIAL CANCER PROGRESSION	1	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 26APR20[redacted]							
30MAY20[redacted] / 11JUN20[redacted]	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
30MAY20[redacted] / 11JUN20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（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 09NOV20[redacted]							
29NOV20[redacted] / 08DEC20[redacted]	Injury, poisoning and procedural complications/ Femur fracture/ FRACTURA FEMORIS SUBTROCHANTERICA L.DX.	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
29NOV20[redacted] / 08DEC20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to bone/ BONE RIGHT HIP CANCER METASTASIS	1	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
29NOV20[redacted] / 08DEC20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cancer recurrent/ RENAL CANCER RECURRENCE	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

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, 5[redacted] years, first treated 27FEB20[redacted]							
07APR20[redacted] / 10APR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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 28NOV20[redacted]							
03JAN20[redacted] / 07JAN20[redacted]	Cardiac disorders/ Myocardial ischaemia/ MYOCARDIAL ISCHEMIA	2	Yes/ SEVERE	RECOVERED/ RESOLVED WITH SEQUELAE	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 18JAN20[redacted]							
24APR20[redacted] / 30APR20[redacted]	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ ACUTE EPISTAXIS	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
25APR20[redacted] / 25APR20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ACUTE ANEMIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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 18JAN20[redacted]							
25APR20[redacted] / 30APR20[redacted]	Blood and lymphatic system disorders/ Thrombocytopenia/ WORSENING OF THROMBOCYTOPENIA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
Patient: [redacted] female, 3[redacted] years, first treated 24APR20[redacted]							
29JUN20[redacted] / 02JUL20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
21JUL20[redacted] / 30JUL20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related

Actual treatment: Aprepitant/Palo

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, 5[redacted] years, first treated 05JUN20[redacted]							
26JUN20[redacted] / 03JUL20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ THROMBOEMBOLIA OF SMALL BRANCHES OF RIGHT PULMONARY ARTERIES	1	Yes/ MILD	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
27JUN20[redacted] / 27JUN20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ EXUDATIVE PLEURAL EFFUSION ON THE LEFT	1	Yes/ MODERATE	RECOVERED/ RESOLVED	None	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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, 5[redacted] years, first treated 22FEB20[redacted]							
07JUN20[redacted] / 14JUN20[redacted]	Gastrointestinal disorders/ Nausea/ NAUSEA	5	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
07JUN20[redacted] / 14JUN20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 18APR20[redacted]							
08JUN20[redacted] / 20JUN20[redacted]	Gastrointestinal disorders/ Intestinal perforation/ SIGMATIC BOWEL PERFORATION	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization	Not Related	Not Related

Actual treatment: Aprepitant/Palo

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 18APR20[redacted]							
08JUN20[redacted] / 20JUN20[redacted]	Gastrointestinal disorders/ Peritonitis/ DIFFUSE PERITONITIS	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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 23APR20[redacted]							
11JUL20[redacted] / 26JUL20[redacted]	Gastrointestinal disorders/ Ileus/ ILEUS	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] male, 7[redacted] years, first treated 13MAR20[redacted]							
02APR20[redacted] / 04APR20[redacted]	Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF THE KNOWN ARTHRITIS OF THE RIGHT KNEE	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

Actual treatment: Aprepitant/Palo

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 16JAN20[redacted]							
24JUN20[redacted] / 05JUL20[redacted]	Renal and urinary disorders/ Renal failure/ RENAL INSUFFICIENCY	6	Yes/ MODERATE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
02JUL20[redacted] / 05JUL20[redacted]	Nervous system disorders/ Convulsion/ CEREBRAL SEIZURES	6	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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, 5[redacted] years, first treated 06SEP20[redacted]							
11SEP20[redacted] / 17SEP20[redacted]	Renal and urinary disorders/ Renal failure/ RENAL FAILURE (CISPLATIN-INDUCED)	1	Yes/ SEVERE	RECOVERED/ RESOLVED WITH SEQUELAE	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
30SEP20[redacted] / 18OCT20[redacted]	Vascular disorders/ Peripheral ischaemia/ PERIPHERAL ARTERIAL ISCHEMIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED WITH SEQUELAE	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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, 7[redacted] years, first treated 16SEP20[redacted]							
01FEB20[redacted] / 17FEB20[redacted]	Infections and infestations/ Otitis media/ OTITIS MEDIA LEFT	6	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Unlikely
Patient: [redacted], male, 5[redacted] years, first treated 02NOV20[redacted]							
30NOV20[redacted] / 01DEC20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
14FEB20[redacted] / 17FEB20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	5	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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, 5[redacted] years, first treated 12OCT20[redacted]							
25DEC20[redacted] / 02JAN20[redacted]	Blood and lymphatic system disorders/ Agranulocytosis/ AGRANULOCYTOSIS	4	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
25DEC20[redacted] / 02JAN20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	4	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
25DEC20[redacted] / 02JAN20[redacted]	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	4	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

Actual treatment: Aprepitant/Palo

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 23FEB20[redacted]							
15MAR20[redacted] / 20MAR20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm malignant/ LUNG CANCER PROGRESSION	1	Yes/ SEVERE	RECOVERED/ RESOLVED WITH SEQUELAE	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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 14MAR20[redacted]							
14MAY20[redacted] / 11JUN20[redacted]	Gastrointestinal disorders/ Ileus/ ILEUS	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
14MAY20[redacted] / 11JUN20[redacted]	Gastrointestinal disorders/ Peritonitis/ PERITONITIS	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

Actual treatment: Aprepitant/Palo

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 14MAR20[redacted]							
15MAY20[redacted] / 11JUN20[redacted]	Infections and infestations/ Sepsis/ SEPSIS	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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 24MAY20[redacted]							
16AUG20[redacted] 17AUG20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] female, 5[redacted] years, first treated 18APR20[redacted]							
16JUN20[redacted] 19JUN20[redacted]	Renal and urinary disorders/ Dysuria/ DYSURIA	4	Yes/ MODERATE	RECOVERED/ RESOLVED WITH SEQUELAE	(Prolonged) Hospitalization	Not Related	Not Related

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）（続き）

Actual treatment: Aprepitant/Palo

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, 7[redacted] years, first treated 02JAN20[redacted]							
21FEB20[redacted] / 24FEB20[redacted]	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	3	Yes/ MILD	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] male, 5[redacted] years, first treated 09MAY20[redacted]							
29MAY20[redacted] / 04JUN20[redacted]	Vascular disorders/ Deep vein thrombosis/ DEEP VEIN TROMBOSIS OF THE RIGHT LEG	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely

A missing cycle of onset represents a TEAE with a start date after date of last contact.
MedDRA Version 14.0.

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(21) 海外 NEPA-17-05 試験

表 2.7.4.8.4.2-7　重篤な有害事象一覧（NEPA-17-05）

Actual Treatment: IV NEPA FDC

Patient ID/ Country	Preferred Term/ VERBATIM	Cycle of Onset [1]	Start Date/Time (Study Day, Cycle Day)[2] End Date/Time	Serious/ Severity Grade	Outcome	Study Drug Related	Dex. Related	Study Drug Action	Other Action
[redacted] USA	Vomiting/ VOMITTING	1	02JUL20[redacted]/ (13, 13)/ 03JUL20[redacted]	Yes/ 3	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med
[redacted] USA	Pyrexia/ FEVER	4	14JUN20[redacted]T23:26/ (45, 3)/ 16JUN20[redacted]T23:54	Yes/ 2	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	None
	Urinary tract infection/ URINARY TRACT INFECTION	4	14JUN20[redacted]T23:26/ (45, 3)/ 16JUN20[redacted]T23:54	Yes/ 3	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med

表 2.7.4.8.4.2-7　重篤な有害事象一覧（NEPA-17-05）（続き）

Actual Treatment: IV NEPA FDC

Patient ID/ Country	Preferred Term/ VERBATIM	Cycle of Onset [1]	Start Date/Time (Study Day, Cycle Day)[2] End Date/Time	Serious/ Severity Grade	Outcome	Study Drug Related	Dex. Related	Study Drug Action	Other Action
[redacted] UKR	Erysipelas/ ERYSIPELAS	1	18JUN20[redacted] (6, 6)/ 22JUN20[redacted]	Yes/ 2	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med
[redacted] RUS	Anaemia/ ANEMIA	3	06SEP20[redacted]T14:00/ (53, 11)/ 11SEP20[redacted]	Yes/ 3	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med
	Neutropenia/ NEUTROPENIA	3	06SEP20[redacted]T14:00/ (53, 11)/ 11SEP20[redacted]	Yes/ 4	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med
[redacted] RUS	Biliary colic/ GALLSTONE ATTACK	3	19AUG20[redacted]T02:00/ (63, 19)/	Yes/ 2	NOT RECOVERED/ NOT RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med

表 2.7.4.8.4.2-7　重篤な有害事象一覧（NEPA-17-05）（続き）

Actual Treatment: Oral NEPA FDC

Patient ID/ Country	Preferred Term/ VERBATIM	Cycle of Onset [1]	Start Date/Time (Study Day, Cycle Day)[2] End Date/Time	Serious/ Severity Grade	Outcome	Study Drug Related	Dex. Related	Study Drug Action	Other Action
[redacted] USA	Urinary tract infection/ URINARY TRACT INFECTION	1	07JUL20[redacted]T09:58/ (13, 13)/ 09JUL20[redacted]T17:15	Yes/ 3	RECOVERED/ RESOLVED	NOT RELATED	POSSIBLY RELATED	DOSE NOT CHANGED	Therapy/Med
[redacted] USA	Clostridium difficile colitis/ BACTERIAL COLITIS/C. DIFFICILE INFECTION	2	10AUG20[redacted]/ (40, 8)/ 13AUG20[redacted]	Yes/ 3	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	None
[redacted] USA	Febrile neutropenia/ NEUTROPENIC FEVER	4	30JUL20[redacted]T03:00/ (50, 8)/ 06AUG20[redacted]T16:10	Yes/ 4	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med

表 2.7.4.8.4.2-7　重篤な有害事象一覧（NEPA-17-05）（続き）

Actual Treatment: Oral NEPA FDC

Patient ID/ Country	Preferred Term/ VERBATIM	Cycle of Onset [1]	Start Date/Time (Study Day, Cycle Day)[2] End Date/Time	Serious/ Severity Grade	Outcome	Study Drug Related	Dex. Related	Study Drug Action	Other Action
[redacted] USA	Anaemia/ ANEMIA	4	30JUL20[redacted]T15:21/ (50, 8)/ 06AUG20[redacted]T16:10	Yes/ 4	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	None
	Neutropenia/ NEUTROPENIA	4	30JUL20[redacted]T15:21/ (50, 8)/ 06AUG20[redacted]T16:10	Yes/ 4	RECOVERED/ RESOLVED	NOT RELATED	NOT RELATED	DOSE NOT CHANGED	Therapy/Med
[redacted] USA	Atrial fibrillation/ ATRIAL FIBRILLATION	4	09AUG20[redacted]/ (52, 10)/	Yes/ 3	RECOVERING/ RESOLVING	POSSIBLY RELATED	UNLIKELY RELATED	DOSE NOT CHANGED	Therapy/Med

[1] Cycle of onset assigned based on last cycle where AE start date is on or after date of first study drug intake in cycle.
[2] Study Day relative to date of first study drug administration (Oral and IV NEPA FDC or matching Placebo) in Cycle 1.
Cycle Day relative to date of first study drug administration (Oral and IV NEPA FDC or matching Placebo) in cycle of onset.

Note: Severity rated by Investigator according to grades of Common Terminology Criteria for Adverse Events (CTCAE v. 4.03: June 14, 2010).

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