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 07MAR20[redacted]							
21MAR20[redacted] / 04APR20[redacted]	Gastrointestinal disorders/ Stomatitis/ ORAL MUCOSITIS	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 08MAR20[redacted]							
31MAY20[redacted] / 08JUN20[redacted]	Nervous system disorders/ Hypoaesthesia/ NUMBNESS OF RIGHT-SIDE LIMBS	4	Yes/ MODERATE	RECOVERED/ RESOLVED	None	Not Related	Possible
05JUN20[redacted] / -	Investigations/ Fibrin D dimer increased/ D-DIMER INCREASE	4	Yes/ SEVERE	RECOVERING/ RESOLVING	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Possible
05JUN20[redacted] / 17AUG20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	4	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 11APR20[redacted]							
20MAY20[redacted] / 21MAY20[redacted]	Reproductive system and breast disorders/ Metrorrhagia/ METRORRHAGIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
30MAY20[redacted] / -	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cervix carcinoma/ CERVIX UTERI CANCER	2	Yes/ SEVERE	NOT RECOVERED/ NOT RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 11APR20[redacted]							
21MAY20[redacted] / 28MAY20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 08MAY20[redacted]							
29MAY20[redacted] / -	Musculoskeletal and connective tissue disorders/ Pathological fracture/ PATHOLOGICAL FRACTURE OF TH6	1	Yes/ SEVERE	NOT RECOVERED/ NOT RESOLVED	Study drug discontinued / 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 26JUN20[redacted]							
06JUL20[redacted] 20JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
09JUL20[redacted] 12JUL20[redacted]	Gastrointestinal disorders/ Stomatitis/ STOMATITIS	1	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 11JUL20[redacted]							
19JUL20[redacted] 19JUL20[redacted]	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
19JUL20[redacted] 23JUL20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	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, 6[redacted] years, first treated 03JUL20[redacted]							
17AUG20[redacted] / 03SEP20[redacted]	Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS ON RIGHT ARM	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(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: Palo alone

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 24JUL20[redacted]							
28JUL20[redacted] / 07AUG20[redacted]	Infections and infestations/ Cellulitis/ CELLULITIS	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 24JUL20[redacted]							
26SEP20[redacted] / 03OCT20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING	4	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 3[redacted] years, first treated 29FEB20[redacted]							
30MAR20[redacted] / 08APR20[redacted]	Infections and infestations/ Gastrointestinal infection/ GASTROINTESTINAL INFECTION	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Unlikely
31MAR20[redacted] / 04APR20[redacted]	Metabolism and nutrition disorders/ Dehydration/ MODERATE DEHYDRATION	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Unlikely
31MAR20[redacted] / 04APR20[redacted]	Metabolism and nutrition disorders/ Electrolyte imbalance/ ELECTROLYTE IMBALANCE	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	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: Palo alone

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, 3[redacted] years, first treated 29FEB20[redacted]							
31MAR20[redacted] / 04APR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	2	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 3[redacted] years, first treated 09MAR20[redacted]							
22MAR20[redacted] / 25MAR20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	Yes/ MODERATE	RECOVERED/ RESOLVED	None	Not Related	Not Related
04JUN20[redacted] / 05JUN20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
Patient: [redacted] female, 6[redacted] years, first treated 10MAY20[redacted]							
09JUL20[redacted] / 12JUL20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
09JUL20[redacted] / 12JUL20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	3	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: Palo alone

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 08JUL20[redacted]							
19SEP20[redacted] 26SEP20[redacted]	Infections and infestations/ Herpes zoster/ HERPES ZOSTER	4	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Possible
20SEP20[redacted] 25SEP20[redacted]	General disorders and administration site conditions/ Asthenia/ GENERALIZED WEAKNESS	4	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 07JUN20[redacted]							
18AUG20[redacted] 27AUG20[redacted]	Infections and infestations/ Soft tissue infection/ SOFT TISSUE INFECTION	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
21AUG20[redacted] 27AUG20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NUTROPENIA	4	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: Palo alone

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, 3[redacted] years, first treated 01FEB20[redacted]							
12MAY20[redacted] / 21MAY20[redacted]	Injury, poisoning and procedural complications/ Femoral neck fracture/ TRAUMATIC FRACTURE-NECK OF FEMUR RIGHT SIDE	5	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 3[redacted] years, first treated 15FEB20[redacted]							
27APR20[redacted] / 28APR20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer metastatic/ DISEASE PROGRESSION METASTATIC BREAST CANCER	3	Yes/ SEVERE	FATAL	None	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 30MAY20[redacted]							
31MAY20[redacted] / 01JUN20[redacted]	Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	1	Yes/ SEVERE	FATAL	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
31MAY20[redacted] / 01JUN20[redacted]	Cardiac disorders/ Cardiac failure acute/ ACUTE HEART FAITURE	1	Yes/ SEVERE	FATAL	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: Palo alone

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 20OCT20[redacted]							
02NOV20[redacted] / 03NOV20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEVER NEUTROPENIA	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 21JUN20[redacted]							
18JUL20[redacted] / 24JUL20[redacted]	Vascular disorders/ Thrombosis/ ACUTE THROMBOSIS OF THE LEFT LARGE SAPHENA OF THIGH	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
07AUG20[redacted] / 20AUG20[redacted]	Infections and infestations/ Erysipelas/ ERYSIPELAS OF RIGHT UPPER EXTREMITY AND FRONT ABDOMINAL WALL	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 04JUL20[redacted]							
18SEP20[redacted] / -	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ BRAIN METASTASIS	4	Yes/ SEVERE	NOT RECOVERED/ NOT RESOLVED	None	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 04JUL20[redacted]							
25JUL20[redacted] / 25JUL20[redacted]	Reproductive system and breast disorders/ Endometrial hyperplasia/ HYPERPLASIA OF ENDOMETRIUM.	1	Yes/ MILD	RECOVERED/ RESOLVED	None	Not Related	Not Related
25JUL20[redacted] / 25JUL20[redacted]	Reproductive system and breast disorders/ Ovarian cyst/ CYSTS OF OVARII.	1	Yes/ MILD	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: Palo alone

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 17MAY20[redacted]							
29MAY20[redacted] / 04JUN20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENY	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 29MAY20[redacted]							
04JUN20[redacted] / 10JUN20[redacted]	Vascular disorders/ Thrombophlebitis/ THROMBOPHLEBITIS ON LEFT LEG	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 4[redacted] years, first treated 12APR20[redacted]							
20JUN20[redacted] / 02JUL20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
20JUN20[redacted] / 02JUL20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	4	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
01AUG20[redacted] / 09AUG20[redacted]	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	6	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Not Related
01AUG20[redacted] / 09AUG20[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: Palo alone

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 31MAY20[redacted]							
02JUN20[redacted] / 04JUN20[redacted]	Gastrointestinal disorders/ Nausea/ NAUSEA	1	Yes/ MODERATE	RECOVERED/ RESOLVED	Study drug discontinued / Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 7[redacted] years, first treated 26APR20[redacted]							
14MAY20[redacted] / 16MAY20[redacted]	Cardiac disorders/ Atrial fibrillation/ WORSENING ATRIAL FIBRILLATION	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 15FEB20[redacted]							
26JUL20[redacted] / 29JUL20[redacted]	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	6	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Unlikely	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 12MAR20[redacted]							
29MAY20[redacted] / 04JUN20[redacted]	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLY	4	Yes/ SEVERE	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
29MAY20[redacted] / 04JUN20[redacted]	Vascular disorders/ Venous thrombosis/ TROMBOSIS OF SUBCLAVIAN- AND JUGULAR VIEN	4	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication	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: Palo alone

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 30MAY20[redacted]							
05JUN20[redacted]/ 06JUN20[redacted]	Surgical and medical procedures/ Catheterisation venous/ VENOUS ACCESS PORT IMPLANTATION	1	Yes/ MODERATE	RECOVERED/ RESOLVED	None	Not Related	Not Related
09AUG2012/ 10AUG2012	Vascular disorders/ Venous recanalisation/ RECANALISATION OF VENOUS PORT	4	Yes/ MILD	RECOVERED/ RESOLVED	None	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 13DEC20[redacted]							
28MAR20[redacted]/ 28MAR20[redacted]	Surgical and medical procedures/ Central venous catheterisation/ VENU PORT INSERTION	4	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 07JUN20[redacted]							
10JUN20[redacted]/ 10JUN20[redacted]	General disorders and administration site conditions/ Chills/ SHIVER	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related
11JUN20[redacted]/ 27JUN20[redacted]	Vascular disorders/ Thrombosis/ PARTIAL THROMBOSIS ON RIGHT ARM	1	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: Palo alone

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 07JUN20[redacted]							
13JUN20[redacted] / 15JUN20[redacted]	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	1	Yes/ MILD	RECOVERED/ RESOLVED	Specific Therapy/Medication / (Prolonged) Hospitalization	Not Related	Not Related

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第 5.3.5.1.7 項 NETU-08-18 CSR Listing 16.2.7.3

(20) 海外 NETU-10-29 試験

表 2.7.4.8.4.2-6　重篤な有害事象一覧（NETU-10-29）

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 18OCT20[redacted]							
03NOV20[redacted] / 11NOV20[redacted]	Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	1	Yes/ SEVERE	RECOVERED/ RESOLVED	None	Not Related	Unlikely
Patient: [redacted], female, 6[redacted] years, first treated 03OCT20[redacted]							
10OCT20[redacted] / 10OCT20[redacted]	Psychiatric disorders/ Confusional state/ CONFUSION	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Unlikely	Unlikely
10OCT20[redacted] / 14OCT20[redacted]	General disorders and administration site conditions/ Asthenia/ WORSENING OF WEAKNESS	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
10OCT20[redacted] / 14OCT20[redacted]	Gastrointestinal disorders/ Diarrhoea/ WORSENING OF DIARRHEA	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Unlikely	Unlikely
11OCT20[redacted] / 13OCT20[redacted]	Vascular disorders/ Deep vein thrombosis/ DVT OF LEFT INTERNAL JUGULAR VEIN	1	Yes/ MODERATE	RECOVERED/ RESOLVED	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: 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 31JAN20[redacted]							
09FEB20[redacted]/ 21FEB20[redacted]	Infections and infestations/ Diverticulitis/ WORSENING DIVERTICULITIS	1	Yes/ MILD	RECOVERED/ RESOLVED	(Prolonged) Hospitalization	Unlikely	Unlikely
19MAR20[redacted]/ 10APR20[redacted]	Infections and infestations/ Diverticulitis/ WORSENING ACUTE DIVERTICULITIS	3	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
25APR20[redacted]/ 07MAY20[redacted]	Infections and infestations/ Diverticulitis/ WORSENING ACUTE DIVERTICULITIS	4	Yes/ MILD	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, 5[redacted] years, first treated 25APR20[redacted]							
03MAY20[redacted] / 09MAY20[redacted]	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	1	Yes/ MILD	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
03MAY20[redacted] / 09MAY20[redacted]	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCOUGH	1	Yes/ MILD	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
03MAY20[redacted] / 09MAY20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING,	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	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] female, 3[redacted] years, first treated 04MAY20[redacted]							
23MAY20[redacted] / 24MAY20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
12JUN20[redacted] / 22JUN20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	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 12MAY20[redacted]							
29MAY20[redacted] –	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	1	Yes/ SEVERE	NOT RECOVERED/ NOT RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
07JUN20[redacted] / 07JUN20[redacted]	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNOEA	1	Yes/ SEVERE	FATAL	Specific Therapy/Medication	Not Related	Not Related
07JUN20[redacted] / 07JUN20[redacted]	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	1	Yes/ SEVERE	FATAL	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: 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 19APR20[redacted]							
03AUG20[redacted] / -	Cardiac disorders/ Ventricular extrasystoles/ VENTRICULAR BIGEMINY	6	Yes/ MODERATE	RECOVERING/ RESOLVING	(Prolonged) Hospitalization / Specific Therapy/Medication	Probable	Unlikely
Patient: [redacted] female, 5[redacted] years, first treated 23APR20[redacted]							
30APR20[redacted] / -	Metabolism and nutrition disorders/ Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	1	Yes/ SEVERE	RECOVERING/ RESOLVING	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely
30APR20[redacted] / 05MAY20[redacted]	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	1	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: 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 04MAY20[redacted]							
10AUG20[redacted] / 10AUG20[redacted]	Nervous system disorders/ Convulsion/ SEIZURE	5	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], male, 6[redacted] years, first treated 07MAY20[redacted]							
02JUN20[redacted] / -	Gastrointestinal disorders/ Vomiting/ VOMITING	2	Yes/ MODERATE	RECOVERING/ RESOLVING	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	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 21MAY20[redacted]							
11JUL20[redacted] / 13JUL20[redacted]	Infections and infestations/ Lower respiratory tract infection/ LOWER RESPIRATORY TRACT INFECTION	3	Yes/ SEVERE	FATAL	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
11JUL20[redacted] / 13JUL20[redacted]	Blood and lymphatic system disorders/ Pancytopenia/ PANCYTOPENIA	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], male, 3[redacted] years, first treated 29MAY20[redacted]							
11JUL20[redacted] / 11JUL20[redacted]	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEED	3	Yes/ SEVERE	FATAL	Specific Therapy/Medication	Not Related	Unlikely
Patient: [redacted], male, 6[redacted] years, first treated 03MAR20[redacted]							
12JUN20[redacted] / 14JUN20[redacted]	Injury, poisoning and procedural complications/ Radiation mucositis/ RADIATION INDUCED MUCOSITIS	4	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 30NOV20[redacted]							
29MAR20[redacted] / 29MAR20[redacted]	General disorders and administration site conditions/ Multi-organ failure/ MULTIORGAN FAILURE	5	Yes/ SEVERE	FATAL	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: 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 28DEC20[redacted]							
12JAN20[redacted] / 12JAN20[redacted]	General disorders and administration site conditions/ Multi-organ failure/ MULTIORGAN FAILURE DUE TO CANCER INTOXICATION	1	Yes/ SEVERE	FATAL	None	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 18APR20[redacted]							
22APR20[redacted] / -	Nervous system disorders/ Cerebral ischaemia/ CEREBROVASCULAR ISCHEMIA	1	Yes/ MODERATE	NOT RECOVERED/ NOT RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
27APR20[redacted] / 06MAY20[redacted]	Cardiac disorders/ Cardiopulmonary failure/ PULMONARY HEART INSUFFICIENCY	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] male, 6[redacted] years, first treated 29MAR20[redacted]							
09JUL20[redacted] / 09JUL20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm progression/ TUMOR DISEASE PROGRESSION	4	Yes/ SEVERE	FATAL	None	Not Related	Not Related
Patient: [redacted] male, 6[redacted] years, first treated 09APR20[redacted]							
06JUN20[redacted] / 14JUN20[redacted]	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2	Yes/ MODERATE	RECOVERED/ RESOLVED	Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted] male, 5[redacted] years, first treated 17APR20[redacted]							
23APR20[redacted] / 27APR20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm malignant/ PROGRESSION OF BONE METASTASIS	1	Yes/ SEVERE	RECOVERED/ RESOLVED WITH SEQUELAE	(Prolonged) Hospitalization	Not Related	Not Related
05MAY20[redacted] / 11MAY20[redacted]	Nervous system disorders/ Ischaemic stroke/ ISCHEMIC STROKE	1	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, 7[redacted] years, first treated 14SEP20[redacted]							
30OCT20[redacted] / 03NOV20[redacted]	Gastrointestinal disorders/ Constipation/ OBSTIPATION	3	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
02NOV20[redacted] / 02NOV20[redacted]	Vascular disorders/ Hypertensive crisis/ HYPERTENSIVE CRISIS	3	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
02NOV20[redacted] / 03NOV20[redacted]	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	3	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] male, 5[redacted] years, first treated 12OCT20[redacted]							
14DEC20[redacted] -	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Bronchial carcinoma/ PROGRESSION OF THE BRONCHIAL CA		Yes/ MODERATE	NOT RECOVERED/ NOT RESOLVED	Study drug discontinued / (Prolonged) Hospitalization	Not Related	Not Related
Patient: [redacted] female, 4[redacted] years, first treated 29SEP20[redacted]							
25OCT20[redacted] 02NOV20[redacted]	Renal and urinary disorders/ Renal failure/ RENAL FAILURE	2	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
31OCT20[redacted] 05NOV20[redacted]	General disorders and administration site conditions/ Pyrexia/ FEVER OF UNKNOWN ORIGIN	2	Yes/ MILD	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, 4[redacted] years, first treated 29SEP20[redacted]							
21NOV20[redacted] / 24NOV20[redacted]	Gastrointestinal disorders/ Vomiting/ EMESIS	3	Yes/ MODERATE	RECOVERED/ RESOLVED WITH SEQUELAE	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
27NOV20[redacted] / 11JUN20[redacted]	Injury, poisoning and procedural complications/ Radiation oesophagitis/ RADIO-OESOPHAGITIS	3	Yes/ SEVERE	RECOVERED/ RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
09DEC20[redacted] / 14DEC20[redacted]	Renal and urinary disorders/ Renal failure acute/ ACUTE RENAL FAILURE	3	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 17JAN20[redacted]							
14MAR20[redacted] / 21MAR20[redacted]	Infections and infestations/ Catheter site infection/ CATHETER SITE INFECTION	3	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 5[redacted] years, first treated 23JAN20[redacted]							
23APR20[redacted] / 27APR20[redacted]	Cardiac disorders/ Long QT syndrome/ LONG QT-SYNDROME	5	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Not Related
14MAY20[redacted] / 16MAY20[redacted]	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm malignant/ LUNG-CANCER-PROGRESSION (PREVIOUSLY: PROGRESS OF UNDERLYING DISEASE)	5	Yes/ SEVERE	FATAL	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: 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 21MAY20[redacted]							
04JUN20[redacted] / 08JUN20[redacted]	General disorders and administration site conditions/ Device dislocation/ DISLOCATION OF PORT-A-CATH SYSTEM	1	Yes/ MILD	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
20JUN20[redacted] / 28AUG20[redacted]	Surgical and medical procedures/ Chemotherapy extravasation management/ PARAVASATION OF OXALIPLATIN	3	Yes/ MODERATE	RECOVERED/ RESOLVED WITH SEQUELAE	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, 6[redacted] years, first treated 21DEC20[redacted]							
24JAN20[redacted] / 27JAN20[redacted]	Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO LEVOFLOXACIN	2	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Not Related	Not Related
Patient: [redacted], female, 6[redacted] years, first treated 01NOV20[redacted]							
20FEB20[redacted] / 01MAR20[redacted]	Infections and infestations/ Urinary tract infection pseudomonal/ RECURRENT URINARY TRACT INFECTION WITH PROBLEMATIC GERMS (PSEUDOMONAS)	6	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, 4[redacted] years, first treated 18APR20[redacted]							
22APR20[redacted] / -	Psychiatric disorders/ Acute psychosis/ ACUTE PSYCHOSIS	1	Yes/ SEVERE	NOT RECOVERED/ NOT RESOLVED	Study drug discontinued / (Prolonged) Hospitalization / Specific Therapy/Medication	Possible	Probable
Patient: [redacted] male, 6[redacted] years, first treated 16FEB20[redacted]							
20FEB20[redacted] / 20FEB20[redacted]	Gastrointestinal disorders/ Vomiting/ VOMITING	1	Yes/ MODERATE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Not Related
20FEB20[redacted] / 14MAR20[redacted]	Gastrointestinal disorders/ Nausea/ NAUSEA	1	Yes/ SEVERE	RECOVERED/ RESOLVED	(Prolonged) Hospitalization / Specific Therapy/Medication	Unlikely	Unlikely