(17) 海外 NETU-07-07 試験

表 2.7.4.8.4.2-3　重篤な有害事象一覧（NETU-07-07）

Site - Subject Id	AE Verbatim Term MedDRA SOC Name MedDRA Preferred Term	Start Date Stop Date Duration(Days)	Day of Onset	Serious	Occurrence	Intensity	Relationship to: Study Drugs	Relationship to: Dexamethasone	Action Taken	Outcome
[redacted]	PNEUMONIA Infections and infestations Pneumonia	14APR20[redacted] 12:52 28APR20[redacted] 12:00 14	11	Yes	SINGLE EPISODE	MODERATE	NOT RELATED	NOT RELATED	Specific therapy/medication; (Prolonged)Hospitalization	RECOVERED
[redacted]	HYDROCEPHALUS Nervous system disorders Hydrocephalus	18AUG20[redacted] 10:00 19AUG20[redacted] 15:00 1	8	Yes	SINGLE EPISODE	MODERATE	NOT RELATED	NOT RELATED	(Prolonged) hospitalization)	RECOVERED
[redacted]	ATRIAL FIBRILLATION Cardiac disorders Atrial fibrillation	13MAY20[redacted] 08:00 14MAY20[redacted] 15:00 1	7	Yes	SINGLE EPISODE	MILD	NOT RELATED	NOT RELATED	Specific therapy/medication	RECOVERED
[redacted]	MULTIPLE ORGAN FAILURE General disorders and administration site conditions Multi-organ failure	27SEP20[redacted] 14:00 29SEP20[redacted] 01:10 1	4	Yes	INTERMITTENT	SEVERE	NOT RELATED	NOT RELATED	Specific therapy/medication	DEATH
[redacted]	LOSS OF CONSCIOUSNESS Nervous system disorders Loss of consciousness	02JUL20[redacted] 11:35 02JUL20[redacted] 12:05 0	1	Yes	SINGLE EPISODE	MODERATE	POSSIBLE	NOT RELATED	DISCONTINUED	RECOVERED

第 5.3.5.1.5 項 NETU-07-07 CSR Listing 23

(18) 海外 NEPA-15-18 試験

表 2.7.4.8.4.2-4　重篤な有害事象一覧（NETU-15-18）

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
Austria	[redacted]		F	IATROGENER PNEUMOTHORAX AFTER PORT-A-CATH IMPLANT Injury, poisoning and procedural complications Pneumothorax traumatic	11MAY20[redacted]/11:39 17MAY20[redacted]/09:00 5D21H21M 20	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
Croatia			M	FATAL HAEMORRHAGE SUSPECTED Vascular disorders Haemorrhage	27MAR20[redacted] 27MAR20[redacted]/07:55 1D 13	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
			M	SUDDEN DEATH General disorders and administration site conditions Sudden death	27MAR20[redacted] 27MAR20[redacted] 1D 13	Grade 5 - DTH	Unlikely - Unlikely	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
Croatia	[redacted]		F	POSTCHEMO NAUSEA Gastrointestinal disorders Nausea	29MAR20[redacted]/14:00 05APR20[redacted]/15:00 7D01H00M 7	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
Czech Republic			M	ACUTE KIDNEY INJURY Renal and urinary disorders Acute kidney injury	16MAY20[redacted] 30MAY20[redacted] 15D 8	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved With Sequelae
			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	09MAY20[redacted]/10:30 11MAY20[redacted]/09:33 1D23H03M 21	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
Czech Republic	[redacted]		M	INFECTION Infections and infestations Infection	10MAY20[redacted] 13MAY20[redacted] 4D 22	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	13JUN20[redacted]/08:38 15JUN20[redacted]/06:03 1D21H25M 56	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	16MAY20[redacted]/06:30 17MAY20[redacted]/06:45 1D00H15M 28	Grade 2 - HOSP	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
Germany	[redacted]		M	PNEUMOTHORAX Respiratory, thoracic and mediastinal disorders Pneumothorax	20APR20[redacted] 26APR20[redacted] 7D 2	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				BIGEMINUS Cardiac disorders Extrasystoles	21JUN20[redacted]/09:07 21JUN20[redacted]/12:00 0D02H53M 64	Grade 1 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
Italy			M	HEART FAILURE Cardiac disorders Cardiac failure	02JUL20[redacted]/16:00 02JUL20[redacted]/16:00 0D00H00M 74	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
Poland	[redacted]		M	BRAIN METASTASES Neoplasms benign, malignant and unspecified (incl cysts and polyps) Metastases to central nervous system	14MAY20[redacted]/22:45 6	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
			M	HYPONATREMY Metabolism and nutrition disorders Hyponatraemia	05JAN20[redacted] 07JAN20[redacted] 3D 36	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	17DEC20[redacted] 19DEC20[redacted] 3D 17	Grade 4 - 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	PNEUMONIA Infections and infestations Pneumonia	17DEC20[redacted] 22DEC20[redacted] 6D 17	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	FEBRILE NEUTROPENIA Blood and lymphatic system disorders Febrile neutropenia	12FEB20[redacted] 23FEB20[redacted] 12D 65	Grade 4 - HOSP	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovered /Resolved
				FEBRILE NEUTROPENIA Blood and lymphatic system disorders Febrile neutropenia	26DEC20[redacted] 31DEC20[redacted] 6D 17	Grade 4 - 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	PNEUMONIA Infections and infestations Pneumonia	05FEB20[redacted] 12FEB20[redacted] 8D 30	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				DETERIORATION OF HEALTH STATUS General disorders and administration site conditions General physical health deterioration	05FEB20[redacted] 12FEB20[redacted] 8D 30	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	INCREASED CREATININE Investigations Blood creatinine increased	18APR20[redacted] 47	Grade 1 - HOSP	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study; 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	FEVER General disorders and administration site conditions Pyrexia	21APR20[redacted] 22APR20[redacted] 2D 8	Grade 1 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				FATIGUE General disorders and administration site conditions Fatigue	21APR20[redacted]/19:00 26APR20[redacted] 6D 8	Grade 3 - HOSP	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovered /Resolved
			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	21MAR20[redacted] 29MAR20[redacted] 9D 64	Grade 3 - HOSP	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
Poland	[redacted]	[redacted]	F	NEUTROPENIA III Blood and lymphatic system disorders Neutropenia	18MAR20[redacted]/08:18 23MAR20[redacted]/05:36 4D21H18M 46	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				NEUTROPENIA III Blood and lymphatic system disorders Neutropenia	23FEB20[redacted]/07:41 28FEB20[redacted]/05:56 4D22H15M 22	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	ATRIAL FIBRILLATION Cardiac disorders Atrial fibrillation	23FEB20[redacted] 07MAR20[redacted] 14D 2	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
Poland	[redacted]		M	NEUTROPENIA III Blood and lymphatic system disorders Neutropenia	06APR20[redacted]/08:19 11APR20[redacted]/06:01 4D21H42M 21	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				RIGHT BRONCHOPNEUMONY Infections and infestations Pneumonia	23MAY20[redacted] 29MAY20[redacted] 7D 68	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	PANCREATITIS Gastrointestinal disorders Pancreatitis	05APR20[redacted]/08:00 12APR20[redacted]/10:00 7D02H00M 7	Grade 2 - HOSP	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
Poland	[redacted]		M	RENAL FAILURE Renal and urinary disorders Renal failure	19APR20[redacted] 21	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Subject Withdrawn From Study	Recovering /Resolving
			M	FEVER General disorders and administration site conditions Pyrexia	08APR20[redacted] 11APR20[redacted] 4D 5	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				PNEUMONIA Infections and infestations Pneumonia	10MAY20[redacted] 22MAY20[redacted] 13D 37	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
Poland	[redacted]		F	NEUTROPENIA FEVER Blood and lymphatic system disorders Febrile neutropenia	04MAY20[redacted] 06MAY20[redacted] 3D 15	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
			M	ASYMPTOMATIC NEUTROPENIA Blood and lymphatic system disorders Neutropenia	29JUN20[redacted] 03JUL20[redacted] 5D 42	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	HIGH FEVER General disorders and administration site conditions Pyrexia	24MAY20[redacted] 30MAY20[redacted] 7D 21	Grade 1 - 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]		F	VOMITING Gastrointestinal disorders Vomiting	05JAN20[redacted]/10:00 07JAN20[redacted]/06:51 1D20H51M 7	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	BRONCHITIS Infections and infestations Bronchitis	20JUN20[redacted] 24JUN20[redacted] 5D 78	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	PHARYNGITIS Infections and infestations Pharyngitis	02MAY20[redacted] 11MAY20[redacted] 10D 7	Grade 1 - 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	WEAKNESS General disorders and administration site conditions Asthenia	05JUN20[redacted] 41	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovering /Resolving
				HYPONATREMIA Metabolism and nutrition disorders Hyponatraemia	06JUN20[redacted] 09JUN20[redacted] 4D 42	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			M	FEBRILE NEUTROPENIA Blood and lymphatic system disorders Febrile neutropenia	05MAY20[redacted] 10MAY20[redacted] 6D 10	Grade 4 - 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	05JUL20[redacted]/08:14 09JUL20[redacted]/09:13 4D00H59M 62	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	19MAY20[redacted]/09:34 23MAY20[redacted]/10:44 4D01H10M 15	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				THROMBOCYTOPENIA Blood and lymphatic system disorders Thrombocytopenia	27JUL20[redacted]/08:56 30JUL20[redacted] 4D 84	Grade 4 - 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	BRONCHOPNEUMONIA BILATERALIS Infections and infestations Pneumonia	25MAY20[redacted]/14:10 26MAY20[redacted]/18:34 1D04H24M 8	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Fatal
			M	MASSIVE HEMOPTYSIS Respiratory, thoracic and mediastinal disorders Haemoptysis	24MAR20[redacted]/23:10 24MAR20[redacted]/23:20 0D00H10M 3	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
Spain			M	RESPIRATORY INFECTION Infections and infestations Respiratory tract infection	07MAR20[redacted]/12:23 18MAR20[redacted] 12D 43	Grade 3 - HOSP	Not Related - Not Related	Drug Withdrawn - 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	DIPLOPIA Eye disorders Diplopia	07APR20[redacted] 15APR20[redacted] 9D 25	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				MESENCEPHALIC ICTUS Nervous system disorders Cerebrovascular accident	08APR20[redacted] 15APR20[redacted] 8D 26	Grade 2 - HOSP	Unlikely - Not Related	Dose Not Changed - None	Recovered /Resolved
Ukraine			F	INTESTINAL OBSTRUCTION Gastrointestinal disorders Intestinal obstruction	02MAR20[redacted] 05MAR20[redacted] 4D 50	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]		M	PYOPNEUMOTHORAX OF THE RIGHT LUNG Infections and infestations Pyopneumothorax	29JAN20[redacted]/07:30 29JAN20[redacted]/11:20 0D03H50M 11	Grade 5 - HOSP,DTH	Not Related - Not Related	Dose Not Changed - None	Fatal
			F	MECHANICAL JAUNDICE DUE TO LIVER METASTASIS IN PORTA HEPATIS Hepatobiliary disorders Jaundice cholestatic	30DEC20[redacted] 02JAN20[redacted] 4D 22	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	NEUTROPHILE COUNT DECREASED Investigations Neutrophil count decreased	05APR20[redacted]/08:42 11APR20[redacted]/10:20 6D01H38M 100	Grade 4 - IME	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
Ukraine	[redacted]		M	ACUTE GASTRIC BLEEDING DUE TO ACUTE STOMACH ULCERS Gastrointestinal disorders Gastric ulcer haemorrhage	11JAN20[redacted] 13JAN20[redacted] 3D 15	Grade 5 - DTH	Not Related - Possibly	Dose Not Changed - None	Fatal
			F	RIGHT PLEUROPNEVMONIA Infections and infestations Pneumonia	08FEB20[redacted]/10:30 17FEB20[redacted] 10D 27	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
United States			M	ACCIDENTAL VALIUM OVERDOSE Injury, poisoning and procedural complications Accidental overdose	19JUN20[redacted] 19JUN20[redacted] 1D 42	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
Croatia	[redacted]		F	SEPSIS Infections and infestations Sepsis	29MAR20[redacted] 02APR20[redacted]/17:45 5D 13	Grade 5 - DTH	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Fatal
			F	PULMONARY EMBOLISM Respiratory, thoracic and mediastinal disorders Pulmonary embolism	08MAR20[redacted]/08:48 16MAR20[redacted]/10:00 8D01H12M 28	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	ILEUS Gastrointestinal disorders Ileus	22APR20[redacted]/07:37 24APR20[redacted]/06:59 1D23H22M 46	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
Croatia	[redacted]		F	AGRANULOCYTOSIS Blood and lymphatic system disorders Agranulocytosis	22APR20[redacted]/07:37 46	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
				SEPSIS Infections and infestations Sepsis	22APR20[redacted]/07:37 46	Grade 4 - LT	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
			M	PNEUMONIA Infections and infestations Pneumonia	25MAY20[redacted] 02JUN20[redacted] 9D 16	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
Croatia	[redacted]		M	ARTERIAL EMBOLISM OF LEFT LEG Vascular disorders Peripheral embolism	12APR20[redacted] 14APR20[redacted]/04:00 3D 29	Grade 5 - DTH	Unlikely - Unlikely	Dose Not Changed - Specific Therapy / Medication	Fatal
Czech Republic			M	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	21JUN20[redacted]/09:19 27JUN20[redacted] 7D 63	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
Germany			M	ACUTE KIDNEY INJURY Renal and urinary disorders Acute kidney injury	11JUN20[redacted] 15JUN20[redacted] 5D 48	Grade 1 - 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
Germany	[redacted]		M	PNEUMONIA Infections and infestations Pneumonia	28JUN20[redacted] 65	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Not Recovered /Not Resolved
			M	FEVER General disorders and administration site conditions Pyrexia	08JUN20[redacted] 09JUN20[redacted] 2D 37	Grade 1 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				URINARY TRACT INFECTION Infections and infestations Urinary tract infection	08JUN20[redacted] 17JUN20[redacted] 10D 37	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
Germany	[redacted]		M	HYPOKALEMIA Metabolism and nutrition disorders Hypokalaemia	13MAY20[redacted] 14MAY20[redacted]/11:30 2D 11	Grade 2 - HOSP	Not Related - Possibly	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				HYPOKALEMIA Metabolism and nutrition disorders Hypokalaemia	24MAY20[redacted]/09:49 24MAY20[redacted]/21:28 0D11H39M 22	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
Italy			M	DYSPNEA Respiratory, thoracic and mediastinal disorders Dyspnoea	05MAY20[redacted]/08:00 30MAY20[redacted] 26D 2	Grade 3 - HOSP	Unlikely - 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
Italy	[redacted]		M	ATRIAL FIBRILLATION Cardiac disorders Atrial fibrillation	09MAY20[redacted]/23:30 10MAY20[redacted]/15:09 0D15H39M 6	Grade 2 - HOSP	Unlikely - Unlikely	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
			F	LEUKOPENIA Blood and lymphatic system disorders Leukopenia	21MAR20[redacted]/11:00 25MAR20[redacted]/10:08 3D23H08M 57	Grade 4 - LT	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	21MAR20[redacted]/11:00 25MAR20[redacted]/10:08 3D23H08M 57	Grade 4 - LT	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	PERIRECTAL & LEFT BUTTOCK ABSCESS Infections and infestations Perirectal abscess	04MAY20[redacted] 06MAY20[redacted] 3D 31	Grade 3 - HOSP	Not Related - Possibly	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovered /Resolved With Sequelae
				WEAKNESS General disorders and administration site conditions Asthenia	21APR20[redacted]/11:10 24APR20[redacted] 4D 18	Grade 3 - HOSP	Not Related - Possibly	Dose Not Changed - None	Recovered /Resolved
				WEAKNESS General disorders and administration site conditions Asthenia	25APR20[redacted] 27APR20[redacted] 3D 22	Grade 2 - HOSP	Not Related - Possibly	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
Poland	[redacted]		F	NEUTROPENIA Blood and lymphatic system disorders Neutropenia	03FEB20[redacted] 03FEB20[redacted] 1D 44	Grade 2 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	04FEB20[redacted] 07FEB20[redacted] 4D 45	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved
				ASYMPTOMATIC NEUTROPENIA Blood and lymphatic system disorders Neutropenia	11JAN20[redacted] 11JAN20[redacted] 1D 21	Grade 2 - HOSP	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
Poland	[redacted]		F	ASYMPTOMATIC NEUTROPENIA Blood and lymphatic system disorders Neutropenia	12JAN20[redacted] 13JAN20[redacted] 2D 22	Grade 3 - HOSP	Not Related - Not Related	Dose Not Changed - None	Recovered /Resolved
				NEUTROPENIA Blood and lymphatic system disorders Neutropenia	28FEB20[redacted] 08MAR20[redacted] 10D 69	Grade 3 - HOSP	Not Related - Not Related	Drug Withdrawn - Subject Withdrawn From Study; Specific Therapy / Medication	Recovered /Resolved
			M	FEBRILE NEUTROPENIA Blood and lymphatic system disorders Febrile neutropenia	13FEB20[redacted] 19FEB20[redacted] 7D 13	Grade 4 - HOSP	Not Related - Not Related	Dose Not Changed - Specific Therapy / Medication	Recovered /Resolved