表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	大腸炎	胃腸障害	36	35D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	レジオネラ菌性肺炎	感染症および寄生虫症	51	20D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	自己免疫性大腸炎	胃腸障害	75	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	110	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	脱水	代謝および栄養障害	75	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	菌血症	感染症および寄生虫症	957	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	肺炎	感染症および寄生虫症	34	27D	Grade 4	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
1 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	失神	神経系障害	32	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	141	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	120	12.9H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	141	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	大腸閉塞	胃腸障害	125	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	365	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
2 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	413	23D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	胃出血	胃腸障害	144		Grade 5	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	122	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	薬物性肝障害	肝胆道系障害	66	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	急性腎不全	腎および尿路障害	65	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	高カリウム血症	代謝および栄養障害	97	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
3 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	低ナトリウム血症	代謝および栄養障害	76	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	65	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	76	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	65	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	76	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
4 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	3[redacted]/M/C/USA	血栓症	血管障害	576	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	3[redacted]/M/C/USA	血栓症	血管障害	736		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/F/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	189	5D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	肺塞栓症	呼吸器、胸郭および縦隔障害	65	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	2[redacted]/F/B/USA	呼吸困難	呼吸器、胸郭および縦隔障害	31	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	2[redacted]/F/B/USA	喀血	呼吸器、胸郭および縦隔障害	25	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
5 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	2[redacted]/F/B/USA	脊椎骨折	傷害、中毒および処置合併症	135	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	131	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	低血圧	血管障害	131	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	91	21D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	脱水	代謝および栄養障害	50	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	トランスアミナーゼ上昇	臨床検査	91	21D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
6 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	134	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	183	30D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	134	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	183	8D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	トランスアミナーゼ上昇	臨床検査	22	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	一過性脳虚血発作	神経系障害	59	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
7 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	嘔吐	胃腸障害	581	24.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	嘔吐	胃腸障害	948	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	581	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	低酸素症	呼吸器、胸郭および縦隔障害	581	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	下痢	胃腸障害	95	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	リンパ節症	血液およびリンパ系障害	222	24.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	3	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
8 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	11	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	無気肺	呼吸器、胸郭および縦隔障害	30	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	無気肺	呼吸器、胸郭および縦隔障害	32		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	脊髄圧迫	神経系障害	381	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	脊髄圧迫	神経系障害	391	17D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/F/C/USA	下痢	胃腸障害	6	46.0H	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
9 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/F/C/USA	可逆性後白質脳症症候群	神経系障害	325	44.5H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	自己免疫性肝炎	肝胆道系障害	84	22D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	下垂体炎	内分泌障害	51	2D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/F/C/USA	悪心	胃腸障害	22	10.7H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/F/C/USA	下痢	胃腸障害	22	10.7H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/F/C/USA	腹痛	胃腸障害	22	10.7H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/F/C/USA	嘔吐	胃腸障害	22	10.7H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
10 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	22	19.1H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	229	3D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	162	3D	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/F/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	229	10D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	下痢	胃腸障害	71	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	ウイルス性胃腸炎	感染症および寄生虫症	97	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
11 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	下痢	胃腸障害	55	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	133		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	40	104D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	大腸炎	胃腸障害	46	61D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	10	3D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	358	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
12 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	感染性小腸結腸炎	感染症および寄生虫症	43	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	7[redacted]/M/C/USA	背部痛	筋骨格系および結合組織障害	350	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	227		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	UNKNOWN
NIVO 1+IPI 3 (MG/KG)	[redacted]	4[redacted]/M/C/USA	喀血	呼吸器、胸郭および縦隔障害	10	3D	Grade 2	Involves Cancer, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	下痢	胃腸障害	44	48.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	大腸炎	胃腸障害	95	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
13 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	筋骨格痛	筋骨格系および結合組織障害	9	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	骨折	傷害、中毒および処置合併症	16	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	小腸閉塞	胃腸障害	81	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	ウイルス感染	感染症および寄生虫症	278	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 1+IPI 3 (MG/KG)	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	59	28D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	肺炎	感染症および寄生虫症	67	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
14 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	239		Grade 4	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	240		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	中枢神経系転移	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	204		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	平衡障害	神経系障害	157		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	189	116D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
15 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/CAN	胃腸炎	感染症および寄生虫症	115	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/CAN	副腎機能不全	内分泌障害	115	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	悪心	胃腸障害	511	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	急性腎不全	腎および尿路障害	56	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	腎不全	腎および尿路障害	85	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	108		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
16 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	3[redacted]/F/B/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	127		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVO 3+IPI 1 (MG/KG)	[redacted]	3[redacted]/M/C/USA	洞性頻脈	心臓障害	3	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	下痢	胃腸障害	26	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	皮膚感染	感染症および寄生虫症	41	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	血中クレアチニン増加	臨床検査	29	248D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/A/USA	痙攣発作	神経系障害	279	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	背部痛	筋骨格系および結合組織障害	467	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
17 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	心房細動	心臓障害	460	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	下痢	胃腸障害	137	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	粘膜潰瘍	一般・全身障害および投与部位の状態	466	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	咳嗽	呼吸器、胸郭および縦隔障害	6	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	トランスアミナーゼ上昇	臨床検査	6	14D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/M/C/USA	一過性全健忘	神経系障害	168	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	下痢	胃腸障害	94	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
18 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	腹痛	胃腸障害	242	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	下垂体機能低下症	内分泌障害	99	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	345	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	甲状腺機能亢進症	内分泌障害	25	21.4H	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	4[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	97	34.3H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	4[redacted]/M/C/USA	急性腎不全	腎および尿路障害	155	11D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
19 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	4[redacted]/M/C/USA	血小板数減少	臨床検査	98	29.9H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/F/C/USA	足関節部骨折	傷害、中毒および処置合併症	292	21D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	6[redacted]/F/C/USA	高カルシウム血症	代謝および栄養障害	79	26.6H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	胸水	呼吸器、胸郭および縦隔障害	40	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	2[redacted]/F/C/USA	下痢	胃腸障害	2	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	2[redacted]/F/C/USA	全身性炎症反応症候群	一般・全身障害および投与部位の状態	269	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	2[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	25	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
20 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	2[redacted]/F/C/USA	メトヘモグロビン血症	血液およびリンパ系障害	63	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	2[redacted]/F/C/USA	血小板数減少	臨床検査	269		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	びらん性胃炎	胃腸障害	85	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	びらん性十二指腸炎	胃腸障害	85	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	下部消化管出血	胃腸障害	108	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	上部消化管出血	胃腸障害	103	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	82	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
21 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	4[redacted]/F/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	632	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	悪寒	一般・全身障害および投与部位の状態	5	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	5	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	肺感染	感染症および寄生虫症	7	32D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	低酸素症	呼吸器、胸郭および縦隔障害	6	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	頭蓋内出血	神経系障害	50	15D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	急性腎不全	腎および尿路障害	29	114D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
22 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	高カルシウム血症	代謝および栄養障害	29	23D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	腫瘍フレア	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7	32D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	血中クレアチニン増加	臨床検査	29	21D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED /RESOLVED WITH SEQUELAE
NIVO 3+IPI 1 (MG/KG)	[redacted]	3[redacted]/F/C/USA	背部痛	筋骨格系および結合組織障害	60	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/CAN	自己免疫性肝炎	肝胆道系障害	60	15D	Grade 4	Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED /RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/A/CAN	肺感染	感染症および寄生虫症	200	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
23 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/A/CAN	肺臓炎	呼吸器、胸郭および縦隔障害	135	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 3+IPI 1 (MG/KG)	[redacted]	4[redacted]/M/C/USA	頚部痛	筋骨格系および結合組織障害	278	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVO 3+IPI 1 (MG/KG)	[redacted]	5[redacted]/M/C/USA	筋骨格系胸痛	筋骨格系および結合組織障害	143	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	下痢	胃腸障害	50	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	悪性新生物進行	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	251	5D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	自己免疫性大腸炎	胃腸障害	91	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
24 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	30	9D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	心筋虚血	心臓障害	495	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	全身性炎症反応症候群	一般・全身障害および投与部位の状態	328	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	111	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	ウイルス感染	感染症および寄生虫症	288	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	複視	眼障害	77	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	[redacted]/M/C/USA	高血圧	血管障害	270	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED /RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
25 / 26

表2.7.4.7-3　重篤な有害事象の一覧表（016試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	低血圧	血管障害	121	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	骨折	傷害、中毒および処置合併症	60	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/M/C/USA	失神	神経系障害	148	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVO 3+IPI 3 (MG/KG)	[redacted]	5[redacted]/F/C/USA	肺感染	感染症および寄生虫症	30	41D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver18.1
CTCAE ver4.0
26 / 26