Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-154-[redacted]	6[redacted]/M/A/JPN	08MAR20[redacted]	12MAR20[redacted]	08OCT20[redacted]	28AUG20[redacted] *	325	DEATH	DISEASE	
CA209025-155-[redacted]	5[redacted]/F/A/JPN	17OCT20[redacted]	18OCT20[redacted]	16OCT20[redacted] *	01APR20[redacted] **	168	DEATH	DISEASE	
CA209025-158-[redacted]	7[redacted]/M/A/JPN	13MAY20[redacted]	14MAY20[redacted]	27MAY20[redacted]	10DEC20[redacted] *	563	DEATH	DISEASE	
CA209025-172-[redacted]	8[redacted]/F/A/JPN	27MAY20[redacted]	28MAY20[redacted]	01JUL20[redacted]	27OCT20[redacted]	119	DEATH	DISEASE	
CA209025-174-[redacted]	6[redacted]/M/A/JPN	10OCT20[redacted]	11OCT20[redacted]	28DEC20[redacted]	27FEB20[redacted] *	62	DEATH	DISEASE	
CA209025-121-[redacted]	7[redacted]/M/C/ARG	03APR20[redacted]	03APR20[redacted]	13NOV20[redacted]	18MAR20[redacted] *	126	DEATH	DISEASE	
CA209025-121-[redacted]	4[redacted]/F/C/ARG	18JUL20[redacted]	20JUL20[redacted]	07NOV20[redacted]	31JAN20[redacted] *	86	DEATH	DISEASE	
CA209025-77-[redacted]	6[redacted]/M/C/ARG	08JUL20[redacted]	09JUL20[redacted]	19DEC20[redacted]	13OCT20[redacted] *	299	DEATH	DISEASE	
CA209025-78-[redacted]	5[redacted]/M/C/ARG	30DEC20[redacted]	30DEC20[redacted]	25FEB20[redacted] *	10MAY20[redacted] *	75	DEATH	DISEASE	
CA209025-78-[redacted]	5[redacted]/M/C/ARG	16JAN20[redacted]	16JAN20[redacted]	16MAR20[redacted]	05JUL20[redacted]	112	DEATH	DISEASE	
CA209025-78-[redacted]	5[redacted]/M/C/ARG	15JAN20[redacted]	15JAN20[redacted]	19MAY20[redacted]	31JAN20[redacted] *	258	DEATH	DISEASE	
CA209025-78-[redacted]	7[redacted]/M/C/ARG	14AUG20[redacted]	14AUG20[redacted]	22OCT20[redacted]	11JAN20[redacted] *	82	DEATH	DISEASE	
CA209025-78-[redacted]	5[redacted]/M/C/ARG	10SEP20[redacted]	10SEP20[redacted]	29SEP20[redacted]	30SEP20[redacted]	2	DEATH	DISEASE	
CA209025-79-[redacted]	6[redacted]/F/C/ARG	25FEB20[redacted]	27FEB20[redacted]	30APR20[redacted]	15JUN20[redacted]	47	DEATH	DISEASE	

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　　：「3年後」を意味する
##　　：「4年後」を意味する

Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-79-[redacted]	7[redacted]/M/C/ARG	04SEP20[redacted]	05SEP20[redacted]	26NOV20[redacted]	16OCT20[redacted]*	325	DEATH	DISEASE	
CA209025-84-[redacted]	7[redacted]/F/C/ARG	05JUN20[redacted]	07JUN20[redacted]	25JUL20[redacted]	02NOV20[redacted]*	466	DEATH	DISEASE	
CA209025-84-[redacted]	5[redacted]/M/C/ARG	12JUL20[redacted]	12JUL20[redacted]	04SEP20[redacted]	28OCT20[redacted]	55	DEATH	DISEASE	
CA209025-85-[redacted]	6[redacted]/M/C/ARG	24OCT20[redacted]	25OCT20[redacted]	31JAN20[redacted]*	31JAN20[redacted]*	1	DEATH	DISEASE	
CA209025-95-[redacted]	7[redacted]/M/C/AUS	13MAR20[redacted]	14MAR20[redacted]	25APR20[redacted]*	26APR20[redacted]*	2	DEATH	DISEASE	
CA209025-95-[redacted]	5[redacted]/M/C/AUS	02SEP20[redacted]	03SEP20[redacted]	25SEP20[redacted]	05OCT20[redacted]*	11	DEATH	DISEASE	
CA209025-95-[redacted]	5[redacted]/M/C/AUS	10SEP20[redacted]	12SEP20[redacted]	18SEP20[redacted]*	27DEC20[redacted]*	101	DEATH	DISEASE	
CA209025-97-[redacted]	6[redacted]/F/C/AUS	23APR20[redacted]	24APR20[redacted]	06SEP20[redacted]	04NOV20[redacted]	60	DEATH	DISEASE	
CA209025-97-[redacted]	6[redacted]/F/C/AUS	06MAY20[redacted]	07MAY20[redacted]	28MAY20[redacted]	29MAY20[redacted]	2	DEATH	STUDY DRUG TOXICITY	ACUTE SMALL BOWEL ISCHAEMIA
CA209025-97-[redacted]	4[redacted]/F/C/AUS	27AUG20[redacted]	28AUG20[redacted]	19OCT20[redacted]	18NOV20[redacted]	31	DEATH	DISEASE	
CA209025-97-[redacted]	6[redacted]/M/C/AUS	27SEP20[redacted]	02OCT20[redacted]	27OCT20[redacted]	07NOV20[redacted]	12	DEATH	DISEASE	
CA209025-98-[redacted]	6[redacted]/M/C/AUS	15JUL20[redacted]	16JUL20[redacted]	17SEP20[redacted]	12NOV20[redacted]	57	DEATH	DISEASE	
CA209025-98-[redacted]	8[redacted]/F/C/AUS	17OCT20[redacted]			22OCT20[redacted]		DEATH	DISEASE	

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Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-92-[redacted]	6[redacted]/M/C/AUT	22APR20[redacted]	24APR20[redacted]	02SEP20[redacted]	09FEB20[redacted] *	161	DEATH	DISEASE	
CA209025-92-[redacted]	4[redacted]/M/C/AUT	07OCT20[redacted]	07OCT20[redacted]	07DEC20[redacted]	11JUN20[redacted] *	187	DEATH	DISEASE	
CA209025-93-[redacted]	7[redacted]/F/C/AUT	17JUL20[redacted]	17JUL20[redacted]	29SEP20[redacted]	10JUL20[redacted] *	285	DEATH	DISEASE	
CA209025-33-[redacted]	7[redacted]/M/C/BEL	30OCT20[redacted]	02NOV20[redacted]	14DEC20[redacted]	31AUG20[redacted] *	261	DEATH	DISEASE	
CA209025-33-[redacted]	5[redacted]/F/C/BEL	05SEP20[redacted]	05SEP20[redacted]	27DEC20[redacted]	08APR20[redacted] **	468	DEATH	DISEASE	
CA209025-35-[redacted]	5[redacted]/M/C/BEL	27MAY20[redacted]	28MAY20[redacted]	23JUN20[redacted] *	22JAN20[redacted] **	214	DEATH	DISEASE	
CA209025-36-[redacted]	6[redacted]/M/C/BEL	14MAY20[redacted]	15MAY20[redacted]	17JAN20[redacted] *	19APR20[redacted] *	93	DEATH	DISEASE	
CA209025-124-[redacted]	6[redacted]/M/C/BRA	17OCT20[redacted]	18OCT20[redacted]	05SEP20[redacted] *	09NOV20[redacted] *	66	DEATH	DISEASE	
CA209025-125-[redacted]	6[redacted]/M/C/BRA	11JUL20[redacted]	11JUL20[redacted]	11NOV20[redacted]	10JUN20[redacted] *	212	DEATH	DISEASE	
CA209025-125-[redacted]	6[redacted]/F/C/BRA	17JUL20[redacted]	17JUL20[redacted]	09SEP20[redacted]	03NOV20[redacted]	56	DEATH	DISEASE	
CA209025-141-[redacted]	6[redacted]/M/C/CAN	27JUN20[redacted]	27JUN20[redacted]	16OCT20[redacted]	25FEB20[redacted] *	133	DEATH	DISEASE	
CA209025-143-[redacted]	7[redacted]/M/C/CAN	08AUG20[redacted]	08AUG20[redacted]	30SEP20[redacted]	30OCT20[redacted]	31	DEATH	DISEASE	
CA209025-144-[redacted]	6[redacted]/F/C/CAN	25JUN20[redacted]	27JUN20[redacted]	03APR20[redacted] *	09SEP20[redacted] *	160	DEATH	DISEASE	
CA209025-144-[redacted]	5[redacted]/M/C/CAN	17SEP20[redacted]	20SEP20[redacted]	12MAR20[redacted] *	08MAY20[redacted] **	423	DEATH	DISEASE	

Gender: M=Male; F=Female.

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"First/Last Dose Date"及び"Death Date"において，
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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-145-[redacted]	6[redacted]/M/C/CAN	06JUN20[redacted]	06JUN20[redacted]	03SEP20[redacted]	26OCT20[redacted]	54	DEATH	DISEASE	
CA209025-147-[redacted]	7[redacted]/F/C/CAN	01AUG20[redacted]	01AUG20[redacted]	27AUG20[redacted]	30SEP20[redacted]*	400	DEATH	DISEASE	
CA209025-153-[redacted]	6[redacted]/M/C/CAN	01AUG20[redacted]	01AUG20[redacted]	22SEP20[redacted]	02JAN20[redacted]*	103	DEATH	UNKNOWN	
CA209025-69-[redacted]	6[redacted]/F/C/CZE	09MAY20[redacted]	09MAY20[redacted]	03DEC20[redacted]	15OCT20[redacted]*	317	DEATH	DISEASE	
CA209025-69-[redacted]	6[redacted]/M/C/CZE	10SEP20[redacted]	11SEP20[redacted]	07NOV20[redacted]	12NOV20[redacted]	6	DEATH	OTHER	SUICIDE
CA209025-112-[redacted]	3[redacted]/M/C/DEU	11MAR20[redacted]	12MAR20[redacted]	30APR20[redacted]	05SEP20[redacted]	129	DEATH	DISEASE	
CA209025-113-[redacted]	7[redacted]/F/C/DEU	19JUL20[redacted]	19JUL20[redacted]	17AUG20[redacted]	19AUG20[redacted]	3	DEATH	OTHER	APPOPLECTIC INSULT
CA209025-113-[redacted]	7[redacted]/M/C/DEU	29JAN20[redacted]	29JAN20[redacted]	18FEB20[redacted]	02SEP20[redacted]	197	DEATH	DISEASE	
CA209025-114-[redacted]	6[redacted]/M/C/DEU	28JAN20[redacted]	29JAN20[redacted]	22MAR20[redacted]	27MAR20[redacted]	6	DEATH	DISEASE	
CA209025-119-[redacted]	5[redacted]/M/C/DEU	29APR20[redacted]	29APR20[redacted]	26JUN20[redacted]	15AUG20[redacted]	51	DEATH	DISEASE	
CA209025-126-[redacted]	7[redacted]/M/C/DEU	25MAR20[redacted]	26MAR20[redacted]	07APR20[redacted]	06OCT20[redacted]*	548	DEATH	DISEASE	
CA209025-126-[redacted]	8[redacted]/M/C/DEU	08APR20[redacted]	08APR20[redacted]	06MAY20[redacted]	18MAY20[redacted]	13	DEATH	DISEASE	WORSENING OF GENERAL CONDITION AFTER FEMUR FRACTURE AND HOSPITALIZATION
CA209025-137-[redacted]	5[redacted]/M/C/DNK	25FEB20[redacted]	25FEB20[redacted]	14MAY20[redacted]	21OCT20[redacted]	161	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-137-[redacted]	5[redacted]/M/C/DNK	25JAN20[redacted]	28JAN20[redacted]	10NOV20[redacted]	27DEC20[redacted] *	413	DEATH	DISEASE	
CA209025-73-[redacted]	6[redacted]/M/C/DNK	19FEB20[redacted]	19FEB20[redacted]	27JUN20[redacted]	19AUG20[redacted] *	419	DEATH	DISEASE	
CA209025-89-[redacted]	5[redacted]/F/C/DNK	12MAR20[redacted]	13MAR20[redacted]	13JUN20[redacted]	03APR20[redacted] *	295	DEATH	DISEASE	
CA209025-89-[redacted]	5[redacted]/M/C/DNK	16MAY20[redacted]	16MAY20[redacted]	10JUL20[redacted]	25SEP20[redacted]	78	DEATH	DISEASE	
CA209025-89-[redacted]	6[redacted]/M/C/DNK	24JUL20[redacted]	25JUL20[redacted]	19SEP20[redacted]	04JAN20[redacted] *	108	DEATH	DISEASE	
CA209025-89-[redacted]	6[redacted]/M/C/DNK	23JAN20[redacted]	24JAN20[redacted]	29OCT20[redacted]	19MAY20[redacted] *	203	DEATH	DISEASE	
CA209025-61-[redacted]	7[redacted]/M/C/ESP	21FEB20[redacted]	21FEB20[redacted]	13JUN20[redacted]	15MAR20[redacted] **	641	DEATH	DISEASE	
CA209025-61-[redacted]	8[redacted]/M/C/ESP	23APR20[redacted]	23APR20[redacted]	08OCT20[redacted]	02NOV20[redacted]	26	DEATH	DISEASE	
CA209025-62-[redacted]	7[redacted]/M/C/ESP	26FEB20[redacted]	26FEB20[redacted]	18JUN20[redacted]	02SEP20[redacted]	77	DEATH	DISEASE	
CA209025-62-[redacted]	4[redacted]/M/C/ESP	21MAY20[redacted]	21MAY20[redacted]	17SEP20[redacted]	11NOV20[redacted]	56	DEATH	DISEASE	
CA209025-62-[redacted]	7[redacted]/M/C/ESP	06AUG20[redacted]	06AUG20[redacted]	19MAR20[redacted] *	31JUL20[redacted] *	135	DEATH	DISEASE	
CA209025-62-[redacted]	5[redacted]/M/C/ESP	21AUG20[redacted]	21AUG20[redacted]	11DEC20[redacted]	17JUL20[redacted] *	219	DEATH	DISEASE	
CA209025-62-[redacted]	6[redacted]/F/C/ESP	30JAN20[redacted]	01FEB20[redacted]	18FEB20[redacted]	28APR20[redacted]	70	DEATH	DISEASE	
CA209025-64-[redacted]	6[redacted]/M/C/ESP	08JUL20[redacted]	09JUL20[redacted]	25JUL20[redacted]	10SEP20[redacted]	48	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-64-[redacted]	4[redacted]/F/C/ESP	26AUG20[redacted]	27AUG20[redacted]	21JAN20[redacted]*	10MAR20[redacted]*	49	DEATH	DISEASE	
CA209025-64-[redacted]	6[redacted]/F/C/ESP	05NOV20[redacted]	05NOV20[redacted]	27JAN20[redacted]*	25OCT20[redacted]*	272	DEATH	DISEASE	
CA209025-65-[redacted]	6[redacted]/M/C/ESP	19APR20[redacted]	19APR20[redacted]	10MAY20[redacted]	27MAY20[redacted]	18	DEATH	DISEASE	
CA209025-65-[redacted]	6[redacted]/M/C/ESP	19JUN20[redacted]	19JUN20[redacted]	11DEC20[redacted]	19JAN20[redacted]*	40	DEATH	DISEASE	
CA209025-65-[redacted]	6[redacted]/F/C/ESP	12JUN20[redacted]	12JUN20[redacted]	05AUG20[redacted]	07APR20[redacted]*	246	DEATH	DISEASE	
CA209025-65-[redacted]	8[redacted]/M/C/ESP	30JUL20[redacted]	30JUL20[redacted]	17OCT20[redacted]	11DEC20[redacted]*	421	DEATH	DISEASE	
CA209025-75-[redacted]	7[redacted]/F/C/FIN	26OCT20[redacted]	30OCT20[redacted]	04JUL20[redacted]*	02AUG20[redacted]**	395	DEATH	OTHER	ANTERIOR MYOCARDIAL INFARCTION
CA209025-75-[redacted]	6[redacted]/F/C/FIN	18JUL20[redacted]	18JUL20[redacted]	06NOV20[redacted]	27AUG20[redacted]*	295	DEATH	DISEASE	
CA209025-75-[redacted]	7[redacted]/M/C/FIN	16JUL20[redacted]	17JUL20[redacted]	21AUG20[redacted]	15DEC20[redacted]	117	DEATH	DISEASE	
CA209025-75-[redacted]	7[redacted]/M/C/FIN	02SEP20[redacted]	03SEP20[redacted]	28OCT20[redacted]	09MAY20[redacted]*	194	DEATH	DISEASE	
CA209025-118-[redacted]	6[redacted]/M/C/FRA	12MAR20[redacted]	13MAR20[redacted]	03APR20[redacted]	04APR20[redacted]	2	DEATH	STUDY DRUG TOXICITY	SEPTIC SHOCK DUE TO AN INFECTIOUS PNEUMONITIS
CA209025-118-[redacted]	6[redacted]/M/C/FRA	27JUN20[redacted]	28JUN20[redacted]	20AUG20[redacted]	08OCT20[redacted]	50	DEATH	DISEASE	CANCER PROGRESSION
CA209025-2-[redacted]	6[redacted]/M/C/FRA	12MAR20[redacted]	12MAR20[redacted]	22SEP20[redacted]	13JAN20[redacted]*	114	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-2-[redacted]	5[redacted]/M/C/FRA	19NOV20[redacted]	19NOV20[redacted]	25AUG20[redacted] *	30AUG20[redacted]**	371	DEATH	DISEASE	
CA209025-2-[redacted]	7[redacted]/F/C/FRA	19FEB20[redacted]	21FEB20[redacted]	01APR20[redacted]	31MAY20[redacted]	61	DEATH	DISEASE	
CA209025-2-[redacted]	7[redacted]/M/B/FRA	11DEC20[redacted]	17DEC20[redacted]	05JUN20[redacted]*	03FEB20[redacted]**	244	DEATH	DISEASE	
CA209025-2-[redacted]	6[redacted]/M/C/FRA	27DEC20[redacted]	27DEC20[redacted]	13JAN20[redacted]*	02AUG20[redacted] *	202	DEATH	DISEASE	
CA209025-2-[redacted]	5[redacted]/F/C/FRA	27JUN20[redacted]	28JUN20[redacted]	13AUG20[redacted]	12FEB20[redacted] *	184	DEATH	DISEASE	
CA209025-2-[redacted]	6[redacted]/M/C/FRA	13AUG20[redacted]	13AUG20[redacted]	01DEC20[redacted]	14APR20[redacted]**	500	DEATH	DISEASE	
CA209025-2-[redacted]	6[redacted]/F/C/FRA	23SEP20[redacted]	23SEP20[redacted]	19JAN20[redacted] *	10FEB20[redacted]**	388	DEATH	DISEASE	
CA209025-2-[redacted]	3[redacted]/M/C/FRA	15OCT20[redacted]	15OCT20[redacted]	02FEB20[redacted] *	22OCT20[redacted] *	263	DEATH	DISEASE	
CA209025-2-[redacted]	5[redacted]/F/C/FRA	22OCT20[redacted]	22OCT20[redacted]	12JAN20[redacted]**	25APR20[redacted]**	104	DEATH	DISEASE	
CA209025-4-[redacted]	5[redacted]/M/C/FRA	13MAY20[redacted]	13MAY20[redacted]	13MAR20[redacted]**	05APR20[redacted]**	24	DEATH	DISEASE	
CA209025-4-[redacted]	7[redacted]/M/C/FRA	28DEC20[redacted]	31DEC20[redacted]	24FEB20[redacted]*	11SEP20[redacted]*	200	DEATH	DISEASE	
CA209025-4-[redacted]	5[redacted]/M/C/FRA	05SEP20[redacted]	05SEP20[redacted]	20SEP20[redacted]	05OCT20[redacted]	16	DEATH	DISEASE	
CA209025-5-[redacted]	6[redacted]/F/C/FRA	07JAN20[redacted]	09JAN20[redacted]	27MAY20[redacted]	03JUL20[redacted]	38	DEATH	DISEASE	
CA209025-5-[redacted]	7[redacted]/M/C/FRA	23JUL20[redacted]	26JUL20[redacted]	11OCT20[redacted]	27DEC20[redacted]	78	DEATH	DISEASE	

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-5-[redacted]	5[redacted]/M/C/FRA	30AUG20[redacted]	03SEP20[redacted]	23SEP20[redacted] *	31MAR20[redacted] **	190	DEATH	DISEASE	
CA209025-6-[redacted]	6[redacted]/F/C/FRA	08MAR20[redacted]	11MAR20[redacted]	07NOV20[redacted]	04JUN20[redacted] **	575	DEATH	DISEASE	
CA209025-8-[redacted]	4[redacted]/M/C/FRA	10JUL20[redacted]	10JUL20[redacted]	22DEC20[redacted]	15OCT20[redacted] *	298	DEATH	DISEASE	
CA209025-39-[redacted]	5[redacted]/M/C/GBR	28MAR20[redacted]	02APR20[redacted]	11MAY20[redacted]	30MAR20[redacted] *	324	DEATH	DISEASE	
CA209025-39-[redacted]	6[redacted]/M/C/GBR	02AUG20[redacted]	06AUG20[redacted]	02SEP20[redacted]	05JUL20[redacted] *	307	DEATH	DISEASE	
CA209025-39-[redacted]	6[redacted]/M/C/GBR	16AUG20[redacted]	20AUG20[redacted]	30SEP20[redacted]	01NOV20[redacted]	33	DEATH	OTHER	ACUTE KIDNEY INJURY& DECOMPENSATION-UNKNOWN CAUSE.NOT DIRECTLY RELATED TO IMP/UNDERLYING DISEASE
CA209025-39-[redacted]	7[redacted]/M/C/GBR	23SEP20[redacted]	24SEP20[redacted]	08OCT20[redacted]	21MAR20[redacted] **	530	DEATH	DISEASE	
CA209025-48-[redacted]	6[redacted]/M/C/GBR	01NOV20[redacted]	11NOV20[redacted]	26DEC20[redacted]	18APR20[redacted] *	114	DEATH	DISEASE	
CA209025-50-[redacted]	6[redacted]/M/C/GBR	18JUN20[redacted]	21JUN20[redacted]	09OCT20[redacted]	26FEB20[redacted] *	141	DEATH	DISEASE	
CA209025-55-[redacted]	5[redacted]/M/C/GRC	22JUL20[redacted]	23JUL20[redacted]	09OCT20[redacted]	24OCT20[redacted]	16	DEATH	DISEASE	
CA209025-56-[redacted]	7[redacted]/M/C/GRC	08AUG20[redacted]	08AUG20[redacted]	16SEP20[redacted]	23SEP20[redacted]	8	DEATH	DISEASE	
CA209025-37-[redacted]	5[redacted]/M/C/IRL	29NOV20[redacted]	30NOV20[redacted]	15APR20[redacted] *	21APR20[redacted] *	7	DEATH	OTHER	STROKE

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"First/Last Dose Date"及び"Death Date"において，
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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-40-[redacted]	7[redacted]/M/C/IRL	26JUN20[redacted]	27JUN20[redacted]	04AUG20[redacted]	11AUG20[redacted]	8	DEATH	OTHER	LOWER RESPIRATORY TRACT INFECTION/PNEUMONIA
CA209025-87-[redacted]	5[redacted]/M/C/IRL	22OCT20[redacted]	23OCT20[redacted]	17DEC20[redacted]	09APR20[redacted]*	114	DEATH	DISEASE	
CA209025-148-[redacted]	7[redacted]/M/C/ISR	23MAY20[redacted]	23MAY20[redacted]	02APR20[redacted] *	12APR20[redacted]*	11	DEATH	DISEASE	
CA209025-148-[redacted]	7[redacted]/M/C/ISR	23OCT20[redacted]	24OCT20[redacted]	14NOV20[redacted]	05DEC20[redacted]	22	DEATH	OTHER	INFECTION
CA209025-149-[redacted]	7[redacted]/M/C/ISR	24APR20[redacted]	25APR20[redacted]	12AUG20[redacted]	15AUG20[redacted]*	369	DEATH	DISEASE	
CA209025-149-[redacted]	7[redacted]/M/C/ISR	23APR20[redacted]	23APR20[redacted]	28SEP20[redacted] *	03MAY20[redacted]**	218	DEATH	DISEASE	
CA209025-149-[redacted]	6[redacted]/M/C/ISR	17SEP20[redacted]	18SEP20[redacted]	01DEC20[redacted]	30APR20[redacted]*	151	DEATH	DISEASE	
CA209025-149-[redacted]	7[redacted]/F/C/ISR	24SEP20[redacted]	24SEP20[redacted]	02DEC20[redacted]	13DEC20[redacted]	12	DEATH	DISEASE	
CA209025-151-[redacted]	6[redacted]/F/C/ISR	21JUL20[redacted]	22JUL20[redacted]	30APR20[redacted] *	05MAY20[redacted]*	6	DEATH	DISEASE	
CA209025-151-[redacted]	6[redacted]/M/C/ISR	30JUL20[redacted]	31JUL20[redacted]	27AUG20[redacted]	16SEP20[redacted]	21	DEATH	DISEASE	
CA209025-102-[redacted]	6[redacted]/M/C/ITA	06MAY20[redacted]	07MAY20[redacted]	24OCT20[redacted]	16MAR20[redacted]*	144	DEATH	DISEASE	
CA209025-58-[redacted]	6[redacted]/M/O/ITA	28JUN20[redacted]	01JUL20[redacted]	15JUL20[redacted]	11JAN20[redacted]**	546	DEATH	DISEASE	
CA209025-59-[redacted]	5[redacted]/F/C/ITA	10JUN20[redacted]	10JUN20[redacted]	08AUG20[redacted] *	24DEC20[redacted] *	139	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-59-[redacted]	7[redacted]/M/C/ITA	05SEP20[redacted]	05SEP20[redacted]	30OCT20[redacted]	03APR20[redacted]*	156	DEATH	DISEASE	
CA209025-80-[redacted]	7[redacted]/M/C/ITA	07DEC20[redacted]	07DEC20[redacted]	08APR20[redacted]*	23SEP20[redacted]**	534	DEATH	DISEASE	
CA209025-80-[redacted]	6[redacted]/M/C/ITA	28DEC20[redacted]	31DEC20[redacted]	24JUN20[redacted]*	05MAR20[redacted]#	620	DEATH	DISEASE	
CA209025-80-[redacted]	8[redacted]/M/C/ITA	01JUL20[redacted]	02JUL20[redacted]	13JAN20[redacted]*	09MAR20[redacted]**	421	DEATH	DISEASE	
CA209025-82-[redacted]	3[redacted]/M/C/ITA	25MAR20[redacted]	27MAR20[redacted]	04JUN20[redacted]	05AUG20[redacted]	63	DEATH	DISEASE	PROGRESSION DISEASE
CA209025-82-[redacted]	6[redacted]/M/C/ITA	04JUN20[redacted]	05JUN20[redacted]	04OCT20[redacted]	30JAN20[redacted]*	119	DEATH	DISEASE	
CA209025-72-[redacted]	4[redacted]/M/C/NOR	27MAY20[redacted]	28MAY20[redacted]	06JUN20[redacted]	04OCT20[redacted]	121	DEATH	DISEASE	
CA209025-72-[redacted]	7[redacted]/M/C/NOR	27MAY20[redacted]	28MAY20[redacted]	24JUL20[redacted]	08FEB20[redacted]*	200	DEATH	DISEASE	
CA209025-111-[redacted]	7[redacted]/F/C/POL	22MAY20[redacted]	23MAY20[redacted]	05AUG20[redacted]	14JAN20[redacted]*	163	DEATH	UNKNOWN	
CA209025-116-[redacted]	5[redacted]/M/C/POL	26JUL20[redacted]	26JUL20[redacted]	16SEP20[redacted]*	13NOV20[redacted]*	59	DEATH	UNKNOWN	
CA209025-177-[redacted]	5[redacted]/M/C/POL	30OCT20[redacted]	01NOV20[redacted]	16JUN20[redacted]*	11JUL20[redacted]*	26	DEATH	DISEASE	
CA209025-180-[redacted]	5[redacted]/F/C/RUS	27FEB20[redacted]	27FEB20[redacted]	24APR20[redacted]	14SEP20[redacted]	144	DEATH	DISEASE	
CA209025-74-[redacted]	6[redacted]/M/C/SWE	14JAN20[redacted]	16JAN20[redacted]	16JUN20[redacted]	04NOV20[redacted]	142	DEATH	DISEASE	
CA209025-90-[redacted]	6[redacted]/M/C/SWE	07OCT20[redacted]	07OCT20[redacted]	23OCT20[redacted]	31JAN20[redacted]**	466	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-90-[redacted]	5[redacted]/M/C/SWE	12FEB20[redacted]	12FEB20[redacted]	08AUG20[redacted]	01AUG20[redacted] *	359	DEATH	DISEASE	
CA209025-1-[redacted]	6[redacted]/M/C/USA	19MAR20[redacted]	21MAR20[redacted]	10MAY20[redacted]	18NOV20[redacted]	193	DEATH	DISEASE	
CA209025-1-[redacted]	7[redacted]/M/C/USA	11DEC20[redacted]	11DEC20[redacted]	23APR20[redacted] *	11MAY20[redacted] #	749	DEATH	DISEASE	
CA209025-1-[redacted]	6[redacted]/M/C/USA	05DEC20[redacted]	06DEC20[redacted]	31JAN20[redacted] *	09APR20[redacted] **	434	DEATH	DISEASE	
CA209025-1-[redacted]	6[redacted]/F/C/USA	10MAY20[redacted]	14MAY20[redacted]	09JUN20[redacted] *	16DEC20[redacted] *	191	DEATH	DISEASE	
CA209025-1-[redacted]	5[redacted]/M/C/USA	01JUL20[redacted]	02JUL20[redacted]	28AUG20[redacted]	21MAR20[redacted] **	571	DEATH	DISEASE	
CA209025-1-[redacted]	6[redacted]/M/C/USA	27AUG20[redacted]	30AUG20[redacted]	11OCT20[redacted]	31MAY20[redacted] *	233	DEATH	DISEASE	
CA209025-1-[redacted]	7[redacted]/M/C/USA	02DEC20[redacted]	03DEC20[redacted]	17JAN20[redacted] *	18DEC20[redacted] *	336	DEATH	DISEASE	
CA209025-1-[redacted]	5[redacted]/F/A/USA	05DEC20[redacted]	05DEC20[redacted]	27JAN20[redacted] *	24FEB20[redacted] **	394	DEATH	DISEASE	
CA209025-11-[redacted]	6[redacted]/M/B/USA	25FEB20[redacted]	27FEB20[redacted]	04JUN20[redacted]	08SEP20[redacted] *	462	DEATH	DISEASE	
CA209025-11-[redacted]	5[redacted]/M/C/USA	08OCT20[redacted]	09OCT20[redacted]	07DEC20[redacted]	03MAY20[redacted] *	148	DEATH	DISEASE	
CA209025-13-[redacted]	4[redacted]/M/C/USA	11APR20[redacted]	17APR20[redacted]	25NOV20[redacted]	19NOV20[redacted] *	360	DEATH	DISEASE	
CA209025-13-[redacted]	6[redacted]/M/C/USA	08FEB20[redacted]	12FEB20[redacted]	23FEB20[redacted]	03MAR20[redacted]	9	DEATH	DISEASE	
CA209025-138-[redacted]	7[redacted]/M/C/USA	04MAR20[redacted]	15MAR20[redacted]	25APR20[redacted]	13OCT20[redacted]	172	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-138-[redacted]	5[redacted]/M/C/USA	23JUL20[redacted]	07AUG20[redacted]	10DEC20[redacted]	09MAR20[redacted]**	455	DEATH	DISEASE	
CA209025-139-[redacted]	6[redacted]/M/C/USA	05MAR20[redacted]	05MAR20[redacted]	30APR20[redacted]	30JUN20[redacted]*	427	DEATH	UNKNOWN	
CA209025-139-[redacted]	6[redacted]/M/C/USA	13AUG20[redacted]	15AUG20[redacted]	13OCT20[redacted]	04DEC20[redacted]	53	DEATH	DISEASE	
CA209025-139-[redacted]	5[redacted]/M/C/USA	16SEP20[redacted]	18SEP20[redacted]	14JAN20[redacted]*	31MAY20[redacted]*	138	DEATH	UNKNOWN	
CA209025-139-[redacted]	5[redacted]/M/A/USA	25SEP20[redacted]	27SEP20[redacted]	11MAR20[redacted]*	20APR20[redacted]**	406	DEATH	OTHER	NATURAL CAUSES
CA209025-139-[redacted]	6[redacted]/F/C/USA	08OCT20[redacted]	11OCT20[redacted]	14NOV20[redacted]	10JAN20[redacted]*	58	DEATH	DISEASE	
CA209025-139-[redacted]	7[redacted]/M/C/USA	24OCT20[redacted]	26OCT20[redacted]	15JAN20[redacted]*	19MAR20[redacted]*	64	DEATH	DISEASE	
CA209025-139-[redacted]	5[redacted]/M/C/USA	07JAN20[redacted]	09JAN20[redacted]	16JUN20[redacted]	02JAN20[redacted]*	201	DEATH	UNKNOWN	
CA209025-139-[redacted]	6[redacted]/F/C/USA	16JAN20[redacted]	24JAN20[redacted]	13MAR20[redacted]	18APR20[redacted]*	402	DEATH	UNKNOWN	
CA209025-14-[redacted]	6[redacted]/M/C/USA	02JAN20[redacted]	09JAN20[redacted]	02MAR20[redacted]	08APR20[redacted]*	403	DEATH	UNKNOWN	
CA209025-15-[redacted]	4[redacted]/F/C/USA	26JUL20[redacted]	30JUL20[redacted]	10SEP20[redacted]	28FEB20[redacted]*	172	DEATH	DISEASE	
CA209025-15-[redacted]	5[redacted]/M/C/USA	20SEP20[redacted]	23SEP20[redacted]	14NOV20[redacted]	02APR20[redacted]*	140	DEATH	DISEASE	
CA209025-17-[redacted]	5[redacted]/M/C/USA	07MAR20[redacted]	07MAR20[redacted]	24APR20[redacted]	08MAY20[redacted]	15	DEATH	DISEASE	
CA209025-17-[redacted]	6[redacted]/M/A/USA	30MAY20[redacted]	31MAY20[redacted]	22AUG20[redacted]	10NOV20[redacted]	81	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-17-[redacted]	6[redacted]/F/C/USA	06JUN20[redacted]	07JUN20[redacted]	28SEP20[redacted]*	29DEC20[redacted]*	93	DEATH	DISEASE	
CA209025-17-[redacted]	4[redacted]/M/C/USA	07FEB20[redacted]	11FEB20[redacted]	02OCT20[redacted]	15JUL20[redacted]*	287	DEATH	DISEASE	
CA209025-18-[redacted]	7[redacted]/M/C/USA	22FEB20[redacted]	26FEB20[redacted]	18JUN20[redacted]	07JAN20[redacted]*	204	DEATH	DISEASE	
CA209025-182-[redacted]	8[redacted]/M/C/USA	29AUG20[redacted]	31AUG20[redacted]	29OCT20[redacted]	28APR20[redacted]**	547	DEATH	DISEASE	
CA209025-20-[redacted]	7[redacted]/F/C/USA	22JAN20[redacted]	24JAN20[redacted]	17MAR20[redacted]	29MAR20[redacted]	13	DEATH	DISEASE	
CA209025-20-[redacted]	5[redacted]/F/C/USA	14FEB20[redacted]	21FEB20[redacted]	08APR20[redacted]	28APR20[redacted]	21	DEATH	DISEASE	
CA209025-20-[redacted]	5[redacted]/M/C/USA	10MAR20[redacted]	14MAR20[redacted]	26AUG20[redacted]	23NOV20[redacted]	90	DEATH	DISEASE	
CA209025-20-[redacted]	7[redacted]/M/C/USA	11MAR20[redacted]	12MAR20[redacted]	06MAY20[redacted]	01NOV20[redacted]*	545	DEATH	DISEASE	
CA209025-20-[redacted]	4[redacted]/M/C/USA	09APR20[redacted]	11APR20[redacted]	04JUN20[redacted]	26SEP20[redacted]*	480	DEATH	DISEASE	
CA209025-20-[redacted]	7[redacted]/M/C/USA	10SEP20[redacted]	22SEP20[redacted]	24OCT20[redacted]	31JAN20[redacted]*	100	DEATH	DISEASE	RENAL CELL CARCINOMA
CA209025-20-[redacted]	2[redacted]/M/C/USA	23SEP20[redacted]			27JAN20[redacted]*		DEATH	DISEASE	
CA209025-20-[redacted]	7[redacted]/M/C/USA	25SEP20[redacted]	26SEP20[redacted]	14JAN20[redacted]*	06FEB20[redacted]**	389	DEATH	DISEASE	
CA209025-20-[redacted]	4[redacted]/F/C/USA	11FEB20[redacted]	18FEB20[redacted]	07APR20[redacted]	04APR20[redacted]*	363	DEATH	DISEASE	
CA209025-21-[redacted]	6[redacted]/M/C/USA	22JUL20[redacted]	25JUL20[redacted]	18SEP20[redacted]	05FEB20[redacted]*	141	DEATH	DISEASE	

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Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-21-[redacted]	7[redacted]/M/C/USA	29JUL20[redacted]	01AUG20[redacted]	29AUG20[redacted]	21OCT20[redacted]	54	DEATH	DISEASE	
CA209025-21-[redacted]	5[redacted]/M/C/USA	19AUG20[redacted]	22AUG20[redacted]	16OCT20[redacted]	23APR20[redacted]*	190	DEATH	DISEASE	
CA209025-21-[redacted]	5[redacted]/F/C/USA	04NOV20[redacted]	07NOV20[redacted]	12DEC20[redacted]	12JAN20[redacted]**	397	DEATH	DISEASE	
CA209025-22-[redacted]	3[redacted]/M/C/USA	06JAN20[redacted]	09JAN20[redacted]	05FEB20[redacted]	03SEP20[redacted]	211	DEATH	DISEASE	
CA209025-22-[redacted]	4[redacted]/M/C/USA	20MAY20[redacted]	23MAY20[redacted]	17JUL20[redacted]	15MAY20[redacted]*	303	DEATH	DISEASE	
CA209025-23-[redacted]	6[redacted]/M/C/USA	01APR20[redacted]	03APR20[redacted]	18JUN20[redacted]	07AUG20[redacted]*	416	DEATH	DISEASE	
CA209025-23-[redacted]	7[redacted]/M/C/USA	15JAN20[redacted]	16JAN20[redacted]	13FEB20[redacted]	16SEP20[redacted]	216	DEATH	DISEASE	
CA209025-23-[redacted]	7[redacted]/M/C/USA	07DEC20[redacted]	11DEC20[redacted]	17MAR20[redacted]*	14DEC20[redacted]*	273	DEATH	OTHER	SEPTIC SHOCK SECONDARY TO HCAP
CA209025-23-[redacted]	6[redacted]/F/C/USA	08FEB20[redacted]	11FEB20[redacted]	20OCT20[redacted]	28FEB20[redacted]**	497	DEATH	DISEASE	
CA209025-25-[redacted]	6[redacted]/F/C/USA	31JAN20[redacted]	03FEB20[redacted]	20MAR20[redacted]	04APR20[redacted]	16	DEATH	DISEASE	
CA209025-25-[redacted]	6[redacted]/M/C/USA	25FEB20[redacted]	28FEB20[redacted]	05MAR20[redacted]	07OCT20[redacted]	217	DEATH	DISEASE	
CA209025-25-[redacted]	6[redacted]/F/C/USA	06DEC20[redacted]	11DEC20[redacted]	19APR20[redacted]*	16NOV20[redacted]*	212	DEATH	OTHER	INCARCERATED HERNIA
CA209025-26-[redacted]	6[redacted]/M/C/USA	18FEB20[redacted]	22FEB20[redacted]	21MAR20[redacted]	16MAY20[redacted]*	422	DEATH	DISEASE	
CA209025-26-[redacted]	5[redacted]/M/C/USA	05AUG20[redacted]	06AUG20[redacted]	09OCT20[redacted]	05DEC20[redacted]*	423	DEATH	DISEASE	

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　　：「3年後」を意味する
##　　：「4年後」を意味する

Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-27-[redacted]	6[redacted]/M/C/USA	08JUL20[redacted]	09JUL20[redacted]	02SEP20[redacted]	25FEB20[redacted] *	177	DEATH	DISEASE	
CA209025-28-[redacted]	7[redacted]/M/C/USA	05AUG20[redacted]	07AUG20[redacted]	07JUL20[redacted] *	24FEB20[redacted] **	233	DEATH	DISEASE	
CA209025-29-[redacted]	6[redacted]/F/C/USA	07MAY20[redacted]	09MAY20[redacted]	31MAY20[redacted]	04JUL20[redacted]	35	DEATH	DISEASE	
CA209025-29-[redacted]	5[redacted]/M/C/USA	22OCT20[redacted]	25OCT20[redacted]	01AUG20[redacted] *	23FEB20[redacted] **	207	DEATH	DISEASE	
CA209025-29-[redacted]	5[redacted]/M/C/USA	03JUL20[redacted]	08JUL20[redacted]	03SEP20[redacted]	28FEB20[redacted] **	544	DEATH	DISEASE	
CA209025-29-[redacted]	6[redacted]/F/C/USA	08JAN20[redacted]	10JAN20[redacted]	28JAN20[redacted]	28JUN20[redacted] *	517	DEATH	DISEASE	
CA209025-29-[redacted]	6[redacted]/M/C/USA	07AUG20[redacted]	12AUG20[redacted]	26JAN20[redacted] *	06MAR20[redacted] *	40	DEATH	DISEASE	
CA209025-29-[redacted]	5[redacted]/M/C/USA	31JAN20[redacted]	05FEB20[redacted]	13FEB20[redacted]	26MAY20[redacted]	103	DEATH	DISEASE	
CA209025-31-[redacted]	6[redacted]/M/C/USA	17JUN20[redacted]	20JUN20[redacted]	09AUG20[redacted]	11AUG20[redacted] *	368	DEATH	DISEASE	
CA209025-41-[redacted]	7[redacted]/F/C/USA	08JUL20[redacted]	11JUL20[redacted]	29AUG20[redacted]	21NOV20[redacted] *	450	DEATH	UNKNOWN	
CA209025-41-[redacted]	6[redacted]/M/C/USA	12NOV20[redacted]	16NOV20[redacted]	07FEB20[redacted] *	28FEB20[redacted] *	22	DEATH	DISEASE	CARDIOPULMONARY ARREST DUE TO POD IN LUNGS
CA209025-42-[redacted]	4[redacted]/M/C/USA	04FEB20[redacted]	04FEB20[redacted]	03MAR20[redacted]	15JUL20[redacted]	135	DEATH	DISEASE	
CA209025-42-[redacted]	6[redacted]/M/C/USA	13FEB20[redacted]	17FEB20[redacted]	09APR20[redacted]	14MAY20[redacted]	36	DEATH	DISEASE	

Gender: M=Male; F=Female.

Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.

CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　　：「3年後」を意味する
##　　：「4年後」を意味する

Treatment Group: EVEROLIMUS 10 mg

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-42-[redacted]	4[redacted]/M/C/USA	01FEB20[redacted]	01FEB20[redacted]	04MAR20[redacted]	27FEB20[redacted]*	361	DEATH	DISEASE	
CA209025-42-[redacted]	5[redacted]/F/C/USA	02DEC20[redacted]	05DEC20[redacted]	14DEC20[redacted]	06FEB20[redacted]*	55	DEATH	DISEASE	
CA209025-43-[redacted]	5[redacted]/F/C/USA	01AUG20[redacted]	02AUG20[redacted]	22NOV20[redacted]	30MAR20[redacted]**	494	DEATH	DISEASE	
CA209025-43-[redacted]	6[redacted]/F/C/USA	16OCT20[redacted]	17OCT20[redacted]	06MAR20[redacted]*	12JAN20[redacted]**	313	DEATH	DISEASE	
CA209025-43-[redacted]	5[redacted]/M/C/USA	01NOV20[redacted]	09NOV20[redacted]	22NOV20[redacted]	22JAN20[redacted]*	62	DEATH	DISEASE	
CA209025-44-[redacted]	2[redacted]/M/C/USA	23JAN20[redacted]	27JAN20[redacted]	23MAR20[redacted]	26MAY20[redacted]	65	DEATH	DISEASE	MALIGNANT NEOPLASM PROGRESSION
CA209025-47-[redacted]	4[redacted]/F/C/USA	25JUN20[redacted]	27JUN20[redacted]	31JUL20[redacted]	16AUG20[redacted]	17	DEATH	DISEASE	
CA209025-47-[redacted]	6[redacted]/M/C/USA	11OCT20[redacted]	16OCT20[redacted]	04NOV20[redacted]	04JAN20[redacted]*	62	DEATH	DISEASE	PATIENT PASSED DURING HOME HOSPICE DUE TO PROGRESSION OF DISEASE
CA209025-53-[redacted]	5[redacted]/F/C/USA	03JAN20[redacted]	07JAN20[redacted]	30MAR20[redacted]	14JUN20[redacted]	77	DEATH	DISEASE	
CA209025-53-[redacted]	5[redacted]/M/O/USA	04NOV20[redacted]	05NOV20[redacted]	12JAN20[redacted]*	21FEB20[redacted]*	41	DEATH	DISEASE	
CA209025-9-[redacted]	6[redacted]/F/C/USA	12JUL20[redacted]	17JUL20[redacted]	10SEP20[redacted]	11APR20[redacted]*	214	DEATH	DISEASE	
CA209025-9-[redacted]	6[redacted]/M/C/USA	23JUL20[redacted]	23JUL20[redacted]	16SEP20[redacted]	31OCT20[redacted]	46	DEATH	DISEASE	

Gender: M=Male; F=Female.

Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.

CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　　：「3年後」を意味する
##　　：「4年後」を意味する

Treatment Group: NEVER TREATED

Subject ID	Age/Gender/Race/Country	Randomization Date	First Dose Date	Last Dose Date	Death Date	Days since Last Dose	CRF Source	Cause of Death	Cause of Death, Specify
CA209025-141-[redacted]	3[redacted]/M/C/CAN				04OCT20[redacted]		DEATH	OTHER	RESPIRATORY FAILURE SECONDARY TOPROGRESSIVE METASTATIC RENAL CELL CARCINOMA
CA209025-70-[redacted]	7[redacted]/M/C/CZE				17AUG20[redacted]		DEATH	DISEASE	
CA209025-137-[redacted]	6[redacted]/F/C/DNK				09JAN20[redacted]		DEATH	DISEASE	
CA209025-48-[redacted]	8[redacted]/F/C/GBR				23JUL20[redacted]		OTHER	OTHER	AE/SAE: MALIGNANT NEOPLASM PROGRESSION
CA209025-139-[redacted]	6[redacted]/M/C/USA				04JUN20[redacted]		DEATH	UNKNOWN	
CA209025-14-[redacted]	6[redacted]/M/C/USA				22DEC20[redacted]		DEATH	DISEASE	
CA209025-21-[redacted]	6[redacted]/M/C/USA				01NOV20[redacted]		OTHER	OTHER	AE/SAE: MALIGNANT NEOPLASM PROGRESSION

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
CTC Version 4.0

"First/Last Dose Date"及び"Death Date"において，
"Randomization Date"と比較して，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　　：「3年後」を意味する
##　　：「4年後」を意味する

表 2.7.4.7-10　最終投与後 30 日までに死亡した被験者の死因及び死亡に至った有害事象（国際共同第Ⅲ相試験：ONO-4538-03/CA209025）

投与群	被験者識別コード	死因	死因詳細	PT1（日本語）
NIVOLUMAB	CA209025-126-[redacted]	DISEASE	MULTI ORGAN FAILURE DUE TO DISEASE PROGRESSION	多臓器不全
	CA209025-149-[redacted]	DISEASE		悪性新生物進行
	CA209025-151-[redacted]	OTHER	SUICIDE	自殺既遂
	CA209025-165-[redacted]	OTHER	ISCHEMIC HEART FAILURE	心不全
	CA209025-17-[redacted]	DISEASE		悪性新生物進行
	CA209025-175-[redacted]	OTHER	CARDIAL INFARCTION	心筋梗塞
	CA209025-20-[redacted]	DISEASE		悪性新生物進行
	CA209025-26-[redacted]	DISEASE		悪性新生物進行
	CA209025-42-[redacted]	DISEASE		悪性新生物進行
	CA209025-48-[redacted]	OTHER	PNEUMONIA	肺炎
	CA209025-48-[redacted]	DISEASE		悪性新生物進行
	CA209025-49-[redacted]	DISEASE		悪性新生物進行
	CA209025-59-[redacted]	DISEASE	THE PATIENT DIED FOR DISEASE PROGRESSION	悪性新生物進行
	CA209025-62-[redacted]	DISEASE		悪性新生物進行
	CA209025-65-[redacted]	DISEASE		脳出血
	CA209025-82-[redacted]	DISEASE		悪性新生物
	CA209025-95-[redacted]	DISEASE		悪性新生物進行
	CA209025-95-[redacted]	DISEASE		悪性新生物進行
	CA209025-95-[redacted]	DISEASE		悪性新生物進行
EVEROLIMUS	CA209025-113-[redacted]	OTHER	APPOPLECTIC INSULT	脳血管発作
	CA209025-114-[redacted]	DISEASE		悪性新生物進行
	CA209025-118-[redacted]	STUDY DRUG TOXICITY	SEPTIC SHOCK DUE TO AN INFECTIOUS PNEUMONITIS	肺炎
	CA209025-126-[redacted]	DISEASE	WORSENING OF GENERAL CONDITION AFTER FEMUR FRACTURE AND HOSPITALIZATION	悪性新生物進行
	CA209025-13-[redacted]	DISEASE		悪性新生物進行
	CA209025-143-[redacted]	DISEASE		悪性新生物進行
	CA209025-148-[redacted]	DISEASE		悪性新生物進行
	CA209025-148-[redacted]	OTHER	INFECTION	消化器感染
	CA209025-149-[redacted]	DISEASE		悪性新生物進行
	CA209025-151-[redacted]	DISEASE		悪性新生物進行
	CA209025-151-[redacted]	DISEASE		悪性新生物進行
	CA209025-17-[redacted]	DISEASE		悪性新生物進行
	CA209025-177-[redacted]	DISEASE		悪性新生物進行
	CA209025-20-[redacted]	DISEASE		悪性新生物進行
	CA209025-20-[redacted]	DISEASE		悪性新生物進行
	CA209025-25-[redacted]	DISEASE		悪性新生物進行
	CA209025-37-[redacted]	OTHER	STROKE	脳血管発作
	CA209025-4-[redacted]	DISEASE		悪性新生物進行
	CA209025-4-[redacted]	DISEASE		全身健康状態低下
	CA209025-40-[redacted]	OTHER	LOWER RESPIRATORY TRACT INFECTION/PNEUMONIA	肺炎
	CA209025-41-[redacted]	DISEASE	CARDIOPULMONARY ARREST DUE TO POD IN LUNGS	心肺停止
	CA209025-47-[redacted]	DISEASE		腹腔内出血
	CA209025-55-[redacted]	DISEASE		痙攣発作
	CA209025-56-[redacted]	DISEASE		悪性新生物進行
	CA209025-61-[redacted]	DISEASE		悪性新生物進行
	CA209025-65-[redacted]	DISEASE		腸閉塞
	CA209025-69-[redacted]	OTHER	SUICIDE	自殺既遂
	CA209025-78-[redacted]	DISEASE		急性腎不全
	CA209025-85-[redacted]	DISEASE		悪性新生物進行
	CA209025-95-[redacted]	DISEASE		悪性新生物進行
	CA209025-95-[redacted]	DISEASE		悪性新生物進行
	CA209025-97-[redacted]	STUDY DRUG TOXICITY	ACUTE SMALL BOWEL ISCHAEMIA	腸管虚血
	CA209025-97-[redacted]	DISEASE		悪性新生物進行
	CA209025-97-[redacted]	DISEASE		悪性新生物進行

医師から報告された有害事象名は，CTCAE v4.0を用いて評価し，MedDRA ver 18.0Jを用いて読み替えた．

表 2.7.4.7-11　最終投与後 30 日までに死亡した被験者の死因及び死亡に至った有害事象

（国際共同第Ⅲ相試験：ONO-4538-03/CA209025，日本人）

投与群	被験者識別コード	死因	死因詳細	PT1（日本語）
NIVOLUMAB	CA209025-165-[redacted]	OTHER	ISCHEMIC HEART FAILURE	心不全

医師から報告された有害事象名は，CTCAE v4.0を用いて評価し，MedDRA ver 18.0Jを用いて読み替えた．

表 2.7.4.7-12　重篤な有害事象一覧表（海外第 I 相試験：CA209003，RCC 患者）

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-1-[redacted] (7[redacted]/MALE/WHITE)	0.9 mg/kg On-treatment	07MAR20[redacted] 12MAR20[redacted] 8	6 8 SAE	胃腸障害 小腸閉塞 SMALL BOWEL OBSTRUCTION	7 2	0
	Post-treatment Post-treatment	12JUN20[redacted] 12JUN20[redacted] 105	1 45 SAE	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） 悪性新生物進行 MALIGNANT NEOPLASM PROGRESSION	7 5	0
MDX1106-03-1-[redacted] (5[redacted]/MALE/WHITE)	1.1 mg/kg On-treatment	17NOV20[redacted] 19NOV20[redacted] 123	3 15 SAE	感染症および寄生虫症 歯肉膿瘍 ABSCESS PERIODONTAL	7 2	6

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur	TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-1-[redacted] (5[redacted]/MALE/WHITE)	0.9 mg/kg On-treatment	21FEB20[redacted] 23FEB20[redacted] 219	3 14	SAE	筋骨格系および結合組織障害 筋力低下 NEW ONSET OF MUSCLE WEAKNESS	7 3	6
MDX1106-03-2-[redacted] (5[redacted]/MALE/WHITE)	Post-treatment Post-treatment	16SEP20[redacted] 16SEP20[redacted] 138	1 96	SAE	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) 悪性新生物進行 MALIGNANT NEOPLASM PROGRESSION	7 5	0
MDX1106-03-4-[redacted] (6[redacted]/MALE/WHITE)	0.9 mg/kg On-treatment	11JAN20[redacted] 17JAN20[redacted] 317	7 9	SAE	呼吸器、胸郭および縦隔障害 急性呼吸不全 ACUTE RESPIRATORY FAILURE	6 3	2

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-4-[redacted] ([redacted]/MALE/WHITE)	0.9 mg/kg On-treatment	11JAN20[redacted] 26JAN20[redacted] 317	16 9	呼吸器、胸郭および縦隔障害 急性呼吸不全 SAE ACUTE RESPIRATORY FAILURE	6 3	2
	0.9 mg/kg On-treatment	11JAN20[redacted] 17JAN20[redacted] 317	7 9	呼吸器、胸郭および縦隔障害 高炭酸ガス血症 SAE HYPERCAPNIA	6 3	2
	0.9 mg/kg On-treatment	11JAN20[redacted] 17JAN20[redacted] 317	7 9	呼吸器、胸郭および縦隔障害 低酸素症 SAE HYPOXEMIA	6 3	2

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-4-[redacted] (5[redacted]/FEMALE/WHITE)	1.1 mg/kg On-treatment	13JUN20[redacted] 14JUN20[redacted] 77	2 7 SAE	呼吸器、胸郭および縦隔障害 胸水 PLEURAL EFFUSION	7 3	0
	Post-treatment Post-treatment	15AUG20[redacted] 15AUG20[redacted] 140	1 41 SAE	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) 悪性新生物進行 MALIGNANT NEOPLASM PROGRESSION	7 5	0
MDX1106-03-5-[redacted] (5[redacted]/MALE/WHITE)	1.0 mg/kg On-treatment	10JUN20[redacted] 13JUN20[redacted] 25	4 11 SAE	呼吸器、胸郭および縦隔障害 呼吸困難 DYSPNEA	7 2	0

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-5-[redacted] (5[redacted]/MALE/WHITE)	Post-treatment	23JUN2C[redacted]		腎および尿路障害	7	0
	Post-treatment	----------	24	急性腎不全	4	
		38	SAE	ACUTE KIDNEY INJURY		
	Post-treatment	23JUN20[redacted]		呼吸器、胸郭および縦隔障害	7	0
	Post-treatment	----------	24	呼吸不全	4	
		38	SAE	RESPIRATORY FAILURE		
MDX1106-03-6-[redacted] (5[redacted]/MALE/WHITE)	1.0 mg/kg	11NOV20[redacted]	7	呼吸器、胸郭および縦隔障害	7	0
	On-treatment	17NOV20[redacted]	5	喀血	3	
		159	SAE	HEMOPTYSIS		

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT C

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-6-[redacted]	1.0 mg/kg	11MAY20[redacted]	19	呼吸器、胸郭および縦隔障害	7	0
(6[redacted]/MALE/WHITE)	On-treatment	29MAY20[redacted]	11	肺塞栓症	4	
		333		SAE THROMBOSIS / PULMONARY EMBOLISM (BILATERAL)		
	Post-treatment	19DEC20[redacted]	21	胃腸障害	6	6
	Post-treatment	08JAN20[redacted]	23	大腸炎	2	
		555		SAE COLITIS		

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-1-[redacted] (5[redacted]/MALE/WHITE)	9.7 mg/kg On-treatment	14DEC2C[redacted] 25MAR20[redacted] 74	102 6 SAE	神経系障害 不全片麻痺 L-SIDED WEAKNESS	7 3	0
	Post-treatment Post-treatment	13FEB2C[redacted] 23FEB20[redacted] 135	11 67 SAE	呼吸器, 胸郭および縦隔障害 呼吸困難 SHORTNESS OF BREATH	7 3	0
	Post-treatment Post-treatment	14FEB20[redacted] 23FEB2C[redacted] 136	10 68 SAE	腎および尿路障害 急性腎不全 ACUTE RENAL FAILURE	7 4	0

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-1-[redacted]	Post-treatment	14FEB20[redacted]	10	血管障害	7	0
(5[redacted]/MALE/WHITE)	Post-treatment	23FEB20[redacted]	68	深部静脈血栓症	3	
		136	SAE	DEEP VEIN THROMBOSIS		
MDX1106-03-1-[redacted]	10.1 mg/kg	21DEC20[redacted]	10	精神障害	7	6
(6[redacted]/FEMALE/WHITE)	On-treatment	30DEC20[redacted]	14	錯乱状態	1	
		70	SAE	CONFUSION		
	Post-treatment	17JAN20[redacted]	53	神経系障害	7	0
	Post-treatment	10MAR20[redacted]	21	痙攣	3	
		97	SAE	SEIZURES		

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-1-[redacted]	10.0 mg/kg	12NOV20[redacted]	5	筋骨格系および結合組織障害	7	6
(3[redacted]/FEMALE/WHITE)	On-treatment	16NOV20[redacted]	14	背部痛	4	
		28	SAE	LOW BACK PAIN		
MDX1106-03-3-[redacted]	9.9 mg/kg	05APR20[redacted]	95	神経系障害	6	6
(4[redacted]/MALE/WHITE)	On-treatment	08JUL20[redacted]	5	末梢性ニューロパチー	2	
		188	SAE	NEUROPATHY		
	Not Dosed	13MAR20[redacted]	1	神経系障害	7	6
	On-treatment	13MAR20[redacted]	25	痙攣	3	
		530	SAE	SEIZURE		

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-4-[redacted] (7[redacted]/FEMALE/WHITE)	10.3 mg/kg On-treatment	17JUN20[redacted] 18AUG20[redacted] 592	63 11 SAE	皮膚および皮下組織障害 そう痒症 PRURITUS	6 3	6
	10.3 mg/kg On-treatment	17JUN20[redacted] 18AUG20[redacted] 592	63 11 SAE	皮膚および皮下組織障害 斑状皮疹 RASH MACULAR	6 3	0
MDX1106-03-5-[redacted] (4[redacted]/FEMALE/WHITE)	Post-treatment Post-treatment	13SEP20[redacted] 14OCT20[redacted] 333	32 53 SAE	胃腸障害 便秘 CONSTIPATION	7 2	0

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-5-[redacted] (4[redacted]/FEMALE/WHITE)	Post-treatment	13SEP20[redacted]	32	胃腸障害	7	0
	Post-treatment	14OCT20[redacted] 333	53 SAE	嘔吐 VOMITING	2	
	Post-treatment	13SEP20[redacted]	32	代謝および栄養障害	7	0
	Post-treatment	14OCT20[redacted] 333	53 SAE	食欲減退 ANOREXIA	2	
	Post-treatment	13SEP20[redacted]	32	良性、悪性および詳細不明の新生物	7	0
	Post-treatment	14OCT20[redacted] 333	53 SAE	(嚢胞およびポリープを含む) 腹膜転移 PERITONEAL CARCINOMATOSIS	3	

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	ACT
MDX1106-03-6-[redacted] (5[redacted]/MALE/WHITE)	10.0 mg/kg On-treatment	29OCT20[redacted] 06NOV20[redacted] 10	9 10 SAE	呼吸器, 胸郭および縦隔障害 呼吸困難 DYSPNEA	7 3	6
	10.0 mg/kg On-treatment	30OCT20[redacted] 16NOV20[redacted] 11	18 11 SAE	心臓障害 心タンポナーデ CARDIAC TAMPONADE	7 4	6
	10.0 mg/kg On-treatment	30OCT20[redacted] 16NOV20[redacted] 11	18 11 SAE	心臓障害 心嚢液貯留 PERICARDIAL EFFUSION	7 4	6

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-6-[redacted] (5[redacted]/MALE/WHITE)	10.0 mg/kg On-treatment	30OCT20[redacted] 16NOV20[redacted] 11	18 11 SAE	呼吸器、胸郭および縦隔障害 胸水 PLEURAL EFFUSION	7 3	6
MDX1106-03-6-[redacted] (4[redacted]/MALE/WHITE)	9.9 mg/kg On-treatment	16DEC20[redacted] 18DEC20[redacted] 52	3 10 SAE	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) 悪性新生物進行 MALIGNANT NEOPLASM PROGRESSION	7 3	6
	10.1 mg/kg On-treatment	10APR20[redacted] 11APR20[redacted] 167	2 6 SAE	神経系障害 痙攣 SEIZURE	7 2	6

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-6-[redacted] ([redacted]/MALE/WHITE)	10.3 mg/kg On-treatment	15MAY20[redacted] --------- 153	13 SAE	筋骨格系および結合組織障害 筋骨格痛 LEFT SHOULDER PAIN	7 3	6
	10.3 mg/kg On-treatment	17MAY20[redacted] --------- 155	15 SAE	臨床検査 アラニンアミノトランスフェラーゼ増加 ELEVATED ALT (364)	6 3	6
	10.3 mg/kg On-treatment	17MAY20[redacted] --------- 155	15 SAE	臨床検査 アスパラギン酸アミノトランスフェラーゼ増加 ELEVATED AST (166)	6 2	6

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-6-[redacted]	10.3 mg/kg	17MAY20[redacted]	15	臨床検査	6	6
(6[redacted]/MALE/WHITE)	On-treatment	31MAY20[redacted]	15	血中アルカリホスファターゼ増加	2	
		155	SAE	ELEVATED ALK. PHOS (388)		
	Post-treatment	28JUN20[redacted]		胆道閉塞障害	7	2
	Post-treatment	---------	57	胆汁うっ滞性黄疸	4	
		197	SAE	OBSTRUCTIVE JAUNDICE		
MDX1106-03-10-[redacted]	9.7 mg/kg	23MAY20[redacted]	10	胃腸障害	7	0
(6[redacted]/MALE/WHITE)	On-treatment	01JUN20[redacted]	14	消化管穿孔	4	
		168	SAE	PERFORATION, GI		

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1

Tumor Type: Renal Cell Carcinoma (RCC)
Treatment Group: TRT E

Subject ID (Age/Gender/Race)	Current Trt Period	Onset Resolution Study Day	Dur TRD	System Organ Class Preferred Term Reported Term	REL CTC	REL ACT
MDX1106-03-10-[redacted] (6[redacted]/MALE/WHITE)	10.1 mg/kg On-treatment	21JUL20[redacted] 22JUL20[redacted] 227	2 1 SAE	筋骨格系および結合組織障害 側腹部痛 L FLANK PAIN	7 3	6
	Post-treatment Post-treatment	22SEP20[redacted] 25SEP20[redacted] 290	4 64 SAE	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) 悪性胸水 RECURRENT MALIGNANT PLEURAL EFFUSION	7 3	0
	Post-treatment Post-treatment	22SEP20[redacted] 25SEP20[redacted] 290	4 64 SAE	呼吸器、胸郭および縦隔障害 呼吸困難 DYSPNEA	7 3	0

Treatment Codes: TRT A = 0.1 mg/kg NIVOLUMAB, TRT B = 0.3 mg/kg NIVOLUMAB, TRT C = 1 mg/kg NIVOLUMAB, TRT D = 3 mg/kg NIVOLUMAB, TRT E = 10 mg/kg NIVOLUMAB.
REL (Relationship): 6=RELATED 7=NOT RELATED
CTC (COMMON TOXICITY CRITERIA): 1=GRADE 1 2=GRADE 2 3=GRADE 3 4=GRADE 4 5=GRADE 5
ACT (ACTION): 0=NO ACTION TAKEN 2=DRUG PERM. DISCONTINUED 6=DRUG TEMP. INTERRUPTED 7=DOSE ADJUSTED
TRD=Time relative most recent dose (in Days)
MedDRA VERSION : 15.1
出典 [総括報告書 5.3.3.2-3.1 (海外第 I 相試験 : CA209003) Table S.6.2.1]

表 2.7.4.7-13　重篤な有害事象の一覧表（海外第Ⅱ相試験：CA209010）

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-48-[redacted] 5[redacted]/M/C/CAN	脊髄圧迫 神経系障害	90	20D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209010-59-[redacted] 8[redacted]/M/C/FIN	全身健康状態低下 一般・全身障害および投与部位の状態	45		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Requires or Prolongs Hospitalization
CA209010-63-[redacted] 3[redacted]/F/C/ITA	気道出血 呼吸器、胸郭および縦隔障害	162	7D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-1-[redacted] 7[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	23	24.0H	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-14-[redacted] 7[redacted]/M/C/USA	肺炎 感染症および寄生虫症	267	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	喘鳴 呼吸器、胸郭および縦隔障害	12	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	声帯麻痺 神経系障害	28	23D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA v17.1J
CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-14-[redacted] 7[redacted]/M/C/USA	痙攣 神経系障害	267	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	222	31D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209010-14-[redacted] 6[redacted]/F/C/USA	高カルシウム血症 代謝および栄養障害	31	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-15-[redacted] 5[redacted]/F/C/USA	悪心 胃腸障害	16	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	便秘 胃腸障害	25		NOT RELATED Grade 2	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	疾患進行 一般・全身障害および投与部位の状態	93		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
	疼痛 一般・全身障害および投与部位の状態	33	4D	NOT RELATED Grade 3	N DOSE NOT CHANGED	Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA v17.1J
CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-15-[redacted] 5[redacted]/F/C/USA	呼吸困難 呼吸器、胸郭および縦隔障害	78		NOT RELATED Grade 4	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	2	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	16	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-18-[redacted] 5[redacted]/M/C/USA	疾患進行 一般・全身障害および投与部位の状態	204		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
	クレブシエラ性菌血症 感染症および寄生虫症	74	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胆道性敗血症 感染症および寄生虫症	174	5D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胆管炎 肝胆道系障害	74	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	112		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.
Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA v17.1J
CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-18-[redacted] 5[redacted]/M/C/USA	急性腎不全 腎および尿路障害	189	3D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-18-[redacted] 6[redacted]/M/C/USA	硬膜下血腫 傷害、中毒および処置合併症	589		NOT RELATED Grade 4	Y DRUG INTERRUPTED	UNKNOWN Requires or Prolongs Hospitalization
CA209010-21-[redacted] 6[redacted]/M/C/USA	敗血症 感染症および寄生虫症	114	17D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
	好中球減少症 血液およびリンパ系障害	114	17D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Is Life Threatening
	肺塞栓症 呼吸器、胸郭および縦隔障害	25	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸椎骨折 傷害、中毒および処置合併症	56	30D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization
	末梢性ニューロパチー 神経系障害	41	48.0H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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MedDRA v17.1J
CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-21-[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）	135		NOT RELATED Grade 3	Y DOSE NOT CHANGED	FATAL Requires or Prolongs Hospitalization
CA209010-23-[redacted] 6[redacted]/F/C/USA	高カルシウム血症 代謝および栄養障害	9	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	22	22.7H	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	36		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-26-[redacted] 6[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	-17	16D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209010-3-[redacted] 5[redacted]/M/C/USA	脊髄圧迫 神経系障害	40		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-3-[redacted] 5[redacted]/F/C/USA	腎細胞癌 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）	22	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	腎細胞癌 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）	41		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-3-[redacted] 6[redacted]/M/C/USA	気胸 呼吸器、胸郭および縦隔障害	55	15D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎細胞癌 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）	69		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-30-[redacted] 6[redacted]/F/A/USA	虫垂炎 感染症および寄生虫症	468	28D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脳血管発作 神経系障害	140	6D	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event

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CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-32-[redacted] 7[redacted]/F/C/USA	インフルエンザ 感染症および寄生虫症	591	22D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	4	11D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	低血圧 血管障害	4	11D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	結腸腺癌 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）	4	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	腺癌 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）	128	12D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-32-[redacted] 5[redacted]/F/C/USA	貧血 血液およびリンパ系障害	113	4D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	122	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-32-[redacted] 5[redacted]/F/C/USA	腎不全 腎および尿路障害	122	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	尿生殖器出血 腎および尿路障害	122	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カリウム血症 代謝および栄養障害	113	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-33-[redacted] 7[redacted]/M/C/USA	筋力低下 筋骨格系および結合組織障害	124	3D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	中枢神経系病変 神経系障害	104	6D	NOT RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 6[redacted]/F/C/USA	疲労 一般・全身障害および投与部位の状態	140	3D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 4[redacted]/M/C/USA	頭痛 神経系障害	343	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-37-[redacted] 5[redacted]/F/C/USA	自己免疫障害 免疫系障害	245	10D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-38-[redacted] 7[redacted]/M/C/USA	深部静脈血栓症 血管障害	861		RELATED Grade 2	Y DRUG INTERRUPTED	 Requires or Prolongs Hospitalization
	器質化肺炎 呼吸器、胸郭および縦隔障害	835		RELATED Grade 2	N DRUG INTERRUPTED	 Other Medically Important Serious Event
CA209010-45-[redacted] 6[redacted]/M/C/USA	上肢骨折 傷害、中毒および処置合併症	416	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-5-[redacted] 6[redacted]/M/C/USA	便秘 胃腸障害	48	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-50-[redacted] 5[redacted]/M/C/USA	心膜炎 心臓障害	81	48.0H	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心膜炎 心臓障害	115	3D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-8-[redacted] 6[redacted]/M/C/USA	悪心 胃腸障害	64	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	 Requires or Prolongs Hospitalization
	疼痛 一般・全身障害および投与部位の状態	64	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	 Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 0.3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-8-[redacted] 6[redacted]/M/C/USA	心嚢液貯留 心臓障害	84	3D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	120		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-8-[redacted] 6[redacted]/M/C/USA	急性腎不全 腎および尿路障害	264	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-8-[redacted] 6[redacted]/M/C/USA	頭蓋内出血 神経系障害	168	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	痙攣 神経系障害	143	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	扁平上皮癌 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）	99	95D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-42-[redacted] 7[redacted]/M/C/CAN	脊髄圧迫 神経系障害	89	5D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209010-47-[redacted] 5[redacted]/F/C/CAN	錯感覚 神経系障害	70	30D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-1-[redacted] 5[redacted]/M/C/USA	末梢性浮腫 一般・全身障害および投与部位の状態	226	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	169	16D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209010-18-[redacted] 6[redacted]/M/C/USA	脊髄圧迫 神経系障害	71	13D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	63	5D	NOT RELATED Grade 4	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-18-[redacted] 5[redacted]/F/C/USA	敗血症 感染症および寄生虫症	57	8D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	57	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-18-[redacted] 5[redacted]/F/C/USA	貧血 血液およびリンパ系障害	22	7D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-18-[redacted] 6[redacted]/F/C/USA	腸炎 胃腸障害	349	71D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	膵炎 胃腸障害	349	71D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	上室性頻脈 心臓障害	155	24.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋虚血 心臓障害	155	48.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-2-[redacted] 6[redacted]/F/C/USA	側腹部痛 筋骨格系および結合組織障害	8		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization
	過小食 代謝および栄養障害	8		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-2-[redacted] 6[redacted]/F/C/USA	成長障害 代謝および栄養障害	8		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	8		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization
	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）	17		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
	ヘモグロビン減少 臨床検査	-10	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-26-[redacted] 6[redacted]/F/C/USA	背部痛 筋骨格系および結合組織障害	64		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	85		NOT RELATED Grade 4	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	錯感覚 神経系障害	64		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-26-[redacted]	膵炎	84	3D	NOT RELATED	Y	
6[redacted]/F/C/USA	胃腸障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209010-28-[redacted]	低血圧	99	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
4[redacted]/M/C/USA	血管障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209010-28-[redacted]	部分発作	275	3D	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/USA	神経系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209010-3-[redacted]	脊髄圧迫	164		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
6[redacted]/M/C/USA	神経系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	脊髄圧迫	191	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
	神経系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	血尿	195		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
	腎および尿路障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209010-3-[redacted]	小腸潰瘍	330	2D	NOT RELATED	N	RECOVERED/RESOLVED
5[redacted]/F/C/USA	胃腸障害			Grade 2	DRUG WITHDRAWN	Requires or Prolongs Hospitalization
	消化器痛	308	4D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
	胃腸障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-3-[redacted] 5[redacted]/F/C/USA	腹部感染 感染症および寄生虫症	399		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	259		RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209010-3-[redacted] 8[redacted]/M/C/USA	肝機能検査異常 臨床検査	154	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-30-[redacted] 6[redacted]/F/C/USA	疲労 一般・全身障害および投与部位の状態	-7	48.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	-7	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	16	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	27	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	47	23D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-30-[redacted] 6[redacted]/F/C/USA	腫瘍疼痛 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）	61	15D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-30-[redacted] 5[redacted]/M/C/USA	限局性浮腫 一般・全身障害および投与部位の状態	2	51D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	末梢性浮腫 一般・全身障害および投与部位の状態	2	51D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺出血 呼吸器、胸郭および縦隔障害	56	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨折 傷害、中毒および処置合併症	22	20D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	悪性新生物 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）	250		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

Gender: M=Male; F=Female.
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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-30-[redacted] 6[redacted]/F/C/USA	小腸閉塞 胃腸障害	31	17D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-32-[redacted] 7[redacted]/M/B/USA	甲状腺機能低下症 内分泌障害	126	9D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-32-[redacted] 6[redacted]/M/C/USA	悪心 胃腸障害	49		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	発熱 一般・全身障害および投与部位の状態	31	16D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 6[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	37	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 5[redacted]/M/C/USA	誤嚥 呼吸器、胸郭および縦隔障害	58	22D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-36-[redacted] 6[redacted]/M/B/USA	貧血 血液およびリンパ系障害	149	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	甲状腺腫 内分泌障害	57	62D	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-36-[redacted] 6[redacted]/M/B/USA	甲状腺腫 内分泌障害	101	22D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	甲状腺腫 内分泌障害	122	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-37-[redacted] 6[redacted]/M/C/USA	胃出血 胃腸障害	124	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胃出血 胃腸障害	138	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	感染性胆嚢炎 感染症および寄生虫症	90	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胆道感染 感染症および寄生虫症	328	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胆嚢閉塞 肝胆道系障害	76	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心不全 心臓障害	99	11D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-4-[redacted] 6[redacted]/M/C/USA	急性腎不全 腎および尿路障害	23	7D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	39	8D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	副腎機能不全 内分泌障害	39	12D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	39		NOT RELATED Grade 4	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-5-[redacted] 6[redacted]/M/C/USA	インフルエンザ様疾患 一般・全身障害および投与部位の状態	818		NOT RELATED Grade 2	Y DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	818		NOT RELATED Grade 3	Y DRUG INTERRUPTED	Requires or Prolongs Hospitalization
CA209010-5-[redacted] 6[redacted]/M/C/USA	腹痛 胃腸障害	117	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-5-[redacted] 6[redacted]/M/C/USA	誤嚥性肺炎 呼吸器、胸郭および縦隔障害	130	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-54-[redacted] 6[redacted]/M/C/USA	遠隔転移を伴う腎癌 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）	260	24.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	遠隔転移を伴う腎癌 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）	327	24.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	遠隔転移を伴う腎癌 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）	349	24.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209010-6-[redacted] 5[redacted]/M/A/USA	低血圧 血管障害	219	13.0H	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Is Life Threatening
	慢性閉塞性肺疾患 呼吸器、胸郭および縦隔障害	251	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-6-[redacted] 5[redacted]/M/A/USA	急性心筋梗塞 心臓障害	219	13.0H	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event
CA209010-7-[redacted] 6[redacted]/M/C/USA	歩行障害 一般・全身障害および投与部位の状態	191	5D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	喀血 呼吸器、胸郭および縦隔障害	209	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	処置後出血 傷害、中毒および処置合併症	158	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	構語障害 神経系障害	191	3D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	193	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	193	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-8-[redacted] 6[redacted]/F/C/USA	病的骨折 筋骨格系および結合組織障害	30	19D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-8-[redacted] 5[redacted]/M/C/USA	肺炎 感染症および寄生虫症	18	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	18	6D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-8-[redacted] 5[redacted]/M/C/USA	有害事象 一般・全身障害および投与部位の状態	1165		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death
CA209010-8-[redacted] 7[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）	159		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-9-[redacted] 5[redacted]/M/C/USA	喀血 呼吸器、胸郭および縦隔障害	187		NOT RELATED Grade 3	Y DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 2 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-9-[redacted] 5[redacted]/M/C/USA	腎細胞癌 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		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209010-9-[redacted] 6[redacted]/M/C/USA	腎盂腎炎 感染症および寄生虫症	664		NOT RELATED Grade 3	N DOSE NOT CHANGED	UNKNOWN Requires or Prolongs Hospitalization
	尿路感染 感染症および寄生虫症	530		NOT RELATED Grade 3	Y DOSE NOT CHANGED	UNKNOWN Requires or Prolongs Hospitalization
	脳症 神経系障害	449		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	尿閉 腎および尿路障害	566	4D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	錯乱状態 精神障害	528		NOT RELATED Grade 3	Y DOSE NOT CHANGED	UNKNOWN Other Medically Important Serious Event
	精神状態変化 精神障害	319	5D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-42-[redacted] 4[redacted]/M/C/CAN	下腹部痛 胃腸障害	5	37D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	上腹部痛 胃腸障害	5	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	9		NOT RELATED Grade 2	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209010-1-[redacted] 6[redacted]/M/C/USA	慢性骨髄性白血病 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）	301		NOT RELATED Grade 3	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Involves Cancer
CA209010-14-[redacted] 5[redacted]/M/C/USA	膝関節形成 外科および内科処置	687	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	543	13D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	同名性半盲 神経系障害	30	7D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-14-[redacted] 5[redacted]/M/C/USA	基底細胞癌 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）	136	76D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer
CA209010-15-[redacted] 5[redacted]/M/C/USA	筋力低下 筋骨格系および結合組織障害	36		NOT RELATED Grade 3	Y DOSE NOT CHANGED	 Requires or Prolongs Hospitalization
CA209010-15-[redacted] 6[redacted]/M/C/USA	末梢性浮腫 一般・全身障害および投与部位の状態	37		RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	37		RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	末梢性運動ニューロパチー 神経系障害	36		RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	45		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-22-[redacted] 6[redacted]/M/C/USA	脳新生物 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）	94	1.1H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-23-[redacted] 4[redacted]/M/C/USA	粘膜の炎症 一般・全身障害および投与部位の状態	86	11D	RELATED Grade 3	Y DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	疼痛 一般・全身障害および投与部位の状態	86	48.0H	RELATED Grade 2	Y DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209010-26-[redacted] 5[redacted]/M/C/USA	呼吸困難 呼吸器、胸郭および縦隔障害	46		NOT RELATED Grade 4	Y DRUG WITHDRAWN	FATAL Requires or Prolongs Hospitalization
CA209010-3-[redacted] 5[redacted]/F/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	168	22D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-3-[redacted] 6[redacted]/F/C/USA	運動失調 神経系障害	18		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209010-3-[redacted] 5[redacted]/F/C/USA	胆嚢炎 肝胆道系障害	244	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-3-[redacted] 5[redacted]/F/C/USA	肺塞栓症 呼吸器、胸郭および縦隔障害	211	134D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209010-32-[redacted] 5[redacted]/F/C/USA	喀血 呼吸器、胸郭および縦隔障害	74	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-34-[redacted] 7[redacted]/M/C/USA	高ビリルビン血症 肝胆道系障害	302	32D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	トランスアミナーゼ上昇 臨床検査	302	16D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	血中アルカリホスファターゼ増加 臨床検査	302	32D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 6[redacted]/M/C/USA	頭蓋内出血 神経系障害	204	3D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 6[redacted]/M/C/USA	大腸炎 胃腸障害	96	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	-12	55D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-35-[redacted] 6[redacted]/M/C/USA	呼吸困難 呼吸器、胸郭および縦隔障害	25	19D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 5[redacted]/M/C/USA	腹痛 胃腸障害	268	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 5[redacted]/M/C/USA	肺塞栓症 呼吸器、胸郭および縦隔障害	62		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Other Medically Important Serious Event
	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）	110	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-35-[redacted] 6[redacted]/M/C/USA	貧血 血液およびリンパ系障害	55	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	90		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

Gender: M=Male; F=Female.

Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-37-[redacted] 7[redacted]/M/C/USA	多臓器不全 一般・全身障害および投与部位の状態	33		NOT RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	3	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	蜂巣炎 感染症および寄生虫症	3	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-40-[redacted] 7[redacted]/M/C/USA	悪心 胃腸障害	525	24.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	525	24.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	嘔吐 胃腸障害	525	24.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209010-8-[redacted] 7[redacted]/F/C/USA	小腸閉塞 胃腸障害	518	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腹痛 胃腸障害	396	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-8-[redacted] 7[redacted]/F/C/USA	腹痛 胃腸障害	678	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腹痛 胃腸障害	720	3D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	腸切除 外科および内科処置	786	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	尿路感染 感染症および寄生虫症	678	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	胸膜炎 呼吸器、胸郭および縦隔障害	551	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	794	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	心房細動 心臓障害	551	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	意識レベルの低下 神経系障害	805	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: CA209010)

Treatment Group: NIVOLUMAB 10 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209010-8-[redacted]	低ナトリウム血症	86	6D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
7[redacted]/M/C/USA	代謝および栄養障害			Grade 4	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.

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表 2.7.4.7-14　重篤な有害事象の一覧表（国際共同第Ⅲ相試験：ONO-4538-03/CA209025）

Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-155-[redacted] 4[redacted]/M/A/JPN	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）	393	41D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-155-[redacted] 6[redacted]/M/A/JPN	癌疼痛 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）	225		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-155-[redacted] 4[redacted]/M/A/JPN	貧血 血液およびリンパ系障害	169	152D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-156-[redacted] 6[redacted]/M/A/JPN	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）	374	12D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-156-[redacted] 7[redacted]/M/A/JPN	器質化肺炎 呼吸器、胸郭および縦隔障害	588	57D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋梗塞 心臓障害	246	20D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-156-[redacted] 7[redacted]/M/A/JPN	心筋梗塞 心臓障害	314	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心臓内血栓 心臓障害	626	19D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-158-[redacted] 5[redacted]/F/A/JPN	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）	237	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	286	102D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-158-[redacted] 7[redacted]/M/A/JPN	熱中症 傷害、中毒および処置合併症	-43	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	多形紅斑 皮膚および皮下組織障害	42	17D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-158-[redacted] 3[redacted]/F/A/JPN	肺感染 感染症および寄生虫症	-21	14D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-158-[redacted] 3[redacted]/F/A/JPN	食欲減退 代謝および栄養障害	141	6D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	食欲減退 代謝および栄養障害	148	48.0H	RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	癌疼痛 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）	193	19D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-159-[redacted] 6[redacted]/F/A/JPN	肺炎 感染症および寄生虫症	489	17D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺腺癌 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）	503	24.0H	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer
CA209025-159-[redacted] 7[redacted]/M/A/JPN	下痢 胃腸障害	128	48.0H	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	130	4D	RELATED Grade 1	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-159-[redacted] 7[redacted]/M/A/JPN	下痢 胃腸障害	141	31.9H	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	143	3D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	146	3D	RELATED Grade 1	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	149	9D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	下痢 胃腸障害	158	7D	RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肝機能異常 肝胆道系障害	141	11D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	肝機能異常 肝胆道系障害	153	12D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-160-[redacted] 7[redacted]/F/A/JPN	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）	190		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	癌疼痛 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		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	血中ビリルビン増加 臨床検査	158		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-161-[redacted] 6[redacted]/F/A/JPN	大腸出血 胃腸障害	342	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-161-[redacted] 6[redacted]/F/A/JPN	腸炎 胃腸障害	329	11D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	頭蓋内出血 神経系障害	332	57D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-162-[redacted] 7[redacted]/F/A/JPN	嘔吐 胃腸障害	437	17D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-162-[redacted] 7[redacted]/F/A/JPN	食欲減退 代謝および栄養障害	437	17D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-163-[redacted] 6[redacted]/M/A/JPN	胃腸炎 感染症および寄生虫症	-28	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-165-[redacted] 7[redacted]/M/A/JPN	心不全 心臓障害	828		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death
CA209025-166-[redacted] 6[redacted]/M/A/JPN	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）	228	14D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-77-[redacted] 6[redacted]/M/C/ARG	敗血症 感染症および寄生虫症	83		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	骨痛 筋骨格系および結合組織障害	36	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	軟部組織壊死 筋骨格系および結合組織障害	75		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-77-[redacted] 6[redacted]/M/C/ARG	発熱性好中球減少症 血液およびリンパ系障害	83	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	神経系障害 神経系障害	67		NOT RELATED Grade 4	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	67	43D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	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）	110		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-79-[redacted] 6[redacted]/M/C/ARG	大動脈解離 血管障害	226	12D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-84-[redacted] 4[redacted]/M/C/ARG	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）	172		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

Gender: M=Male; F=Female.

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-85-[redacted]	肝腎不全	284		NOT RELATED	N	FATAL
7[redacted]/M/C/ARG	肝胆道系障害			Grade 5	DRUG WITHDRAWN	Results in Death
CA209025-85-[redacted]	低ナトリウム血症	288	5D	NOT RELATED	Y	RECOVERED/RESOLVED
7[redacted]/M/C/ARG	代謝および栄養障害			Grade 4	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-94-[redacted]	脳膿瘍	417	14D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
6[redacted]/M/C/AUS	感染症および寄生虫症			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
	中枢神経系転移	336	12D	NOT RELATED	Y	RECOVERED/RESOLVED
	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）			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-95-[redacted]	感染による慢性閉塞性気道疾患の増悪	514	5D	NOT RELATED	Y	RECOVERED/RESOLVED
7[redacted]/M/C/AUS	感染症および寄生虫症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	悪性新生物進行	586		NOT RELATED	N	NOT RECOVERED/NOT RESOLVED
	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）			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 8[redacted]/M/C/AUS	呼吸困難 呼吸器、胸郭および縦隔障害	29		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	33		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death
CA209025-95-[redacted] 6[redacted]/M/C/AUS	便秘 胃腸障害	27	9D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	悪性黒色腫 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）	323	62D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer
CA209025-95-[redacted] 6[redacted]/M/C/AUS	肺炎 感染症および寄生虫症	36	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	36	7D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	58	10D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 6[redacted]/M/C/AUS	腎機能障害 腎および尿路障害	58	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎結石症 腎および尿路障害	54	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	58	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	145		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-95-[redacted] 6[redacted]/M/A/AUS	背部痛 筋骨格系および結合組織障害	58		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	急性心筋梗塞 心臓障害	15	15D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	59		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 6[redacted]/M/A/AUS	癌疼痛 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）	15	15D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-95-[redacted] 4[redacted]/M/C/AUS	疼痛 一般・全身障害および投与部位の状態	84		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	9	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	58	16D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	172		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-95-[redacted] 5[redacted]/F/C/AUS	胸水 呼吸器、胸郭および縦隔障害	-2		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 5[redacted]/F/C/AUS	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）	21		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-96-[redacted] 5[redacted]/M/C/AUS	虫垂炎 感染症および寄生虫症	308	48.0H	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	375	98D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	肺転移 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）	368	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-97-[redacted] 6[redacted]/M/A/AUS	骨粗鬆症 筋骨格系および結合組織障害	73	7D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	病的骨折 筋骨格系および結合組織障害	166	28D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-97-[redacted] 7[redacted]/F/C/AUS	尿路感染 感染症および寄生虫症	416	4D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-98-[redacted] 4[redacted]/F/C/AUS	肺塞栓症 呼吸器、胸郭および縦隔障害	82	84D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	処置後合併症 傷害、中毒および処置合併症	59	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	52		NOT RELATED Grade 4	Y DOSE DELAYED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	腫瘍疼痛 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）	220	9D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	頭蓋内腫瘍出血 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）	154	8D	NOT RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-98-[redacted] 7[redacted]/F/C/AUS	歩行障害 一般・全身障害および投与部位の状態	273	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-98-[redacted] 7[redacted]/F/C/AUS	基底細胞癌 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）	15	23D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer
CA209025-101-[redacted] 7[redacted]/M/C/AUT	鼓膜穿孔 耳および迷路障害	525	9D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房粗動 心臓障害	561	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-92-[redacted] 5[redacted]/M/C/AUT	肺臓炎 呼吸器、胸郭および縦隔障害	531	41D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Other Medically Important Serious Event
	肺臓炎 呼吸器、胸郭および縦隔障害	573	36D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	肺臓炎 呼吸器、胸郭および縦隔障害	610	25D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	肺臓炎 呼吸器、胸郭および縦隔障害	636		NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-93-[redacted] 6[redacted]/F/C/AUT	気管支炎 感染症および寄生虫症	28	2D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	遠隔転移を伴う腎細胞癌 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）	42	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨転移 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）	210	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨転移 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）	258	15D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-33-[redacted] 5[redacted]/M/C/BEL	急性冠動脈症候群 心臓障害	14	11D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-33-[redacted] 3[redacted]/F/C/BEL	頚部痛 筋骨格系および結合組織障害	125		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-33-[redacted] 3[redacted]/F/C/BEL	腫瘍疼痛 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）	46	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腫瘍疼痛 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）	114	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	転移部痛 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）	33	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-34-[redacted] 6[redacted]/M/C/BEL	扁平上皮癌 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）	53		NOT RELATED Grade 2	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Other Medically Important Serious Event
CA209025-135-[redacted] 6[redacted]/M/C/BRA	喀血 呼吸器、胸郭および縦隔障害	-38	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-135-[redacted] 5[redacted]/M/C/BRA	骨障害 筋骨格系および結合組織障害	59	8D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺出血 呼吸器、胸郭および縦隔障害	43	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-140-[redacted] 6[redacted]/M/C/CAN	脊髄圧迫 神経系障害	2		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	74		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-143-[redacted] 5[redacted]/M/C/CAN	創傷感染 感染症および寄生虫症	328	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-143-[redacted] 6[redacted]/M/C/CAN	尿路感染 感染症および寄生虫症	15	30D	NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	高カルシウム血症 代謝および栄養障害	15	30D	NOT RELATED Grade 4	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-143-[redacted] 6[redacted]/M/C/CAN	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）	257		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	273		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-143-[redacted] 8[redacted]/M/C/CAN	非心臓性胸痛 一般・全身障害および投与部位の状態	324	3D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	377	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心不全 心臓障害	331	13D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-153-[redacted] 6[redacted]/M/C/CAN	尿路性敗血症 感染症および寄生虫症	150		NOT RELATED Grade 4	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-153-[redacted] 6[redacted]/M/C/CAN	脊髄圧迫 神経系障害	88	8D	NOT RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Is Life Threatening
	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）	154		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-69-[redacted] 5[redacted]/F/C/CZE	イレウス 胃腸障害	155	12D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-70-[redacted] 7[redacted]/M/C/CZE	胆管狭窄 肝胆道系障害	704	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	糖尿病 代謝および栄養障害	665	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	γ－グルタミルトランスフェラーゼ増加 臨床検査	678	22D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-70-[redacted] 7[redacted]/F/C/CZE	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）	81		NOT RELATED Grade 2	N DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-70-[redacted] 6[redacted]/M/C/CZE	狭心症 心臓障害	49	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	左室機能不全 心臓障害	26	3D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-71-[redacted] 6[redacted]/M/C/CZE	気管支炎 感染症および寄生虫症	354	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	505	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
	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）	505		NOT RELATED Grade 4	N DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-113-[redacted] 6[redacted]/M/C/DEU	発熱 一般・全身障害および投与部位の状態	77	4D	RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肝臓痛 肝胆道系障害	3	23D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	77	15D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	43	19D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	80	26D	NOT RELATED Grade 4	N DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	106		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-113-[redacted] 6[redacted]/F/C/DEU	病的骨折 筋骨格系および結合組織障害	174	9D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-113-[redacted] 6[redacted]/M/C/DEU	嘔吐 胃腸障害	146	8D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	122	11D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	122	11D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	200		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-119-[redacted] 6[redacted]/F/C/DEU	顎骨壊死 筋骨格系および結合組織障害	113	7D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血圧クリーゼ 血管障害	87	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-119-[redacted] 6[redacted]/F/C/DEU	高血圧クリーゼ 血管障害	254	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-126-[redacted] 5[redacted]/M/C/DEU	下部消化管出血 胃腸障害	118	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	全身健康状態低下 一般・全身障害および投与部位の状態	131	5D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	多臓器不全 一般・全身障害および投与部位の状態	137		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
	貧血 血液およびリンパ系障害	118	13D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-126-[redacted] 4[redacted]/F/C/DEU	胸水 呼吸器、胸郭および縦隔障害	-3	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	5	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-126-[redacted]	皮膚病変	765	5D	NOT RELATED	Y	RECOVERED/RESOLVED
4[redacted]/F/C/DEU	皮膚および皮下組織障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-175-[redacted]	肺炎	23		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
7[redacted]/M/C/DEU	感染症および寄生虫症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	心筋梗塞	23		NOT RELATED	Y	FATAL
	心臓障害			Grade 5	DRUG WITHDRAWN	Results in Death, Requires or Prolongs Hospitalization
	腎不全	22		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
	腎および尿路障害			Grade 4	DOSE NOT CHANGED	Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-73-[redacted]	肺炎	102	29.3H	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/DNK	感染症および寄生虫症			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-73-[redacted]	非心臓性胸痛	155	2.2H	RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/O/DNK	一般・全身障害および投与部位の状態			Grade 2	DRUG INTERRUPTED	Other Medically Important Serious Event
CA209025-73-[redacted]	肺炎	56	4D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/DNK	感染症および寄生虫症			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-73-[redacted] 6[redacted]/M/C/DNK	筋骨格硬直 筋骨格系および結合組織障害	107	6D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	119	43.1H	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-73-[redacted] 6[redacted]/M/C/DNK	全身健康状態低下 一般・全身障害および投与部位の状態	192	6D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	203	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	140	2D	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-73-[redacted] 6[redacted]/M/C/DNK	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）	112		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-89-[redacted] 5[redacted]/F/C/DNK	敗血症 感染症および寄生虫症	128		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-89-[redacted] 6[redacted]/M/C/DNK	肺感染 感染症および寄生虫症	208	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	関節痛 筋骨格系および結合組織障害	189	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	-3	20.9H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	8	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	16	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	28	39.7H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-89-[redacted] 4[redacted]/M/C/DNK	腹痛 胃腸障害	369	34.7H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-89-[redacted] 4[redacted]/M/C/DNK	便秘 胃腸障害	369	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	発熱 一般・全身障害および投与部位の状態	16	15.9H	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-89-[redacted] 6[redacted]/M/C/DNK	疼痛 一般・全身障害および投与部位の状態	386	27.3H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	疼痛 一般・全身障害および投与部位の状態	389	22.4H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	熱性感染症 感染症および寄生虫症	217	19.9H	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺感染 感染症および寄生虫症	67	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	関節痛 筋骨格系および結合組織障害	39	27D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-89-[redacted] 6[redacted]/M/C/DNK	貧血 血液およびリンパ系障害	31	5.7H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-62-[redacted] 4[redacted]/M/C/ESP	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）	250		NOT RELATED Grade 4	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	252		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-62-[redacted] 6[redacted]/M/C/ESP	大腸穿孔 胃腸障害	50	16D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腸閉塞 胃腸障害	174		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	141	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-62-[redacted] 6[redacted]/M/C/ESP	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）	194		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-62-[redacted] 5[redacted]/M/C/ESP	無力症 一般・全身障害および投与部位の状態	71	9D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	97		NOT RELATED Grade 4	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	99		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-63-[redacted] 5[redacted]/F/C/ESP	筋骨格痛 筋骨格系および結合組織障害	230		NOT RELATED Grade 3	Y DOSE DELAYED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	208	10D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-63-[redacted] 5[redacted]/F/C/ESP	喀血 呼吸器、胸郭および縦隔障害	192	40.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	鎖骨骨折 傷害、中毒および処置合併症	204	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-63-[redacted] 6[redacted]/F/C/ESP	腹水 胃腸障害	225	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	糖尿病性ケトアシドーシス 代謝および栄養障害	71	12D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	265		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-65-[redacted] 7[redacted]/M/C/ESP	急性呼吸不全 呼吸器、胸郭および縦隔障害	433	15D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	419	9D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-65-[redacted] 7[redacted]/M/C/ESP	腎不全 腎および尿路障害	32	4D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-65-[redacted] 7[redacted]/M/C/ESP	硬膜動静脈瘻 神経系障害	184	3D	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脳出血 神経系障害	620		NOT RELATED Grade 4	N DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	脳出血 神経系障害	633		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-65-[redacted] 8[redacted]/F/C/ESP	気道感染 感染症および寄生虫症	64	3D	NOT RELATED Grade 1	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	405	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-65-[redacted] 4[redacted]/F/C/ESP	下痢 胃腸障害	413	26.2H	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	頸部痛 筋骨格系および結合組織障害	516	48.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Is Life Threatening

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Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-65-[redacted] 6[redacted]/M/C/ESP	気道感染 感染症および寄生虫症	96	26D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	28	7D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	64	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-75-[redacted] 7[redacted]/F/C/FIN	自己免疫性肝炎 肝胆道系障害	14	99D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-75-[redacted] 6[redacted]/F/C/FIN	大腸炎 胃腸障害	135	26D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-118-[redacted] 6[redacted]/M/C/FRA	骨痛 筋骨格系および結合組織障害	58	3D	NOT RELATED Grade 2	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-118-[redacted] 6[redacted]/M/C/FRA	斑状丘疹状皮疹 皮膚および皮下組織障害	181	10D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-12-[redacted] 7[redacted]/M/C/FRA	下痢 胃腸障害		29D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-12-[redacted] 6[redacted]/M/C/FRA	喀血 呼吸器、胸郭および縦隔障害	757	6D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脳出血 神経系障害	596	5D	NOT RELATED Grade 2	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-2-[redacted] 3[redacted]/M/O/FRA	脊髄感染 感染症および寄生虫症	15	19D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	46	6D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脊椎圧迫骨折 傷害、中毒および処置合併症	143	12D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-2-[redacted] 3[redacted]/M/C/FRA	脊髄感染 感染症および寄生虫症	10	17D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	297		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	187	4D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-2-[redacted]	腎不全	267	4D	NOT RELATED	Y	RECOVERED/RESOLVED
3[redacted]/M/C/FRA	腎および尿路障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
	悪性新生物進行	318		NOT RELATED	N	FATAL
	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）			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-2-[redacted]	上腕骨骨折	102	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/F/C/FRA	傷害、中毒および処置合併症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	上腕骨骨折	107	17D	NOT RELATED	Y	RECOVERED/RESOLVED
	傷害、中毒および処置合併症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-2-[redacted]	脳虚血	8	7D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
7[redacted]/F/C/FRA	神経系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-2-[redacted]	心筋梗塞	41	3D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/FRA	心臓障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-2-[redacted] 6[redacted]/M/C/FRA	肺転移 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）	537	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-2-[redacted] 3[redacted]/M/C/FRA	背部痛 筋骨格系および結合組織障害	589	9D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-2-[redacted] 4[redacted]/F/C/FRA	メレナ 胃腸障害	90	18D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-3-[redacted] 6[redacted]/F/C/FRA	発熱 一般・全身障害および投与部位の状態	282	5D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	発熱 一般・全身障害および投与部位の状態	297	8D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-4-[redacted] 7[redacted]/M/C/FRA	便秘 胃腸障害	152	48.0H	NOT RELATED Grade 1	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-4-[redacted] 4[redacted]/M/C/FRA	骨痛 筋骨格系および結合組織障害	9		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-4-[redacted] 4[redacted]/M/C/FRA	肺臓炎 呼吸器、胸郭および縦隔障害	13		RELATED Grade 3	Y DRUG WITHDRAWN	UNKNOWN Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	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）	48		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-6-[redacted] 6[redacted]/M/C/FRA	喀血 呼吸器、胸郭および縦隔障害	410	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-8-[redacted] 6[redacted]/M/C/FRA	肝細胞損傷 肝胆道系障害	33	32D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	気胸 呼吸器、胸郭および縦隔障害	44	8D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋梗塞 心臓障害	39	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	房室ブロック 心臓障害	39	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-8-[redacted] 6[redacted]/M/C/FRA	骨転移 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）	-56	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-38-[redacted] 4[redacted]/M/C/GBR	発熱 一般・全身障害および投与部位の状態	267	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	四肢痛 筋骨格系および結合組織障害	41	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	315	11D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	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）	344	48D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-39-[redacted] 6[redacted]/M/C/GBR	高カルシウム血症 代謝および栄養障害	183	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-39-[redacted] 5[redacted]/M/C/GBR	膵転移 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）	226	5D	NOT RELATED Grade 3	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-48-[redacted] 7[redacted]/M/C/GBR	下痢 胃腸障害	85	3D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	疲労 一般・全身障害および投与部位の状態	482	3D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	狭心症 心臓障害	465	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋梗塞 心臓障害	21	6D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋梗塞 心臓障害	125	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心筋梗塞 心臓障害	528	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-48-[redacted] 7[redacted]/M/C/GBR	ヘモグロビン減少 臨床検査	585	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	血中ブドウ糖増加 臨床検査	513	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-48-[redacted] 5[redacted]/M/C/GBR	疼痛 一般・全身障害および投与部位の状態	404	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	404	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	92	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-48-[redacted] 6[redacted]/M/C/GBR	肺炎 感染症および寄生虫症	165		NOT RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	126		NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-48-[redacted] 6[redacted]/M/C/GBR	敗血症 感染症および寄生虫症	227	41D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	58	6D	RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	ヘモグロビン減少 臨床検査	229	39D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-48-[redacted] 6[redacted]/M/C/GBR	眼窩周囲蜂巣炎 感染症および寄生虫症	21	9D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	70		NOT RELATED Grade 3	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-55-[redacted] 7[redacted]/M/C/GRC	腎機能障害 腎および尿路障害	316	3D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎機能障害 腎および尿路障害	349	5D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-55-[redacted] 7[redacted]/M/C/GRC	低ナトリウム血症 代謝および栄養障害	384	15D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-56-[redacted] 4[redacted]/M/C/GRC	貧血 血液およびリンパ系障害	99	48.0H	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	110	18D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	144		NOT RELATED Grade 4	N DOSE NOT CHANGED	FATAL Results in Death, Other Medically Important Serious Event
CA209025-37-[redacted] 5[redacted]/M/C/IRL	疼痛 一般・全身障害および投与部位の状態	21		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	各種物質毒性 傷害、中毒および処置合併症	20	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	53		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-87-[redacted] 6[redacted]/F/C/IRL	疼痛 一般・全身障害および投与部位の状態	145	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	8	15D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-149-[redacted] 7[redacted]/M/C/ISR	胸水 呼吸器、胸郭および縦隔障害	2		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	9		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death
CA209025-151-[redacted] 6[redacted]/F/C/ISR	疼痛 一般・全身障害および投与部位の状態	300	25.4H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-151-[redacted] 7[redacted]/M/C/ISR	胸水 呼吸器、胸郭および縦隔障害	22	36.3H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	151	8D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-151-[redacted] 7[redacted]/M/C/ISR	自殺既遂 精神障害	160		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-179-[redacted] 5[redacted]/M/C/ITA	異常高熱 一般・全身障害および投与部位の状態	79	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-179-[redacted] 4[redacted]/M/C/ITA	呼吸困難 呼吸器、胸郭および縦隔障害	15	9D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-179-[redacted] 6[redacted]/M/C/ITA	上腕骨骨折 傷害、中毒および処置合併症	50	10D	NOT RELATED Grade 2	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	182		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-58-[redacted] 4[redacted]/M/O/ITA	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）	125		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-58-[redacted] 6[redacted]/F/O/ITA	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）	515		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-58-[redacted] 8[redacted]/M/O/ITA	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）	465		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-59-[redacted] 7[redacted]/F/C/ITA	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）	27		NOT RELATED Grade 3	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-80-[redacted] 6[redacted]/M/C/ITA	呼吸困難 呼吸器、胸郭および縦隔障害	585	9D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-80-[redacted] 5[redacted]/M/C/ITA	尿路閉塞 腎および尿路障害	320	18D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-80-[redacted] 5[redacted]/M/C/ITA	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）	514		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-80-[redacted] 6[redacted]/M/C/ITA	急性腎不全 腎および尿路障害	54	7D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-82-[redacted] 5[redacted]/F/C/ITA	インフルエンザ様疾患 一般・全身障害および投与部位の状態	26	5D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-82-[redacted] 6[redacted]/F/C/ITA	悪性新生物 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）	65		NOT RELATED Grade 4	N DRUG WITHDRAWN	FATAL Results in Death
CA209025-82-[redacted] 6[redacted]/M/C/ITA	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）	150		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-82-[redacted] 6[redacted]/M/C/ITA	下痢 胃腸障害	381	6D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Race: A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-82-[redacted] 6[redacted]/M/C/ITA	下痢 胃腸障害	659	6D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	臍ヘルニア 胃腸障害	422	48.0H	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房細動 心臓障害	434	48.0H	NOT RELATED Grade 3	N DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-82-[redacted] 6[redacted]/M/C/ITA	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		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-82-[redacted] 5[redacted]/F/C/ITA	腹痛 胃腸障害	37	8D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	89		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-72-[redacted] 8[redacted]/M/C/NOR	便秘 胃腸障害	73		NOT RELATED Grade 2	Y DOSE NOT CHANGED	UNKNOWN Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-72-[redacted] 8[redacted]/M/C/NOR	全身健康状態低下 一般・全身障害および投与部位の状態	89		NOT RELATED Grade 3	Y DRUG WITHDRAWN	UNKNOWN Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	138		NOT RELATED Grade 3	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
	脊髄圧迫 神経系障害	90	21D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-108-[redacted] 7[redacted]/F/C/POL	薬剤誤投与 傷害、中毒および処置合併症	409	3M	NOT RELATED Grade 4	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	副腎機能不全 内分泌障害	637	16D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-108-[redacted] 6[redacted]/M/C/POL	腎不全 腎および尿路障害	26	9D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	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）	116		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-111-[redacted] 6[redacted]/M/C/POL	急性冠動脈症候群 心臓障害	187	6D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	狭心症 心臓障害	243	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-111-[redacted] 3[redacted]/F/C/POL	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）	174	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-74-[redacted] 6[redacted]/M/C/SWE	感染 感染症および寄生虫症	72	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	9	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	21	9D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸膜炎 呼吸器、胸郭および縦隔障害	24	6D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-90-[redacted] 6[redacted]/F/C/SWE	全身健康状態低下 一般・全身障害および投与部位の状態	195	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-90-[redacted] 7[redacted]/F/C/SWE	胸水 呼吸器、胸郭および縦隔障害	39	22.9H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 7[redacted]/F/C/USA	貧血 血液およびリンパ系障害	20	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	20		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 3[redacted]/F/C/USA	下痢 胃腸障害	29	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腹痛 胃腸障害	89	17D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	便秘 胃腸障害	40	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 6[redacted]/F/C/USA	背部痛 筋骨格系および結合組織障害	113	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-1-[redacted]	心筋梗塞	56	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/USA	心臓障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-1-[redacted]	肺炎	44	9D	NOT RELATED	Y	RECOVERED/RESOLVED
4[redacted]/M/O/USA	感染症および寄生虫症			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	高カルシウム血症	43	32D	NOT RELATED	Y	RECOVERED/RESOLVED
	代謝および栄養障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
	悪性新生物進行	71		NOT RELATED	N	FATAL
	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）			Grade 4	DOSE NOT CHANGED	Results in Death, Requires or Prolongs Hospitalization
CA209025-1-[redacted]	急性腎不全	44	4D	RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/USA	腎および尿路障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-1-[redacted]	背部痛	150	3D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
5[redacted]/F/C/USA	筋骨格系および結合組織障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-1-[redacted]	アスパラギン酸アミノトランスフェラーゼ増加	146	5D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/USA	臨床検査			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-1-[redacted]	アラニンアミノトランスフェラーゼ増加	146	5D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/USA	臨床検査			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-1-[redacted]	背部痛	15	17D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/USA	筋骨格系および結合組織障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
	低血圧	15	7D	RELATED	Y	RECOVERED/RESOLVED
	血管障害			Grade 2	DOSE DELAYED	Requires or Prolongs Hospitalization
	胸水	35	6D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	悪性新生物進行	64		NOT RELATED	N	FATAL
	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）			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-1-[redacted]	背部痛	112	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/USA	筋骨格系および結合組織障害			Grade 3	DRUG WITHDRAWN	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-11-[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）	296	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-11-[redacted] 6[redacted]/F/I/USA	高カルシウム血症 代謝および栄養障害	97	46.0H	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	130		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-11-[redacted] 4[redacted]/M/C/USA	悪心 胃腸障害	305	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	悪心 胃腸障害	323	48.0H	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-13-[redacted] 6[redacted]/M/C/USA	腎腫瘤 腎および尿路障害	365	3D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-13-[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）	517		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	副腎転移 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）	323	2D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-13-[redacted] 6[redacted]/M/C/USA	骨溶解 筋骨格系および結合組織障害	151	8D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-13-[redacted] 7[redacted]/M/C/USA	腰筋膿瘍 感染症および寄生虫症	139	3D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨溶解 筋骨格系および結合組織障害	77	5D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-138-[redacted] 5[redacted]/M/C/USA	斑状丘疹状皮疹 皮膚および皮下組織障害	182		NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-138-[redacted]	アスパラギン酸アミノトランスフェラーゼ増加	31	3D	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/USA	臨床検査			Grade 2	DOSE DELAYED	Requires or Prolongs Hospitalization
	アラニンアミノトランスフェラーゼ増加	31	3D	NOT RELATED	Y	RECOVERED/RESOLVED
	臨床検査			Grade 2	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-138-[redacted]	血液培養陽性	197	8D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/USA	臨床検査			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-138-[redacted]	病的骨折	174	3D	NOT RELATED	Y	RECOVERED/RESOLVED
7[redacted]/M/C/USA	筋骨格系および結合組織障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-138-[redacted]	血管原性脳浮腫	94	8D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
7[redacted]/M/C/USA	神経系障害			Grade 3	DRUG WITHDRAWN	Requires or Prolongs Hospitalization
	中枢神経系出血	94	8D	NOT RELATED	Y	RECOVERED/RESOLVED
	神経系障害			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization
CA209025-138-[redacted]	敗血症	260	15D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/USA	感染症および寄生虫症			Grade 3	DOSE DELAYED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-138-[redacted] 7[redacted]/M/C/USA	脳症 神経系障害	177	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-138-[redacted] 7[redacted]/M/C/USA	尿路感染 感染症および寄生虫症	307	4D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 7[redacted]/F/C/USA	敗血症 感染症および寄生虫症	60	6D	NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	55	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	95	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	144	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	慢性閉塞性肺疾患 呼吸器、胸郭および縦隔障害	144	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	95	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.
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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted] 7[redacted]/F/C/USA	腫瘍疼痛 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）	23	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-139-[redacted] 7[redacted]/M/C/USA	下痢 胃腸障害	447	4D	RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	皮膚感染 感染症および寄生虫症	335	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	79	5D	RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 7[redacted]/M/C/USA	高カルシウム血症 代謝および栄養障害	45	3D	RELATED Grade 1	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 5[redacted]/M/C/USA	腹痛 胃腸障害	771	48.0H	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	膵炎 胃腸障害	191	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted] 5[redacted]/M/C/USA	膵炎 胃腸障害	198	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	膵炎 胃腸障害	239	5D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	角膜障害 眼障害	782	31D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Other Medically Important Serious Event
	霧視 眼障害	764	49D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Other Medically Important Serious Event
CA209025-139-[redacted] 6[redacted]/M/C/USA	胃腸炎 感染症および寄生虫症	271	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	-8	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	副腎機能不全 内分泌障害	279	48.0H	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted] 6[redacted]/M/C/USA	遠隔転移を伴う腎細胞癌 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）	209	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-139-[redacted] 5[redacted]/M/C/USA	遠隔転移を伴う腎細胞癌 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）	123	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 6[redacted]/M/C/USA	遠隔転移を伴う腎細胞癌 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）	73	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 6[redacted]/M/C/USA	末梢性浮腫 一般・全身障害および投与部位の状態	10	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	蜂巣炎 感染症および寄生虫症	90	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	低酸素症 呼吸器、胸郭および縦隔障害	22	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted] 6[redacted]/M/C/USA	浮動性めまい 神経系障害	189	12D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-17-[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）	144		NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	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）	358		NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-17-[redacted] 7[redacted]/M/C/USA	基底細胞癌 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）			NOT RELATED Grade 1	Y DOSE NOT CHANGED	UNKNOWN Involves Cancer
	基底細胞癌 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）	253		NOT RELATED	Y DOSE NOT CHANGED	UNKNOWN Involves Cancer

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-17-[redacted] 6[redacted]/F/C/USA	精神状態変化 精神障害	602		NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-17-[redacted] 4[redacted]/M/O/USA	心不全 心臓障害	85		NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	85		NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-17-[redacted] 6[redacted]/M/C/USA	アナフィラキシー反応 免疫系障害	1	5D	RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Is Life Threatening, Other Medically Important Serious Event
CA209025-17-[redacted] 7[redacted]/M/C/USA	大腸穿孔 胃腸障害	14		NOT RELATED Grade 4	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
	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）	25		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-17-[redacted] 4[redacted]/M/C/USA	腹痛 胃腸障害	11	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-17-[redacted] 4[redacted]/M/C/USA	胆汁うっ滞性黄疸 肝胆道系障害	30	14D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-17-[redacted] 7[redacted]/M/C/USA	蜂巣炎 感染症および寄生虫症	512		NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	192	5D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	高血糖 代謝および栄養障害	196	7D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	196	7D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-17-[redacted] 7[redacted]/F/C/USA	膵転移 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）	470	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-185-[redacted] 5[redacted]/F/C/USA	四肢痛 筋骨格系および結合組織障害	492	48.0H	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-20-[redacted] 8[redacted]/F/C/USA	肺炎 感染症および寄生虫症	137	4D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-20-[redacted] 4[redacted]/M/C/USA	食道閉塞症 胃腸障害	146	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	159		NOT RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-20-[redacted] 4[redacted]/M/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	427	8D	RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	498	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-20-[redacted] 5[redacted]/M/C/USA	大腸炎 胃腸障害	97	9D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	直腸出血 胃腸障害	141	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-20-[redacted] 5[redacted]/M/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	97	9D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	尿細管間質性腎炎 腎および尿路障害	97	9D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カリウム血症 代謝および栄養障害	113	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-21-[redacted] 5[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	7	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-21-[redacted] 6[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）	98		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-21-[redacted] 6[redacted]/M/C/USA	呼吸困難 呼吸器、胸郭および縦隔障害	13	17D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	13	3D	NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Is Life Threatening

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-21-[redacted] 6[redacted]/M/C/USA	血中クレアチニン増加 臨床検査	13	16D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-21-[redacted] 5[redacted]/F/C/USA	視力低下 眼障害	120	7D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Involves Cancer, Requires or Prolongs Hospitalization
	創合併症 傷害、中毒および処置合併症	73	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨転移 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）	75	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-22-[redacted] 4[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	59	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-23-[redacted] 6[redacted]/F/C/USA	病的骨折 筋骨格系および結合組織障害	153	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 6[redacted]/F/C/USA	脊髄圧迫 神経系障害	128	10D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-23-[redacted] 8[redacted]/M/C/USA	貧血 血液およびリンパ系障害	4	3D	RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	38	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	51		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-23-[redacted] 6[redacted]/F/C/USA	悪心 胃腸障害	177		NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	128	11D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 7[redacted]/M/C/USA	小腸閉塞 胃腸障害	233	9D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脳虚血 神経系障害	262	5D	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-23-[redacted] 7[redacted]/M/C/USA	急性腎不全 腎および尿路障害	309		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	悪性腫瘍に伴う高カルシウム血症 内分泌障害	309	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 4[redacted]/M/C/USA	傾眠 神経系障害	41	48.0H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	脳血管発作 神経系障害	248	30D	NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 6[redacted]/M/C/USA	ウイルス性胃腸炎 感染症および寄生虫症	205	46.9H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	25	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	366		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-23-[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）	369		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-23-[redacted] 5[redacted]/M/C/USA	病的骨折 筋骨格系および結合組織障害	-55	58D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 6[redacted]/M/C/USA	肺炎 感染症および寄生虫症	3	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	32	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	病的骨折 筋骨格系および結合組織障害	296	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房細動 心臓障害	32	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	精神障害 精神障害	358	48.0H	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-24-[redacted] 6[redacted]/M/C/USA	基底細胞癌 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）	95	24.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer
CA209025-25-[redacted] 7[redacted]/M/C/USA	肺感染 感染症および寄生虫症	247		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	筋力低下 筋骨格系および結合組織障害	162	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	筋力低下 筋骨格系および結合組織障害	188	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	筋力低下 筋骨格系および結合組織障害	247	6D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	220	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	転倒 傷害、中毒および処置合併症	162	4D	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-25-[redacted] 7[redacted]/M/C/USA	記憶障害 神経系障害	189	48.0H	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脳脊髄液漏 神経系障害	256	5D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	162		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[redacted] 6[redacted]/M/C/USA	尿路閉塞 腎および尿路障害	273	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	225	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	104	3D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低ナトリウム血症 代謝および栄養障害	225	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-25-[redacted] 5[redacted]/F/C/USA	気管支閉塞 呼吸器、胸郭および縦隔障害	4	9D	NOT RELATED Grade 4	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	37	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Involves Cancer, Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	52		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Involves Cancer, Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	52		NOT RELATED Grade 3	N DOSE NOT CHANGED	FATAL Involves Cancer, Results in Death, Requires or Prolongs Hospitalization
CA209025-25-[redacted] 5[redacted]/M/C/USA	発熱 一般・全身障害および投与部位の状態	213	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	発疹 皮膚および皮下組織障害	213	13D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[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	197	5D	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-25-[redacted] 5[redacted]/M/C/USA	四肢痛 筋骨格系および結合組織障害	99	5D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低血圧 血管障害	197	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	197	5D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	230		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-26-[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）	319		NOT RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death
CA209025-26-[redacted] 5[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	138	21D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-26-[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）	573		NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-26-[redacted] 5[redacted]/M/C/USA	悪心 胃腸障害	156	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	糖尿病性胃不全麻痺 胃腸障害	26	48.0H	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	嘔吐 胃腸障害	157	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	疲労 一般・全身障害および投与部位の状態	274		RELATED Grade 2	N DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	末梢性浮腫 一般・全身障害および投与部位の状態	274		RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	咳嗽 呼吸器、胸郭および縦隔障害	274		NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-26-[redacted] 5[redacted]/M/C/USA	食欲減退 代謝および栄養障害	274		RELATED Grade 1	N DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	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）	274		NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	血中クレアチニン増加 臨床検査	28	28.3H	NOT RELATED Grade 2	N DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-27-[redacted] 5[redacted]/M/C/USA	インフルエンザ 感染症および寄生虫症	103	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-27-[redacted] 6[redacted]/M/C/USA	細気管支炎 感染症および寄生虫症	197	8D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-27-[redacted] 7[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）	264		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-29-[redacted] 6[redacted]/M/C/USA	軟部組織感染 感染症および寄生虫症	125	11D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-29-[redacted] 6[redacted]/M/C/USA	軟部組織感染 感染症および寄生虫症	263	8D	NOT RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	関節痛 筋骨格系および結合組織障害	119	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	関節痛 筋骨格系および結合組織障害	413	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	失神 神経系障害	245	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 4[redacted]/M/C/USA	肺出血 呼吸器、胸郭および縦隔障害	94	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	96	48.0H	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 6[redacted]/M/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	99	7D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	195	9D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-29-[redacted] 6[redacted]/M/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	227	9D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 7[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	365	3D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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	394	10D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	頭蓋内出血 神経系障害	209	3D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	309	12D	RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	錯乱状態 精神障害	326	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-30-[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）	151	92D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-30-[redacted] 6[redacted]/F/C/USA	静脈血栓症 血管障害	64		NOT RELATED Grade 3	Y DRUG WITHDRAWN	UNKNOWN Requires or Prolongs Hospitalization
CA209025-31-[redacted] 6[redacted]/F/C/USA	尿路性敗血症 感染症および寄生虫症	120	5D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	失神 神経系障害	135	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-41-[redacted] 7[redacted]/M/C/USA	ブドウ球菌性菌血症 感染症および寄生虫症	169		NOT RELATED Grade 3	Y DOSE DELAYED	UNKNOWN Requires or Prolongs Hospitalization
	敗血症 感染症および寄生虫症	197		NOT RELATED Grade 4	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	198		NOT RELATED Grade 2	Y DOSE DELAYED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	脊椎圧迫骨折 傷害、中毒および処置合併症	117	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-42-[redacted] 5[redacted]/M/C/USA	副腎機能不全 内分泌障害	22	21D	RELATED Grade 3	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-42-[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）	71		NOT RELATED Grade 4	N DOSE NOT CHANGED	FATAL Results in Death, Other Medically Important Serious Event
CA209025-42-[redacted] 5[redacted]/M/C/USA	心肺停止 心臓障害	253	47D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-43-[redacted] 5[redacted]/F/C/USA	末梢腫脹 一般・全身障害および投与部位の状態	71	4D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低血圧 血管障害	60	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	71	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低酸素症 呼吸器、胸郭および縦隔障害	60	48.0H	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-43-[redacted] 4[redacted]/M/C/USA	肺転移 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）	98	6D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer, Requires or Prolongs Hospitalization
CA209025-43-[redacted] 6[redacted]/M/C/USA	脳室内出血 神経系障害	270	6D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-44-[redacted] 5[redacted]/M/C/USA	喀血 呼吸器、胸郭および縦隔障害	92	2D	NOT RELATED Grade 2	Y DOSE DELAYED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-44-[redacted] 7[redacted]/M/C/USA	メレナ 胃腸障害	398	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-49-[redacted] 6[redacted]/M/C/USA	脊髄圧迫 神経系障害	436	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-49-[redacted] 7[redacted]/M/C/USA	発熱 一般・全身障害および投与部位の状態	139	8D	RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血圧 血管障害	428	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: NIVOLUMAB 3 mg/kg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-49-[redacted] 7[redacted]/M/C/USA	錯乱状態 精神障害	446	6D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-49-[redacted] 3[redacted]/F/C/USA	急性腎不全 腎および尿路障害	36	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-49-[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）	6		NOT RELATED Grade 4	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-76-[redacted] 6[redacted]/M/C/USA	肺塞栓症 呼吸器、胸郭および縦隔障害	47	8D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-9-[redacted] 7[redacted]/M/C/USA	膀胱炎 感染症および寄生虫症	131	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-9-[redacted] 6[redacted]/M/C/USA	表皮内悪性黒色腫 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）	290	34D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-154-[redacted] 7[redacted]/M/A/JPN	マイコプラズマ性肺炎 感染症および寄生虫症	31	32D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	膵転移 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）	90		NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-158-[redacted] 5[redacted]/M/A/JPN	腎機能障害 腎および尿路障害	56	3D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎機能障害 腎および尿路障害	59	4D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎機能障害 腎および尿路障害	63	8D	RELATED Grade 1	N DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-158-[redacted] 7[redacted]/M/A/JPN	多形紅斑 皮膚および皮下組織障害	18	12D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-158-[redacted] 6[redacted]/M/A/JPN	副腎転移 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）	106	17D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-159-[redacted] 6[redacted]/M/A/JPN	肺臓炎 呼吸器、胸郭および縦隔障害	43	9D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-162-[redacted] 6[redacted]/F/A/JPN	過量投与 傷害、中毒および処置合併症	1	4D	NOT RELATED Grade 1	N DRUG INTERRUPTED	RECOVERED/RESOLVED
	視床出血 神経系障害	424	105D	RELATED Grade 2	N DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-163-[redacted] 6[redacted]/M/A/JPN	脱水 代謝および栄養障害	284	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-168-[redacted] 4[redacted]/M/A/JPN	遠隔転移を伴う新生物 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）	343	12D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-172-[redacted] 8[redacted]/F/A/JPN	敗血症 感染症および寄生虫症	36	15D	RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Is Life Threatening
	肺炎 感染症および寄生虫症	36	36D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

Gender: M=Male; F=Female.
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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-172-[redacted] 8[redacted]/F/A/JPN	間質性肺疾患 呼吸器、胸郭および縦隔障害	36	36D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	119		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-174-[redacted] 6[redacted]/M/A/JPN	間質性肺疾患 呼吸器、胸郭および縦隔障害	45	31D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	92	48D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	140		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-121-[redacted] 7[redacted]/M/C/ARG	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）	350		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-121-[redacted] 4[redacted]/F/C/ARG	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）	122	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	194		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-78-[redacted] 5[redacted]/M/C/ARG	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）	132		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-78-[redacted] 5[redacted]/M/C/ARG	心嚢液貯留 心臓障害	141		NOT RELATED Grade 4	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	171		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-78-[redacted] 7[redacted]/M/C/ARG	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）	151		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-78-[redacted] 5[redacted]/M/C/ARG	急性腎不全 腎および尿路障害	20		NOT RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-79-[redacted] 6[redacted]/F/C/ARG	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）	97	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	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）	109		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-84-[redacted] 5[redacted]/M/C/ARG	多臓器不全 一般・全身障害および投与部位の状態	109		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-84-[redacted] 5[redacted]/M/C/ARG	癌性リンパ管症 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）	340	7D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-85-[redacted] 6[redacted]/M/C/ARG	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）	99		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-85-[redacted] 7[redacted]/M/C/ARG	尿路感染 感染症および寄生虫症	135	14D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	尿路感染 感染症および寄生虫症	278	18D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-94-[redacted] 5[redacted]/M/C/AUS	病的骨折 筋骨格系および結合組織障害	155	3D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-95-[redacted] 7[redacted]/M/C/AUS	循環虚脱 血管障害	407	24.0H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	喀血 呼吸器、胸郭および縦隔障害	407		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 7[redacted]/M/C/AUS	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）	409		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-95-[redacted] 6[redacted]/M/C/AUS	肺炎 感染症および寄生虫症	451	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-95-[redacted] 5[redacted]/M/C/AUS	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）	33		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-95-[redacted] 5[redacted]/M/C/AUS	下気道感染 感染症および寄生虫症	352	8D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	415	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	140	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低酸素症 呼吸器、胸郭および縦隔障害	352	24.0H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-95-[redacted] 5[redacted]/M/C/AUS	肺梗塞 呼吸器、胸郭および縦隔障害	305	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	471		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-96-[redacted] 6[redacted]/M/C/AUS	非心臓性胸痛 一般・全身障害および投与部位の状態	297	14D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	358	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	372	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-97-[redacted] 6[redacted]/F/C/AUS	慢性心不全 心臓障害	134	8D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-97-[redacted] 6[redacted]/F/C/AUS	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）	195		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-97-[redacted] 6[redacted]/F/C/AUS	腸管虚血 胃腸障害	23		RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-97-[redacted] 4[redacted]/F/C/AUS	腸閉塞 胃腸障害	58	5D	NOT RELATED Grade 2	N DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	細菌性腹膜炎 感染症および寄生虫症	59	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	52	24D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	83		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-97-[redacted] 6[redacted]/M/C/AUS	腹痛 胃腸障害	-6	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	-7	8D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低血圧 血管障害	27		NOT RELATED Grade 4	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
	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）	37		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-98-[redacted] 6[redacted]/M/C/AUS	貧血 血液およびリンパ系障害	55	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	29		NOT RELATED Grade 3	Y DRUG INTERRUPTED	UNKNOWN Requires or Prolongs Hospitalization

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CTC Version 4.0

Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-98-[redacted] 6[redacted]/M/C/AUS	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）	120		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-92-[redacted] 6[redacted]/M/C/AUT	治癒不良 一般・全身障害および投与部位の状態	133	11D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	治癒不良 一般・全身障害および投与部位の状態	161	12D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	事故 傷害、中毒および処置合併症	48	53D	NOT RELATED Grade 1	Y DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-92-[redacted] 6[redacted]/M/C/AUT	腹痛 胃腸障害	295	4D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	281	56D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-92-[redacted] 5[redacted]/M/C/AUT	ヘルニア 一般・全身障害および投与部位の状態	548	9D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-93-[redacted] 7[redacted]/M/C/AUT	肺臓炎 呼吸器、胸郭および縦隔障害	77	38D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-93-[redacted] 5[redacted]/M/C/AUT	全身健康状態低下 一般・全身障害および投与部位の状態	701	3D	NOT RELATED Grade 3	N DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	帯状疱疹 感染症および寄生虫症	266	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	228	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	532	4D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-93-[redacted] 7[redacted]/F/C/AUT	胸水 呼吸器、胸郭および縦隔障害	119	26.4H	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-93-[redacted] 7[redacted]/F/C/AUT	肺臓炎 呼吸器、胸郭および縦隔障害	76	9D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-33-[redacted] 5[redacted]/M/C/BEL	ニューモシスチス・イロベチイ肺炎 感染症および寄生虫症	779	4D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-33-[redacted] 5[redacted]/M/C/BEL	心嚢液貯留 心臓障害	505	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-33-[redacted] 7[redacted]/M/C/BEL	高血糖 代謝および栄養障害	54	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-36-[redacted] 6[redacted]/M/C/BEL	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）	340		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-124-[redacted] 6[redacted]/M/C/BRA	急性呼吸不全 呼吸器、胸郭および縦隔障害	376		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-125-[redacted] 6[redacted]/F/C/BRA	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	48.0H	NOT RELATED Grade 4	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	110		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-143-[redacted] 7[redacted]/M/C/CAN	全身健康状態低下 一般・全身障害および投与部位の状態	80		NOT RELATED Grade 4	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	65	16D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	84		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-145-[redacted] 6[redacted]/M/C/CAN	腹痛 胃腸障害	18	15D	NOT RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-145-[redacted] 6[redacted]/M/C/CAN	遠隔転移を伴う腎細胞癌 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）	90		NOT RELATED Grade 3	Y DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	遠隔転移を伴う腎細胞癌 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）	143		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death
CA209025-145-[redacted] 8[redacted]/F/C/CAN	左室機能不全 心臓障害	37	31D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-147-[redacted] 7[redacted]/F/C/CAN	尿路感染 感染症および寄生虫症	24	4D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-153-[redacted] 6[redacted]/M/C/CAN	無気肺 呼吸器、胸郭および縦隔障害	126		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-69-[redacted] 6[redacted]/F/C/CZE	心房細動 心臓障害	126	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房細動 心臓障害	219	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-69-[redacted]	心房粗動	168	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/CZE	心臓障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-69-[redacted]	自殺既遂	63		NOT RELATED	N	FATAL
6[redacted]/M/C/CZE	精神障害			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-70-[redacted]	貧血	144	4D	RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/CZE	血液およびリンパ系障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	貧血	256	3D	RELATED	Y	RECOVERED/RESOLVED
	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	貧血	343	48.0H	RELATED	Y	RECOVERED/RESOLVED
	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	貧血	424	48.0H	RELATED	Y	RECOVERED/RESOLVED
	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	貧血	486	48.0H	RELATED	Y	RECOVERED/RESOLVED
	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	貧血	536	48.0H	RELATED	Y	RECOVERED/RESOLVED
	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-70-[redacted] 6[redacted]/M/C/CZE	貧血 血液およびリンパ系障害	592	3D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	648	3D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	695	7D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-113-[redacted] 7[redacted]/F/C/DEU	脳血管発作 神経系障害	32		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-113-[redacted] 7[redacted]/M/C/DEU	肺炎 感染症および寄生虫症	21	10D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	咳嗽 呼吸器、胸郭および縦隔障害	21	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-114-[redacted] 6[redacted]/M/C/DEU	急性腎不全 腎および尿路障害	52		NOT RELATED Grade 4	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-114-[redacted] 6[redacted]/M/C/DEU	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）	58		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
	食道腺癌 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）	38	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer, Requires or Prolongs Hospitalization
CA209025-119-[redacted] 5[redacted]/M/C/DEU	貧血 血液およびリンパ系障害	52	27.6H	RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	109		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-126-[redacted] 7[redacted]/M/C/DEU	口内炎 胃腸障害	11	40D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-126-[redacted] 8[redacted]/M/C/DEU	胸水 呼吸器、胸郭および縦隔障害	6	18D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-126-[redacted]	肺臓炎	18		RELATED	Y	NOT RECOVERED/NOT RESOLVED
8[redacted]/M/C/DEU	呼吸器、胸郭および縦隔障害			Grade 3	DRUG WITHDRAWN	Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	大腿骨骨折	31	10D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
	傷害、中毒および処置合併症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	悪性新生物進行	41		NOT RELATED	N	FATAL
	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）			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-137-[redacted]	血中クレアチニン増加	80	34.7H	RELATED	N	RECOVERED/RESOLVED
5[redacted]/M/C/DNK	臨床検査			Grade 2	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
CA209025-137-[redacted]	胆管閉塞	166	21.2H	NOT RELATED	N	RECOVERED/RESOLVED
5[redacted]/M/C/DNK	肝胆道系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-73-[redacted]	筋骨格系胸痛	126	4D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/DNK	筋骨格系および結合組織障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-89-[redacted]	貧血	68	21.6H	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/DNK	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-89-[redacted] 5[redacted]/M/C/DNK	高血糖 代謝および栄養障害	15	38.0H	RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	68	21.6H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-89-[redacted] 6[redacted]/F/C/DNK	感染 感染症および寄生虫症	655	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心停止 心臓障害	643	4D	NOT RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	127	5D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-89-[redacted] 6[redacted]/M/C/DNK	悪心 胃腸障害	64	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-89-[redacted] 6[redacted]/M/C/DNK	尿路感染 感染症および寄生虫症	149	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	149	38.3H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-89-[redacted] 6[redacted]/M/C/DNK	疼痛 一般・全身障害および投与部位の状態	364	2D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	364	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-89-[redacted] 5[redacted]/M/C/DNK	肺炎 感染症および寄生虫症	29	16D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	コントロール不良の糖尿病 代謝および栄養障害	309	25.6H	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高血糖 代謝および栄養障害	29	5D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-61-[redacted] 8[redacted]/M/C/ESP	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		NOT RELATED Grade 4	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	194		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-62-[redacted] 7[redacted]/M/C/ESP	背部痛 筋骨格系および結合組織障害	8	30.8H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	170		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	189		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-62-[redacted] 4[redacted]/M/C/ESP	関節痛 筋骨格系および結合組織障害	120	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-62-[redacted] 4[redacted]/M/C/ESP	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）	168		NOT RELATED Grade 4	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	175		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-62-[redacted] 6[redacted]/M/C/ESP	気腹 胃腸障害	567	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	上部消化管出血 胃腸障害	382	18D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	敗血症 感染症および寄生虫症	588	15D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	十二指腸新生物 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）	552	3D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-62-[redacted] 6[redacted]/F/C/ESP	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）	87		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-64-[redacted] 6[redacted]/M/C/ESP	悪液質 代謝および栄養障害	21	5D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	64		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-64-[redacted] 4[redacted]/F/C/ESP	肺臓炎 呼吸器、胸郭および縦隔障害	148	33.0H	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	196		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-65-[redacted] 6[redacted]/M/C/ESP	腸閉塞 胃腸障害	29		NOT RELATED Grade 3	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-65-[redacted] 4[redacted]/M/C/ESP	発熱 一般・全身障害および投与部位の状態	193	9D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-65-[redacted] 6[redacted]/M/C/ESP	頚部痛 筋骨格系および結合組織障害	176	38D	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	215		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-65-[redacted] 8[redacted]/M/C/ESP	下痢 胃腸障害	51	41.0H	RELATED Grade 3	N DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腎不全 腎および尿路障害	162	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-65-[redacted] 8[redacted]/M/C/ESP	胆管閉塞 肝胆道系障害	223	17D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-65-[redacted] 8[redacted]/F/C/ESP	高アンモニア血性脳症 神経系障害	313	8D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-65-[redacted] 8[redacted]/F/C/ESP	高アンモニア血性脳症 神経系障害	364	3D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-66-[redacted] 5[redacted]/F/C/ESP	肺臓炎 呼吸器、胸郭および縦隔障害	41	16D	RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-75-[redacted] 7[redacted]/F/C/FIN	肺臓炎 呼吸器、胸郭および縦隔障害	59	12D	RELATED Grade 2	Y DOSE REDUCED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-75-[redacted] 7[redacted]/M/C/FIN	発熱 一般・全身障害および投与部位の状態	10	6D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	発熱 一般・全身障害および投与部位の状態	36	10D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房細動 心臓障害	84	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	高カルシウム血症 代謝および栄養障害	84	9D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-75-[redacted] 7[redacted]/M/C/FIN	感染 感染症および寄生虫症	-15	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	筋骨格系胸痛 筋骨格系および結合組織障害	3	48.0H	RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺臓炎 呼吸器、胸郭および縦隔障害	35	10D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-118-[redacted] 5[redacted]/M/C/FRA	遠隔転移を伴う新生物 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）	43	28D	NOT RELATED Grade 2	N DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-118-[redacted] 6[redacted]/M/C/FRA	肺炎 感染症および寄生虫症	23		RELATED Grade 5	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	-6	4D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	11		NOT RELATED Grade 3	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-118-[redacted]	急性熱性好中球性皮膚症	143	10D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/FRA	皮膚および皮下組織障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-118-[redacted]	糖尿病	35	5D	RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/FRA	代謝および栄養障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-118-[redacted]	胸水	223	7D	NOT RELATED	N	RECOVERED/RESOLVED
5[redacted]/M/C/FRA	呼吸器、胸郭および縦隔障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-118-[redacted]	肺塞栓症	106		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
6[redacted]/M/C/FRA	呼吸器、胸郭および縦隔障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	糖尿病	208	5D	RELATED	Y	RECOVERED/RESOLVED
	代謝および栄養障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-118-[redacted]	髄膜炎	92		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
6[redacted]/M/C/FRA	感染症および寄生虫症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization, Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-118-[redacted] 6[redacted]/M/C/FRA	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）	103		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-118-[redacted] 6[redacted]/M/C/FRA	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）	124	3D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-12-[redacted] 6[redacted]/F/C/FRA	一過性脳虚血発作 神経系障害	421	5D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	甲状腺転移 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）	403	4D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-12-[redacted] 5[redacted]/M/C/FRA	リンパ浮腫 血管障害	207		NOT RELATED Grade 1	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-2-[redacted] 5[redacted]/M/C/FRA	急性肝炎 肝胆道系障害	369	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-2-[redacted] 7[redacted]/F/C/FRA	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）	96		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-2-[redacted] 6[redacted]/M/O/FRA	虫垂炎 感染症および寄生虫症	487	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-2-[redacted] 6[redacted]/M/C/FRA	全身健康状態低下 一般・全身障害および投与部位の状態	63	73D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	肺障害 呼吸器、胸郭および縦隔障害	19	21D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-2-[redacted] 5[redacted]/F/C/FRA	腹膜の悪性新生物 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）	117	10D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-2-[redacted] 5[redacted]/F/C/FRA	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）	547		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-4-[redacted] 5[redacted]/M/C/FRA	全身健康状態低下 一般・全身障害および投与部位の状態	654	15D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	全身健康状態低下 一般・全身障害および投与部位の状態	672	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	693		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-4-[redacted] 6[redacted]/F/C/FRA	間質性肺疾患 呼吸器、胸郭および縦隔障害	91	3D	RELATED Grade 2	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-4-[redacted] 5[redacted]/M/C/FRA	全身健康状態低下 一般・全身障害および投与部位の状態	-3	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-4-[redacted] 5[redacted]/M/C/FRA	全身健康状態低下 一般・全身障害および投与部位の状態	19		NOT RELATED Grade 3	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-5-[redacted] 6[redacted]/F/C/FRA	全身健康状態低下 一般・全身障害および投与部位の状態	162		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	111	12D	RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	162		RELATED Grade 3	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	176		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-5-[redacted] 7[redacted]/M/C/FRA	胸水 呼吸器、胸郭および縦隔障害	79		NOT RELATED Grade 3	Y DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-5-[redacted] 7[redacted]/M/C/FRA	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）	155		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-5-[redacted] 5[redacted]/M/C/FRA	活動状態低下 一般・全身障害および投与部位の状態	395	20D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	医療機器関連敗血症 感染症および寄生虫症	455	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨転移 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）	437	48.0H	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-8-[redacted] 4[redacted]/M/C/FRA	発熱 一般・全身障害および投与部位の状態	96	24.0H	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	骨痛 筋骨格系および結合組織障害	191	54D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-8-[redacted]	呼吸困難	96	48.0H	RELATED	N	RECOVERED/RESOLVED
4[redacted]/M/C/FRA	呼吸器、胸郭および縦隔障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-8-[redacted]	気管支閉塞	228	48.0H	NOT RELATED	Y	RECOVERED/RESOLVED
4[redacted]/M/C/FRA	呼吸器、胸郭および縦隔障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	気管支閉塞	274	6D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	気管支閉塞	297	10D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-39-[redacted]	高カルシウム血症	92	27D	NOT RELATED	Y	RECOVERED/RESOLVED
5[redacted]/M/C/GBR	代謝および栄養障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-39-[redacted]	骨溶解	29	30D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/M/C/GBR	筋骨格系および結合組織障害			Grade 2	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	大腿骨骨折	51	9D	NOT RELATED	Y	RECOVERED/RESOLVED
	傷害、中毒および処置合併症			Grade 2	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-39-[redacted]	腎不全	73		NOT RELATED	Y	FATAL
6[redacted]/M/C/GBR	腎および尿路障害			Grade 5	DOSE NOT CHANGED	Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-48-[redacted] 6[redacted]/M/C/GBR	下気道感染 感染症および寄生虫症	-7	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	尿路感染 感染症および寄生虫症	135	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	85	39D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	47	14D	RELATED Grade 4	Y DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-50-[redacted] 6[redacted]/M/C/GBR	胸水 呼吸器、胸郭および縦隔障害	185	3D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	202	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-50-[redacted] 6[redacted]/M/C/GBR	リンパ管炎 感染症および寄生虫症	152	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	152	3D	NOT RELATED Grade 2	N DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-50-[redacted] 6[redacted]/M/C/GBR	呼吸困難 呼吸器、胸郭および縦隔障害	152	3D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-50-[redacted] 5[redacted]/M/C/GBR	肺転移 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）	85	34.0H	NOT RELATED Grade 1	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-55-[redacted] 5[redacted]/M/C/GRC	痙攣発作 神経系障害	92		NOT RELATED Grade 2	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening
	高カルシウム血症 代謝および栄養障害	1	3D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer, Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	高カルシウム血症 代謝および栄養障害	87	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-56-[redacted] 4[redacted]/M/C/GRC	肺臓炎 呼吸器、胸郭および縦隔障害	158	21D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-56-[redacted] 4[redacted]/M/C/GRC	肺臓炎 呼吸器、胸郭および縦隔障害	228	17D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-56-[redacted] 7[redacted]/M/C/GRC	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）	40		NOT RELATED Grade 3	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-37-[redacted] 5[redacted]/M/C/IRL	脳血管発作 神経系障害	139		NOT RELATED Grade 4	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	脳血管発作 神経系障害	143		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-40-[redacted] 7[redacted]/M/C/IRL	肺炎 感染症および寄生虫症	39		NOT RELATED Grade 3	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-87-[redacted] 5[redacted]/M/C/IRL	末梢性浮腫 一般・全身障害および投与部位の状態	72		NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	72	12D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-87-[redacted] 5[redacted]/M/C/IRL	尿失禁 腎および尿路障害	72	12D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-148-[redacted] 7[redacted]/M/C/ISR	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）	325		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-148-[redacted] 7[redacted]/M/C/ISR	単径部感染 感染症および寄生虫症	22		NOT RELATED Grade 4	Y DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
CA209025-149-[redacted] 7[redacted]/M/C/ISR	胸水 呼吸器、胸郭および縦隔障害	6	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-149-[redacted] 7[redacted]/M/C/ISR	便秘 胃腸障害	530	11D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性冠動脈症候群 心臓障害	570	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-149-[redacted] 6[redacted]/M/C/ISR	低ナトリウム血症 代謝および栄養障害	145	4D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-149-[redacted] 7[redacted]/F/C/ISR	気胸 呼吸器、胸郭および縦隔障害	-13	7D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	急性肺水腫 呼吸器、胸郭および縦隔障害	47	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	72		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	81		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-151-[redacted] 6[redacted]/F/C/ISR	上気道感染 感染症および寄生虫症	45	30.2H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	271		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	288		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-151-[redacted] 6[redacted]/M/C/ISR	筋力低下 筋骨格系および結合組織障害	13	14D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	病的骨折 筋骨格系および結合組織障害	-3		NOT RELATED Grade 3	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	急性腎不全 腎および尿路障害	29	7D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	48		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-102-[redacted] 6[redacted]/M/C/ITA	疼痛 一般・全身障害および投与部位の状態	186	16D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	疼痛 一般・全身障害および投与部位の状態	210	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-59-[redacted] 5[redacted]/F/C/ITA	脊椎骨折 傷害、中毒および処置合併症	435		NOT RELATED Grade 3	N DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-82-[redacted] 3[redacted]/M/C/ITA	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）	132		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-82-[redacted] 6[redacted]/M/C/ITA	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		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-72-[redacted] 4[redacted]/M/C/NOR	腹水 胃腸障害	108		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	腹膜出血 胃腸障害	9	8D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	疼痛 一般・全身障害および投与部位の状態	9		NOT RELATED Grade 3	Y DOSE NOT CHANGED	UNKNOWN Requires or Prolongs Hospitalization
CA209025-86-[redacted] 5[redacted]/M/C/NOR	肺転移 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）	77	6D	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Involves Cancer, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-111-[redacted] 4[redacted]/M/C/POL	背部痛 筋骨格系および結合組織障害	399	14D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	病的骨折 筋骨格系および結合組織障害	421	13D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	脊椎転移 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）	315	8D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-111-[redacted] 6[redacted]/F/C/POL	コントロール不良の糖尿病 代謝および栄養障害	529	3D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-111-[redacted] 6[redacted]/M/C/POL	慢性閉塞性肺疾患 呼吸器、胸郭および縦隔障害	470	47.4H	RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-116-[redacted] 5[redacted]/M/C/POL	胃腸炎 感染症および寄生虫症	426	13D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	404	4D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-116-[redacted] 5[redacted]/M/C/POL	自然気胸 呼吸器、胸郭および縦隔障害	232	48.0H	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	自然気胸 呼吸器、胸郭および縦隔障害	287	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	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）	476		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-177-[redacted] 5[redacted]/M/C/POL	気管支肺炎 感染症および寄生虫症	111	10D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	病的骨折 筋骨格系および結合組織障害	239		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	253		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-74-[redacted] 6[redacted]/M/C/SWE	発熱 一般・全身障害および投与部位の状態	161	4.6H	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	発熱 一般・全身障害および投与部位の状態	166	2.7H	NOT RELATED Grade 1	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	発熱 一般・全身障害および投与部位の状態	171	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	感染 感染症および寄生虫症	171	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	処置による疼痛 傷害、中毒および処置合併症	161	4.6H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event
	処置による疼痛 傷害、中毒および処置合併症	166	2.7H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Other Medically Important Serious Event

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-74-[redacted] 6[redacted]/M/C/SWE	骨転移 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）	154	3D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-90-[redacted] 6[redacted]/M/C/SWE	過敏症 免疫系障害	509	17.6H	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-90-[redacted] 6[redacted]/M/C/SWE	脊髄圧迫 神経系障害	23	22D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-90-[redacted] 5[redacted]/M/C/SWE	発熱 一般・全身障害および投与部位の状態	11	3D	NOT RELATED Grade 1	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	発熱 一般・全身障害および投与部位の状態	122	5D	RELATED Grade 1	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 4[redacted]/M/C/USA	直腸出血 胃腸障害	9	48.0H	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 6[redacted]/M/C/USA	うっ血性心不全 心臓障害	58	48.0H	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-1-[redacted] 7[redacted]/M/C/USA	高血圧 血管障害	218	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	新生物 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）	169		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Involves Cancer
CA209025-1-[redacted] 6[redacted]/M/C/USA	背部痛 筋骨格系および結合組織障害	43	7D	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 5[redacted]/M/C/USA	肺炎 感染症および寄生虫症	355	18D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-1-[redacted] 5[redacted]/F/A/USA	貧血 血液およびリンパ系障害	27	8D	RELATED Grade 3	N DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	神経圧迫 神経系障害	27	8D	NOT RELATED Grade 2	N DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-11-[redacted] 6[redacted]/M/B/USA	腹部感染 感染症および寄生虫症	157	28D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-11-[redacted] 6[redacted]/M/B/USA	脾感染 感染症および寄生虫症	29	6D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-13-[redacted] 6[redacted]/M/C/USA	腎結石症 腎および尿路障害	89	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-13-[redacted] 6[redacted]/M/C/USA	疲労 一般・全身障害および投与部位の状態	6		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	肺炎 感染症および寄生虫症	7	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	6		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	低酸素症 呼吸器、胸郭および縦隔障害	-8	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	嗜眠 神経系障害	-8	2D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-13-[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）	20		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-138-[redacted] 6[redacted]/M/C/USA	肺塞栓症 呼吸器、胸郭および縦隔障害	343		NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
CA209025-138-[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）	146		NOT RELATED Grade 3	Y DOSE NOT CHANGED	UNKNOWN Involves Cancer, Requires or Prolongs Hospitalization
CA209025-138-[redacted] 5[redacted]/M/C/USA	腎仙痛 腎および尿路障害	38	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	排尿困難 腎および尿路障害	38	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-138-[redacted] 5[redacted]/F/C/USA	胃腸炎 感染症および寄生虫症	78	48.0H	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-139-[redacted] 6[redacted]/M/C/USA	脊髄圧迫 神経系障害	56	44.5H	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[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）	112		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-139-[redacted] 5[redacted]/M/C/USA	疲労 一般・全身障害および投与部位の状態	186	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	転倒 傷害、中毒および処置合併症	199	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	遠隔転移を伴う腎細胞癌 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）	256		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-139-[redacted] 7[redacted]/M/C/USA	遠隔転移を伴う腎細胞癌 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）	85	160D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-139-[redacted] 6[redacted]/F/C/USA	肺感染 感染症および寄生虫症	36	7D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted]	貧血	36	7D	NOT RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/USA	血液およびリンパ系障害			Grade 3	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	呼吸不全	36	7D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 4	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	悪性新生物進行	92		NOT RELATED	N	FATAL
	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）			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-139-[redacted]	呼吸不全	111	28D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
7[redacted]/M/C/USA	呼吸器、胸郭および縦隔障害			Grade 4	DRUG WITHDRAWN	Requires or Prolongs Hospitalization
	肺臓炎	83	21D	RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
	呼吸器、胸郭および縦隔障害			Grade 3	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	心筋梗塞	111	28D	NOT RELATED	Y	RECOVERED/RESOLVED
	心臓障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	急性腎不全	140		NOT RELATED	Y	RECOVERING/RESOLVING
	腎および尿路障害			Grade 4	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-139-[redacted]	悪性新生物進行	145		NOT RELATED	N	FATAL
7[redacted]/M/C/USA	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）			Grade 5	DOSE NOT CHANGED	Results in Death
CA209025-139-[redacted]	腫瘍疼痛	74	4D	NOT RELATED	Y	RECOVERED/RESOLVED WITH SEQUELAE
6[redacted]/F/C/USA	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）			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
CA209025-14-[redacted]	悪性新生物進行	366	3D	NOT RELATED	Y	RECOVERED/RESOLVED
7[redacted]/F/C/USA	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）			Grade 2	DOSE NOT CHANGED	Involves Cancer, Requires or Prolongs Hospitalization
CA209025-15-[redacted]	呼吸困難	53	6D	NOT RELATED	Y	RECOVERED/RESOLVED
4[redacted]/F/C/USA	呼吸器、胸郭および縦隔障害			Grade 2	DRUG WITHDRAWN	Requires or Prolongs Hospitalization
CA209025-17-[redacted]	貧血	49		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
5[redacted]/M/C/USA	血液およびリンパ系障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	胸水	30	6D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 3	DRUG INTERRUPTED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-17-[redacted] 5[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	49	5D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	63		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-17-[redacted] 6[redacted]/M/A/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）	164		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-17-[redacted] 6[redacted]/F/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	472	9D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	571		NOT RELATED Grade 5	Y DOSE NOT CHANGED	FATAL Results in Death
CA209025-17-[redacted] 7[redacted]/M/C/USA	尿路感染 感染症および寄生虫症	31	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-18-[redacted] 7[redacted]/M/C/USA	下痢 胃腸障害	141	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腹痛 胃腸障害	141		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	敗血症 感染症および寄生虫症	113	48.0H	NOT RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	-10		NOT RELATED Grade 2	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-182-[redacted] 8[redacted]/M/C/USA	肺炎 感染症および寄生虫症	64	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-183-[redacted] 6[redacted]/M/C/USA	うっ血性心不全 心臓障害	520		NOT RELATED Grade 3	Y DOSE NOT CHANGED	UNKNOWN Requires or Prolongs Hospitalization, Other Medically Important Serious Event
CA209025-185-[redacted] 4[redacted]/M/C/USA	筋力低下 筋骨格系および結合組織障害	399	5D	NOT RELATED Grade 2	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-20-[redacted] 7[redacted]/F/C/USA	急性呼吸不全 呼吸器、胸郭および縦隔障害	54	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-20-[redacted] 7[redacted]/F/C/USA	呼吸窮迫 呼吸器、胸郭および縦隔障害	64		NOT RELATED Grade 4	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	65		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-20-[redacted] 5[redacted]/F/C/USA	胸水 呼吸器、胸郭および縦隔障害	-4	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胸水 呼吸器、胸郭および縦隔障害	2	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	67		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-20-[redacted] 5[redacted]/M/C/USA	胸水 呼吸器、胸郭および縦隔障害	145	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-20-[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）	255		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-20-[redacted] 5[redacted]/M/C/USA	腎尿細管壊死 腎および尿路障害	77	17D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
CA209025-20-[redacted] 7[redacted]/M/C/USA	血栓症 血管障害	114	8D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization, Is Life Threatening
	脱水 代謝および栄養障害	34	3D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	124		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	124		NOT RELATED Grade 3	Y DOSE NOT CHANGED	FATAL Results in Death, Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-20-[redacted]	小腸閉塞	101	9D	RELATED	Y	RECOVERED/RESOLVED
6[redacted]/F/C/USA	胃腸障害			Grade 3	DRUG WITHDRAWN	Requires or Prolongs Hospitalization
CA209025-21-[redacted]	肺炎	252		NOT RELATED	Y	RECOVERING/RESOLVING
6[redacted]/M/C/USA	感染症および寄生虫症			Grade 3	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
	肺感染	562	5D	NOT RELATED	Y	RECOVERED/RESOLVED
	感染症および寄生虫症			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	血管浮腫	422	3D	NOT RELATED	Y	RECOVERED/RESOLVED
	皮膚および皮下組織障害			Grade 4	DRUG INTERRUPTED	Requires or Prolongs Hospitalization
CA209025-21-[redacted]	腸管穿孔	73		NOT RELATED	Y	NOT RECOVERED/NOT RESOLVED
7[redacted]/M/C/USA	胃腸障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	胸水	37	5D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization
	肺塞栓症	50	7D	NOT RELATED	Y	RECOVERED/RESOLVED
	呼吸器、胸郭および縦隔障害			Grade 3	DOSE NOT CHANGED	Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-21-[redacted] 7[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）	82		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-22-[redacted] 3[redacted]/M/C/USA	腹水 胃腸障害	47	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
CA209025-22-[redacted] 4[redacted]/M/C/USA	小腸閉塞 胃腸障害	83	4D	NOT RELATED Grade 3	N DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	皮膚感染 感染症および寄生虫症	148	6D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	120	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-22-[redacted] 7[redacted]/F/C/USA	医療機器関連敗血症 感染症および寄生虫症	335	15D	NOT RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	背部痛 筋骨格系および結合組織障害	7	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-23-[redacted] 6[redacted]/M/C/USA	急性腎不全 腎および尿路障害	91	3D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 7[redacted]/M/C/USA	肺炎 感染症および寄生虫症	32	6D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-23-[redacted] 7[redacted]/M/C/USA	肺臓炎 呼吸器、胸郭および縦隔障害	98	7D	RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心不全 心臓障害	106	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-24-[redacted] 6[redacted]/M/C/USA	小腸閉塞 胃腸障害	409	8D	NOT RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[redacted] 6[redacted]/F/C/USA	小腸閉塞 胃腸障害	12	7D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	腹水 胃腸障害	48		NOT RELATED Grade 2	N DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	便秘 胃腸障害	48		NOT RELATED Grade 2	N DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-25-[redacted] 6[redacted]/F/C/USA	低ナトリウム血症 代謝および栄養障害	48		NOT RELATED Grade 3	Y DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	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）	61		NOT RELATED Grade 5	N DRUG WITHDRAWN	FATAL Results in Death, Requires or Prolongs Hospitalization
	血中クレアチニン増加 臨床検査	48		RELATED Grade 2	N DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[redacted] 6[redacted]/M/C/USA	低酸素症 呼吸器、胸郭および縦隔障害	6	18D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[redacted] 5[redacted]/M/C/USA	血管浮腫 皮膚および皮下組織障害	174	6D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-25-[redacted] 6[redacted]/F/C/USA	悪心 胃腸障害	14	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-26-[redacted] 5[redacted]/M/C/USA	瘢痕ヘルニア 傷害、中毒および処置合併症	57	48.0H	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-28-[redacted] 7[redacted]/M/C/USA	蜂巣炎 感染症および寄生虫症	394	15D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 6[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）	57		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-29-[redacted] 5[redacted]/M/C/USA	肺感染 感染症および寄生虫症	20	3D	RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 6[redacted]/F/C/USA	小腸閉塞 胃腸障害	20	5D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	貧血 血液およびリンパ系障害	56	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 6[redacted]/M/C/USA	筋力低下 筋骨格系および結合組織障害	172	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	錯乱状態 精神障害	191	10D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-29-[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）	207		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
	腫瘍疼痛 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）	139	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-29-[redacted] 5[redacted]/M/C/USA	肺炎 感染症および寄生虫症	10	5D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	譫妄 精神障害	72	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-30-[redacted] 5[redacted]/F/C/USA	胆嚢痛 肝胆道系障害	20	22D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Other Medically Important Serious Event
CA209025-41-[redacted] 7[redacted]/F/C/USA	肺炎 感染症および寄生虫症	81	46D	NOT RELATED Grade 3	Y DRUG WITHDRAWN	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	低血糖症 代謝および栄養障害	81	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-41-[redacted] 7[redacted]/F/C/USA	低血糖症 代謝および栄養障害	95	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-41-[redacted] 6[redacted]/M/C/USA	肺炎 感染症および寄生虫症	96	5D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心肺停止 心臓障害	105		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
	脳血管発作 神経系障害	101		NOT RELATED Grade 3	Y DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
CA209025-42-[redacted] 4[redacted]/M/C/USA	貧血 血液およびリンパ系障害	57	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-42-[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）	87		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-42-[redacted] 6[redacted]/F/C/USA	上室性頻脈 心臓障害	398	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-42-[redacted] 7[redacted]/M/C/USA	非心臓性胸痛 一般・全身障害および投与部位の状態	89	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-42-[redacted] 5[redacted]/F/C/USA	高カルシウム血症 代謝および栄養障害	19	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	脱水 代謝および栄養障害	4	4D	NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	64		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-43-[redacted] 6[redacted]/F/C/USA	肺炎 感染症および寄生虫症	549	11D	RELATED Grade 4	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	心房細動 心臓障害	309		NOT RELATED Grade 3	Y DRUG INTERRUPTED	RECOVERING/RESOLVING Requires or Prolongs Hospitalization
	心房細動 心臓障害	551	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-43-[redacted] 6[redacted]/F/C/USA	貧血 血液およびリンパ系障害	121	5D	RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-43-[redacted] 5[redacted]/M/C/USA	血尿 腎および尿路障害	35	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	75		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-44-[redacted] 2[redacted]/M/C/USA	腹痛 胃腸障害	101		NOT RELATED Grade 3	Y DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED Requires or Prolongs Hospitalization
	肺塞栓症 呼吸器、胸郭および縦隔障害	50	4D	NOT RELATED Grade 2	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	120		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-47-[redacted] 4[redacted]/F/C/USA	腹腔内出血 胃腸障害	48		NOT RELATED Grade 4	Y DOSE NOT CHANGED	FATAL Involves Cancer, Results in Death, Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	-8	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-47-[redacted] 6[redacted]/M/C/USA	呼吸困難 呼吸器、胸郭および縦隔障害	58	7D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	呼吸困難 呼吸器、胸郭および縦隔障害	75	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	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）	81		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-49-[redacted] 4[redacted]/M/C/USA	背部痛 筋骨格系および結合組織障害	38	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-49-[redacted] 6[redacted]/M/C/USA	病的骨折 筋骨格系および結合組織障害	178	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-53-[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）	159		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-53-[redacted] 4[redacted]/F/C/USA	消化性潰瘍 胃腸障害	-17	5D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-53-[redacted] 5[redacted]/M/O/USA	骨病変 筋骨格系および結合組織障害	-39	4D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization, Other Medically Important Serious Event
	頚椎骨折 傷害、中毒および処置合併症	70	17D	NOT RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	腎結石症 腎および尿路障害	53	8D	NOT RELATED Grade 4	Y DRUG INTERRUPTED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	副腎機能不全 内分泌障害	53	9D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-53-[redacted] 5[redacted]/M/O/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）	109		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-9-[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）	101		NOT RELATED Grade 5	N DOSE NOT CHANGED	FATAL Results in Death
CA209025-9-[redacted] 6[redacted]/M/C/USA	上腹部痛 胃腸障害	10	48.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
	胆嚢炎 肝胆道系障害	262	0S	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-9-[redacted] 6[redacted]/M/C/USA	膵炎 胃腸障害	-12	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization
CA209025-9-[redacted] 7[redacted]/F/C/USA	ヘルニア痛 一般・全身障害および投与部位の状態	403	24.0H	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED Requires or Prolongs Hospitalization

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Listing of Serious Adverse Events All Treated Subjects (Trial No: ONO-4538-03/CA209025)

Treatment Group: EVEROLIMUS 10 mg

Subject ID Age/Gender/Race/Country	Preferred Term System Organ Class	Start Relative Day	Duration of Event	Relationship CTC	Treatment Required Action	Outcome Category of Seriousness
CA209025-9-[redacted] 7[redacted]/F/C/USA	うっ血性心不全 心臓障害	439	3D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization
	脳血管発作 神経系障害	447	2D	NOT RELATED Grade 3	Y DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE Requires or Prolongs Hospitalization

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