Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
胸痛	- Any Grade -	43 (6.5%)	5 (3.6%)	15 (5.6%)	23 (9.1%)
	1	20 (3.0%)	3 (2.2%)	5 (1.9%)	12 (4.7%)
	2	16 (2.4%)	1 (0.7%)	6 (2.2%)	9 (3.6%)
	3	7 (1.1%)	1 (0.7%)	4 (1.5%)	2 (0.8%)
末梢性浮腫	- Any Grade -	43 (6.5%)	5 (3.6%)	20 (7.5%)	18 (7.1%)
	1	35 (5.3%)	4 (2.9%)	15 (5.6%)	16 (6.3%)
	2	7 (1.1%)	1 (0.7%)	4 (1.5%)	2 (0.8%)
	3	1 (0.2%)	0	1 (0.4%)	0
インフルエンザ様疾患	- Any Grade -	42 (6.4%)	11 (7.9%)	18 (6.7%)	13 (5.1%)
	1	32 (4.9%)	8 (5.8%)	14 (5.2%)	10 (4.0%)
	2	10 (1.5%)	3 (2.2%)	4 (1.5%)	3 (1.2%)
悪寒	- Any Grade -	34 (5.2%)	4 (2.9%)	15 (5.6%)	15 (5.9%)
	1	31 (4.7%)	4 (2.9%)	14 (5.2%)	13 (5.1%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
疼痛	- Any Grade -	31 (4.7%)	10 (7.2%)	12 (4.5%)	9 (3.6%)
	1	13 (2.0%)	4 (2.9%)	6 (2.2%)	3 (1.2%)
	2	15 (2.3%)	5 (3.6%)	5 (1.9%)	5 (2.0%)
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
倦怠感	- Any Grade -	25 (3.8%)	8 (5.8%)	8 (3.0%)	9 (3.6%)
	1	17 (2.6%)	6 (4.3%)	5 (1.9%)	6 (2.4%)
	2	6 (0.9%)	2 (1.4%)	1 (0.4%)	3 (1.2%)
	3	2 (0.3%)	0	2 (0.7%)	0
粘膜の炎症	- Any Grade -	20 (3.0%)	5 (3.6%)	7 (2.6%)	8 (3.2%)
	1	17 (2.6%)	5 (3.6%)	5 (1.9%)	7 (2.8%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
非心臓性胸痛	- Any Grade -	7 (1.1%)	2 (1.4%)	3 (1.1%)	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
高熱	- Any Grade -	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	1	5 (0.8%)	0	1 (0.4%)	4 (1.6%)
	3	1 (0.2%)	0	1 (0.4%)	0
歩行障害	- Any Grade -	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
乾燥症	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
胸部不快感	- Any Grade -	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
全身健康状態低下	- Any Grade -	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	2 (0.3%)	0	0	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
カテーテル留置部位疼痛	- Any Grade -	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
	1	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
浮腫	- Any Grade -	4 (0.6%)	1 (0.7%)	0	3 (1.2%)
	1	3 (0.5%)	0	0	3 (1.2%)
	2	1 (0.2%)	1 (0.7%)	0	0
末梢腫脹	- Any Grade -	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
	1	4 (0.6%)	1 (0.7%)	3 (1.1%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
腋窩痛	- Any Grade -	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
圧痛	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
顔面浮腫	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
局所腫脹	- Any Grade -	2 (0.3%)	2 (1.4%)	0	0
	1	2 (0.3%)	2 (1.4%)	0	0
限局性浮腫	- Any Grade -	2 (0.3%)	2 (1.4%)	0	0
	1	2 (0.3%)	2 (1.4%)	0	0
突然死	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	5	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
カテーテル留置部位そう痒感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
カテーテル留置部位関連反応	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
カテーテル留置部位腫脹	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
医薬品副作用	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
温度変化不耐症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
泣き	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
死亡	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	0	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
注射部位血管炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
注射部位反応	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
注射部位疼痛	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
注入部位腫脹	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
潰瘍	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
適用部位そう痒感	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
適用部位熱傷	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
熱感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
粘膜乾燥	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
胃腸障害					
- Overall -	- Any Grade -	340 (51.6%)	68 (48.9%)	139 (52.1%)	133 (52.6%)
	1	205 (31.1%)	42 (30.2%)	85 (31.8%)	78 (30.8%)
	2	95 (14.4%)	19 (13.7%)	37 (13.9%)	39 (15.4%)
	3	38 (5.8%)	6 (4.3%)	16 (6.0%)	16 (6.3%)
	4	2 (0.3%)	1 (0.7%)	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
悪心	- Any Grade -	141 (21.4%)	26 (18.7%)	61 (22.8%)	54 (21.3%)
	1	105 (15.9%)	18 (12.9%)	49 (18.4%)	38 (15.0%)
	2	26 (3.9%)	5 (3.6%)	8 (3.0%)	13 (5.1%)
	3	9 (1.4%)	2 (1.4%)	4 (1.5%)	3 (1.2%)
	4	1 (0.2%)	1 (0.7%)	0	0
下痢	- Any Grade -	112 (17.0%)	24 (17.3%)	50 (18.7%)	38 (15.0%)
	1	87 (13.2%)	18 (12.9%)	40 (15.0%)	29 (11.5%)
	2	20 (3.0%)	5 (3.6%)	8 (3.0%)	7 (2.8%)
	3	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
便秘	- Any Grade -	93 (14.1%)	18 (12.9%)	36 (13.5%)	39 (15.4%)
	1	65 (9.9%)	13 (9.4%)	25 (9.4%)	27 (10.7%)
	2	26 (3.9%)	5 (3.6%)	10 (3.7%)	11 (4.3%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
嘔吐	- Any Grade -	86 (13.1%)	16 (11.5%)	35 (13.1%)	35 (13.8%)
	1	64 (9.7%)	11 (7.9%)	27 (10.1%)	26 (10.3%)
	2	14 (2.1%)	4 (2.9%)	4 (1.5%)	6 (2.4%)
	3	8 (1.2%)	1 (0.7%)	4 (1.5%)	3 (1.2%)
腹痛	- Any Grade -	40 (6.1%)	8 (5.8%)	16 (6.0%)	16 (6.3%)
	1	24 (3.6%)	7 (5.0%)	9 (3.4%)	8 (3.2%)
	2	13 (2.0%)	1 (0.7%)	6 (2.2%)	6 (2.4%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
口内乾燥	- Any Grade -	31 (4.7%)	8 (5.8%)	13 (4.9%)	10 (4.0%)
	1	26 (3.9%)	8 (5.8%)	10 (3.7%)	8 (3.2%)
	2	5 (0.8%)	0	3 (1.1%)	2 (0.8%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
上腹部痛	- Any Grade -	20 (3.0%)	4 (2.9%)	6 (2.2%)	10 (4.0%)
	1	11 (1.7%)	1 (0.7%)	5 (1.9%)	5 (2.0%)
	2	7 (1.1%)	2 (1.4%)	1 (0.4%)	4 (1.6%)
	3	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
口内炎	- Any Grade -	19 (2.9%)	5 (3.6%)	7 (2.6%)	7 (2.8%)
	1	15 (2.3%)	3 (2.2%)	6 (2.2%)	6 (2.4%)
	2	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
消化不良	- Any Grade -	15 (2.3%)	4 (2.9%)	6 (2.2%)	5 (2.0%)
	1	11 (1.7%)	3 (2.2%)	4 (1.5%)	4 (1.6%)
	2	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
嚥下障害	- Any Grade -	15 (2.3%)	0	6 (2.2%)	9 (3.6%)
	1	9 (1.4%)	0	5 (1.9%)	4 (1.6%)
	2	2 (0.3%)	0	0	2 (0.8%)
	3	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
胃食道逆流性疾患	- Any Grade -	12 (1.8%)	2 (1.4%)	7 (2.6%)	3 (1.2%)
	1	9 (1.4%)	2 (1.4%)	5 (1.9%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	2 (0.3%)	0	2 (0.7%)	0
胃炎	- Any Grade -	8 (1.2%)	1 (0.7%)	6 (2.2%)	1 (0.4%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
大腸炎	- Any Grade -	8 (1.2%)	4 (2.9%)	2 (0.7%)	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	1 (0.7%)	0	0
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
腹部膨満	- Any Grade -	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	1	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
歯痛	- Any Grade -	6 (0.9%)	1 (0.7%)	1 (0.4%)	4 (1.6%)
	1	4 (0.6%)	1 (0.7%)	0	3 (1.2%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
歯肉痛	- Any Grade -	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
放屁	- Any Grade -	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
	1	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
おくび	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
下腹部痛	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	1 (0.4%)	0
腹水	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	2 (0.3%)	0	0	2 (0.8%)
アフタ性口内炎	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
レッチング	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
口腔内出血	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
痔核	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
痔出血	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
食中毒	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
食道炎	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
食道狭窄	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
直腸出血	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
吐血	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
肛門そう痒症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
肛門周囲痛	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	0	1 (0.4%)
メレナ	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
亜イレウス	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
胃出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
胃排出不全	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
下部消化管出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
急性膵炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
憩室	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
血便排泄	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
口の錯感覚	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
口腔知覚不全	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
口腔内潰瘍形成	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
口唇乾燥	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
十二指腸胃逆流	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
十二指腸炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
出血性胃潰瘍	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
小腸閉塞	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
消化管運動低下	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
食道運動障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
食道静脈瘤出血	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
食道穿孔	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
食道潰瘍	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
舌潰瘍	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
舌変色	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
直腸潰瘍	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
排便回数増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
腹部不快感	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
変色便	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
流涎過多	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
裂孔ヘルニア	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
嚥下痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
膵炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害					
- Overall -	- Any Grade -	338 (51.3%)	78 (56.1%)	122 (45.7%)	138 (54.5%)
	1	147 (22.3%)	24 (17.3%)	60 (22.5%)	63 (24.9%)
	2	123 (18.7%)	38 (27.3%)	39 (14.6%)	46 (18.2%)
	3	57 (8.6%)	15 (10.8%)	19 (7.1%)	23 (9.1%)
	4	7 (1.1%)	0	2 (0.7%)	5 (2.0%)
	5	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
咳嗽	- Any Grade -	144 (21.9%)	33 (23.7%)	45 (16.9%)	66 (26.1%)
	1	93 (14.1%)	17 (12.2%)	34 (12.7%)	42 (16.6%)
	2	46 (7.0%)	16 (11.5%)	8 (3.0%)	22 (8.7%)
	3	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
呼吸困難	- Any Grade -	143 (21.7%)	36 (25.9%)	42 (15.7%)	65 (25.7%)
	1	58 (8.8%)	14 (10.1%)	16 (6.0%)	28 (11.1%)
	2	57 (8.6%)	17 (12.2%)	17 (6.4%)	23 (9.1%)
	3	26 (3.9%)	5 (3.6%)	9 (3.4%)	12 (4.7%)
	4	2 (0.3%)	0	0	2 (0.8%)
喀血	- Any Grade -	35 (5.3%)	9 (6.5%)	14 (5.2%)	12 (4.7%)
	1	24 (3.6%)	5 (3.6%)	11 (4.1%)	8 (3.2%)
	2	8 (1.2%)	4 (2.9%)	2 (0.7%)	2 (0.8%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
湿性咳嗽	- Any Grade -	29 (4.4%)	6 (4.3%)	14 (5.2%)	9 (3.6%)
	1	18 (2.7%)	3 (2.2%)	8 (3.0%)	7 (2.8%)
	2	11 (1.7%)	3 (2.2%)	6 (2.2%)	2 (0.8%)
肺臓炎	- Any Grade -	24 (3.6%)	2 (1.4%)	12 (4.5%)	10 (4.0%)
	1	7 (1.1%)	0	5 (1.9%)	2 (0.8%)
	2	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	3	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)
	4	1 (0.2%)	0	1 (0.4%)	0
	5	1 (0.2%)	0	1 (0.4%)	0
胸水	- Any Grade -	17 (2.6%)	6 (4.3%)	4 (1.5%)	7 (2.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)
	3	5 (0.8%)	4 (2.9%)	0	1 (0.4%)
低酸素症	- Any Grade -	15 (2.3%)	6 (4.3%)	5 (1.9%)	4 (1.6%)
	1	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	2	8 (1.2%)	3 (2.2%)	3 (1.1%)	2 (0.8%)
	3	4 (0.6%)	2 (1.4%)	2 (0.7%)	0
喘鳴	- Any Grade -	15 (2.3%)	1 (0.7%)	4 (1.5%)	10 (4.0%)
	1	11 (1.7%)	0	3 (1.1%)	8 (3.2%)
	2	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
発声障害	- Any Grade -	14 (2.1%)	3 (2.2%)	6 (2.2%)	5 (2.0%)
	1	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)
	2	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
口腔咽頭痛	- Any Grade -	13 (2.0%)	2 (1.4%)	9 (3.4%)	2 (0.8%)
	1	11 (1.7%)	2 (1.4%)	7 (2.6%)	2 (0.8%)
	2	2 (0.3%)	0	2 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肺塞栓症	- Any Grade -	11 (1.7%)	5 (3.6%)	4 (1.5%)	2 (0.8%)
	2	2 (0.3%)	0	2 (0.7%)	0
	3	8 (1.2%)	5 (3.6%)	2 (0.7%)	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
鼻閉	- Any Grade -	11 (1.7%)	7 (5.0%)	2 (0.7%)	2 (0.8%)
	1	8 (1.2%)	4 (2.9%)	2 (0.7%)	2 (0.8%)
	2	3 (0.5%)	3 (2.2%)	0	0
労作性呼吸困難	- Any Grade -	11 (1.7%)	3 (2.2%)	4 (1.5%)	4 (1.6%)
	1	10 (1.5%)	2 (1.4%)	4 (1.5%)	4 (1.6%)
	2	1 (0.2%)	1 (0.7%)	0	0
慢性閉塞性肺疾患	- Any Grade -	10 (1.5%)	4 (2.9%)	3 (1.1%)	3 (1.2%)
	2	7 (1.1%)	3 (2.2%)	3 (1.1%)	1 (0.4%)
	3	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
上気道咳症候群	- Any Grade -	9 (1.4%)	2 (1.4%)	2 (0.7%)	5 (2.0%)
	1	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	2	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
鼻漏	- Any Grade -	8 (1.2%)	1 (0.7%)	6 (2.2%)	1 (0.4%)
	1	6 (0.9%)	1 (0.7%)	4 (1.5%)	1 (0.4%)
	2	2 (0.3%)	0	2 (0.7%)	0
胸膜痛	- Any Grade -	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	1	5 (0.8%)	1 (0.7%)	1 (0.4%)	3 (1.2%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
呼吸不全	- Any Grade -	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	2	1 (0.2%)	0	1 (0.4%)	0
	3	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	5	1 (0.2%)	1 (0.7%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
鼻出血	- Any Grade -	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
	1	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
誤嚥性肺炎	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	2	1 (0.2%)	0	1 (0.4%)	0
	3	2 (0.3%)	0	0	2 (0.8%)
	5	1 (0.2%)	0	1 (0.4%)	0
咽喉乾燥	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
呼吸窮迫	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	3	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	0	1 (0.4%)
喉頭出血	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
肺水腫	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
副鼻腔うっ血	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
アレルギー性鼻炎	- Any Grade -	2 (0.3%)	2 (1.4%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
咽喉刺激感	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
起坐呼吸	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
呼吸時疼痛	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
誤嚥	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
肺高血圧症	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
肺出血	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
頻呼吸	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
副鼻腔不快感	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
喘息	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	1 (0.4%)	0
しゃっくり	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
ラ音	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
レチノイン酸症候群	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
咽頭の炎症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
間質性肺疾患	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
気管狭窄	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
気管支出血	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
気管支閉塞	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
気管支痙攣	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
気胸	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
気道浮腫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血胸	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
喉頭の炎症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
高粘稠性気管支分泌物	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
上気道うっ血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
睡眠時無呼吸症候群	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
肺気腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肺血栓症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
肺硬化	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
肺浸潤	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
肺動脈瘤	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
鼻の炎症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
鼻乾燥	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
副鼻腔分泌過多	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
変色痰	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
慢性気管支炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
夜間呼吸困難	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
筋骨格系および結合組織障害					
- Overall -	- Any Grade -	284 (43.1%)	58 (41.7%)	107 (40.1%)	119 (47.0%)
	1	154 (23.4%)	30 (21.6%)	66 (24.7%)	58 (22.9%)
	2	104 (15.8%)	24 (17.3%)	31 (11.6%)	49 (19.4%)
	3	25 (3.8%)	4 (2.9%)	9 (3.4%)	12 (4.7%)
	4	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
関節痛	- Any Grade -	75 (11.4%)	14 (10.1%)	30 (11.2%)	31 (12.3%)
	1	48 (7.3%)	7 (5.0%)	22 (8.2%)	19 (7.5%)
	2	23 (3.5%)	6 (4.3%)	5 (1.9%)	12 (4.7%)
	3	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
背部痛	- Any Grade -	69 (10.5%)	16 (11.5%)	24 (9.0%)	29 (11.5%)
	1	32 (4.9%)	5 (3.6%)	14 (5.2%)	13 (5.1%)
	2	27 (4.1%)	8 (5.8%)	8 (3.0%)	11 (4.3%)
	3	10 (1.5%)	3 (2.2%)	2 (0.7%)	5 (2.0%)
四肢痛	- Any Grade -	45 (6.8%)	11 (7.9%)	20 (7.5%)	14 (5.5%)
	1	28 (4.2%)	9 (6.5%)	12 (4.5%)	7 (2.8%)
	2	15 (2.3%)	2 (1.4%)	7 (2.6%)	6 (2.4%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
筋骨格痛	- Any Grade -	43 (6.5%)	6 (4.3%)	13 (4.9%)	24 (9.5%)
	1	32 (4.9%)	5 (3.6%)	10 (3.7%)	17 (6.7%)
	2	11 (1.7%)	1 (0.7%)	3 (1.1%)	7 (2.8%)
筋骨格系胸痛	- Any Grade -	32 (4.9%)	9 (6.5%)	12 (4.5%)	11 (4.3%)
	1	15 (2.3%)	4 (2.9%)	6 (2.2%)	5 (2.0%)
	2	15 (2.3%)	5 (3.6%)	6 (2.2%)	4 (1.6%)
	3	2 (0.3%)	0	0	2 (0.8%)
筋肉痛	- Any Grade -	29 (4.4%)	2 (1.4%)	14 (5.2%)	13 (5.1%)
	1	19 (2.9%)	2 (1.4%)	9 (3.4%)	8 (3.2%)
	2	9 (1.4%)	0	4 (1.5%)	5 (2.0%)
	3	1 (0.2%)	0	1 (0.4%)	0
頚部痛	- Any Grade -	22 (3.3%)	6 (4.3%)	7 (2.6%)	9 (3.6%)
	1	19 (2.9%)	5 (3.6%)	6 (2.2%)	8 (3.2%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
筋痙縮	- Any Grade -	15 (2.3%)	5 (3.6%)	5 (1.9%)	5 (2.0%)
	1	10 (1.5%)	3 (2.2%)	4 (1.5%)	3 (1.2%)
	2	5 (0.8%)	2 (1.4%)	1 (0.4%)	2 (0.8%)
骨痛	- Any Grade -	14 (2.1%)	1 (0.7%)	7 (2.6%)	6 (2.4%)
	1	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	2	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	3	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
側腹部痛	- Any Grade -	11 (1.7%)	2 (1.4%)	3 (1.1%)	6 (2.4%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	6 (0.9%)	2 (1.4%)	0	4 (1.6%)
	3	2 (0.3%)	0	2 (0.7%)	0
筋力低下	- Any Grade -	10 (1.5%)	1 (0.7%)	4 (1.5%)	5 (2.0%)
	1	3 (0.5%)	0	3 (1.1%)	0
	2	5 (0.8%)	1 (0.7%)	0	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
顎痛	- Any Grade -	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	1	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
関節炎	- Any Grade -	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	1	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
末梢部痛	- Any Grade -	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
病的骨折	- Any Grade -	4 (0.6%)	0	4 (1.5%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
関節腫脹	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
筋骨格不快感	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
脊椎痛	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
変形性関節症	- Any Grade -	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	1	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
関節可動域低下	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
筋骨格硬直	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
筋攣縮	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
ばち状指	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
リウマチ性障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
横紋筋融解症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
顎骨壊死	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
関節硬直	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
関節周囲炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
筋萎縮	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
骨粗鬆症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
四肢不快感	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
脊柱管狭窄症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
足底筋膜炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
多発性関節炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
椎間板圧迫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
尾骨痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
膝蓋大腿関節痛症候群	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
感染症および寄生虫症					
- Overall -	- Any Grade -	234 (35.5%)	54 (38.8%)	85 (31.8%)	95 (37.5%)
	1	67 (10.2%)	11 (7.9%)	24 (9.0%)	32 (12.6%)
	2	113 (17.1%)	30 (21.6%)	42 (15.7%)	41 (16.2%)
	3	42 (6.4%)	11 (7.9%)	15 (5.6%)	16 (6.3%)
	4	7 (1.1%)	2 (1.4%)	1 (0.4%)	4 (1.6%)
	5	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
上気道感染	- Any Grade -	38 (5.8%)	9 (6.5%)	14 (5.2%)	15 (5.9%)
	1	13 (2.0%)	3 (2.2%)	5 (1.9%)	5 (2.0%)
	2	24 (3.6%)	5 (3.6%)	9 (3.4%)	10 (4.0%)
	3	1 (0.2%)	1 (0.7%)	0	0
尿路感染	- Any Grade -	32 (4.9%)	4 (2.9%)	18 (6.7%)	10 (4.0%)
	1	9 (1.4%)	1 (0.7%)	5 (1.9%)	3 (1.2%)
	2	19 (2.9%)	3 (2.2%)	12 (4.5%)	4 (1.6%)
	3	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
肺炎	- Any Grade -	31 (4.7%)	6 (4.3%)	11 (4.1%)	14 (5.5%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	11 (1.7%)	3 (2.2%)	6 (2.2%)	2 (0.8%)
	3	14 (2.1%)	3 (2.2%)	4 (1.5%)	7 (2.8%)
	4	2 (0.3%)	0	0	2 (0.8%)
	5	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
鼻咽頭炎	- Any Grade -	26 (3.9%)	11 (7.9%)	5 (1.9%)	10 (4.0%)
	1	24 (3.6%)	10 (7.2%)	4 (1.5%)	10 (4.0%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
気管支炎	- Any Grade -	20 (3.0%)	6 (4.3%)	7 (2.6%)	7 (2.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	16 (2.4%)	4 (2.9%)	5 (1.9%)	7 (2.8%)
	3	3 (0.5%)	2 (1.4%)	1 (0.4%)	0
肺感染	- Any Grade -	16 (2.4%)	4 (2.9%)	4 (1.5%)	8 (3.2%)
	2	12 (1.8%)	4 (2.9%)	1 (0.4%)	7 (2.8%)
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	5	1 (0.2%)	0	1 (0.4%)	0
副鼻腔炎	- Any Grade -	13 (2.0%)	3 (2.2%)	4 (1.5%)	6 (2.4%)
	2	13 (2.0%)	3 (2.2%)	4 (1.5%)	6 (2.4%)
鼻炎	- Any Grade -	10 (1.5%)	2 (1.4%)	3 (1.1%)	5 (2.0%)
	1	9 (1.4%)	2 (1.4%)	2 (0.7%)	5 (2.0%)
	2	1 (0.2%)	0	1 (0.4%)	0
インフルエンザ	- Any Grade -	9 (1.4%)	3 (2.2%)	3 (1.1%)	3 (1.2%)
	1	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	2	4 (0.6%)	2 (1.4%)	2 (0.7%)	0
	3	1 (0.2%)	1 (0.7%)	0	0
皮膚感染	- Any Grade -	8 (1.2%)	4 (2.9%)	1 (0.4%)	3 (1.2%)
	1	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
カンジダ感染	- Any Grade -	7 (1.1%)	3 (2.2%)	1 (0.4%)	3 (1.2%)
	1	5 (0.8%)	1 (0.7%)	1 (0.4%)	3 (1.2%)
	2	2 (0.3%)	2 (1.4%)	0	0
気道感染	- Any Grade -	7 (1.1%)	3 (2.2%)	3 (1.1%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	4 (0.6%)	2 (1.4%)	2 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
結膜炎	- Any Grade -	7 (1.1%)	2 (1.4%)	4 (1.5%)	1 (0.4%)
	1	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
帯状疱疹	- Any Grade -	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	1	1 (0.2%)	1 (0.7%)	0	0
	2	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
ウイルス感染	- Any Grade -	6 (0.9%)	1 (0.7%)	1 (0.4%)	4 (1.6%)
	1	5 (0.8%)	1 (0.7%)	0	4 (1.6%)
	2	1 (0.2%)	0	1 (0.4%)	0
感染	- Any Grade -	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	3	1 (0.2%)	0	0	1 (0.4%)
ウイルス性上気道感染	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	3	1 (0.2%)	1 (0.7%)	0	0
下気道感染	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
咽頭炎	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
真菌感染	- Any Grade -	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	2 (0.7%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
蜂巣炎	- Any Grade -	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	2	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
膀胱炎	- Any Grade -	4 (0.6%)	1 (0.7%)	0	3 (1.2%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
憩室炎	- Any Grade -	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
口腔ヘルペス	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
耳感染	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
粘膜感染	- Any Grade -	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
	1	1 (0.2%)	1 (0.7%)	0	0
	2	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
せつ	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
ウイルス性胃腸炎	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
胃腸炎	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	1 (0.7%)	0	0
外陰膣真菌感染	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	2	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
菌血症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
歯膿瘍	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
唾液腺炎	- Any Grade -	2 (0.3%)	2 (1.4%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
爪囲炎	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
敗血症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	4	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
敗血症性ショック	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	1 (0.4%)	0
皮下組織膿瘍	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
膣感染	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
ウイルス性結膜炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
カテーテル留置部位感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
クロストリジウム・ディフィシレ感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
クロストリジウム・ディフィシレ大腸炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
リンパ節感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
医療機器関連感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
外耳炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
感染性胸水	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
感染性大腸炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
気管気管支炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
気管支肺炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
口腔真菌感染	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
口唇感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
喉頭炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
骨髄炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
細菌性結膜炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
細菌性肺炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
歯感染	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
消化管感染	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
腎盂腎炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
脊髄炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
前庭神経炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
大葉性肺炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	4	1 (0.2%)	1 (0.7%)	0	0
蓄膿	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
中耳炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
軟部組織膿瘍	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
熱性感染症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
脳炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
肺膿瘍	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
麦粒腫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
腹部感染	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
腹膜炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	4	1 (0.2%)	1 (0.7%)	0	0
慢性副鼻腔炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
毛包炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
蟯虫症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
代謝および栄養障害					
- Overall -	- Any Grade -	228 (34.6%)	49 (35.3%)	81 (30.3%)	98 (38.7%)
	1	117 (17.8%)	30 (21.6%)	40 (15.0%)	47 (18.6%)
	2	72 (10.9%)	14 (10.1%)	23 (8.6%)	35 (13.8%)
	3	35 (5.3%)	5 (3.6%)	16 (6.0%)	14 (5.5%)
	4	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
食欲減退	- Any Grade -	148 (22.5%)	32 (23.0%)	47 (17.6%)	69 (27.3%)
	1	97 (14.7%)	21 (15.1%)	31 (11.6%)	45 (17.8%)
	2	45 (6.8%)	11 (7.9%)	13 (4.9%)	21 (8.3%)
	3	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
低マグネシウム血症	- Any Grade -	24 (3.6%)	4 (2.9%)	9 (3.4%)	11 (4.3%)
	1	21 (3.2%)	4 (2.9%)	7 (2.6%)	10 (4.0%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
脱水	- Any Grade -	23 (3.5%)	4 (2.9%)	9 (3.4%)	10 (4.0%)
	1	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	2	14 (2.1%)	3 (2.2%)	5 (1.9%)	6 (2.4%)
	3	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
低カリウム血症	- Any Grade -	23 (3.5%)	10 (7.2%)	4 (1.5%)	9 (3.6%)
	1	11 (1.7%)	7 (5.0%)	2 (0.7%)	2 (0.8%)
	2	7 (1.1%)	2 (1.4%)	1 (0.4%)	4 (1.6%)
	3	5 (0.8%)	1 (0.7%)	1 (0.4%)	3 (1.2%)
低ナトリウム血症	- Any Grade -	23 (3.5%)	3 (2.2%)	12 (4.5%)	8 (3.2%)
	1	7 (1.1%)	0	3 (1.1%)	4 (1.6%)
	3	16 (2.4%)	3 (2.2%)	9 (3.4%)	4 (1.6%)
低アルブミン血症	- Any Grade -	18 (2.7%)	3 (2.2%)	7 (2.6%)	8 (3.2%)
	1	9 (1.4%)	3 (2.2%)	2 (0.7%)	4 (1.6%)
	2	8 (1.2%)	0	4 (1.5%)	4 (1.6%)
	3	1 (0.2%)	0	1 (0.4%)	0
高カルシウム血症	- Any Grade -	13 (2.0%)	1 (0.7%)	8 (3.0%)	4 (1.6%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	4	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
高血糖	- Any Grade -	13 (2.0%)	0	4 (1.5%)	9 (3.6%)
	1	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	2	6 (0.9%)	0	1 (0.4%)	5 (2.0%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
高カリウム血症	- Any Grade -	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	1	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
低リン酸血症	- Any Grade -	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	1 (0.4%)	0
高ナトリウム血症	- Any Grade -	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
低カルシウム血症	- Any Grade -	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
体液貯留	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
低血糖症	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	4	2 (0.3%)	0	0	2 (0.8%)
高リン酸塩血症	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
成長障害	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
低蛋白血症	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
１型糖尿病	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
ビタミン欠乏症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
亜鉛欠乏	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
悪液質	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
高マグネシウム血症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
高脂血症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
食欲亢進	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
代謝性アシドーシス	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
痛風	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
鉄欠乏	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
皮膚および皮下組織障害					
- Overall -	- Any Grade -	213 (32.3%)	40 (28.8%)	92 (34.5%)	81 (32.0%)
	1	175 (26.6%)	33 (23.7%)	77 (28.8%)	65 (25.7%)
	2	34 (5.2%)	7 (5.0%)	14 (5.2%)	13 (5.1%)
	3	4 (0.6%)	0	1 (0.4%)	3 (1.2%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
そう痒症	- Any Grade -	76 (11.5%)	16 (11.5%)	31 (11.6%)	29 (11.5%)
	1	67 (10.2%)	15 (10.8%)	27 (10.1%)	25 (9.9%)
	2	9 (1.4%)	1 (0.7%)	4 (1.5%)	4 (1.6%)
発疹	- Any Grade -	60 (9.1%)	12 (8.6%)	27 (10.1%)	21 (8.3%)
	1	52 (7.9%)	11 (7.9%)	25 (9.4%)	16 (6.3%)
	2	6 (0.9%)	1 (0.7%)	2 (0.7%)	3 (1.2%)
	3	2 (0.3%)	0	0	2 (0.8%)
皮膚乾燥	- Any Grade -	40 (6.1%)	12 (8.6%)	15 (5.6%)	13 (5.1%)
	1	38 (5.8%)	10 (7.2%)	15 (5.6%)	13 (5.1%)
	2	2 (0.3%)	2 (1.4%)	0	0
多汗症	- Any Grade -	25 (3.8%)	5 (3.6%)	15 (5.6%)	5 (2.0%)
	1	20 (3.0%)	4 (2.9%)	11 (4.1%)	5 (2.0%)
	2	5 (0.8%)	1 (0.7%)	4 (1.5%)	0
寝汗	- Any Grade -	19 (2.9%)	3 (2.2%)	6 (2.2%)	10 (4.0%)
	1	16 (2.4%)	2 (1.4%)	6 (2.2%)	8 (3.2%)
	2	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
脱毛症	- Any Grade -	13 (2.0%)	4 (2.9%)	5 (1.9%)	4 (1.6%)
	1	12 (1.8%)	3 (2.2%)	5 (1.9%)	4 (1.6%)
	2	1 (0.2%)	1 (0.7%)	0	0
斑状丘疹状皮疹	- Any Grade -	9 (1.4%)	3 (2.2%)	4 (1.5%)	2 (0.8%)
	1	6 (0.9%)	2 (1.4%)	3 (1.1%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
紅斑	- Any Grade -	8 (1.2%)	2 (1.4%)	3 (1.1%)	3 (1.2%)
	1	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	2	1 (0.2%)	1 (0.7%)	0	0
丘疹性皮疹	- Any Grade -	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	1	5 (0.8%)	0	2 (0.7%)	3 (1.2%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
蕁麻疹	- Any Grade -	4 (0.6%)	0	4 (1.5%)	0
	1	3 (0.5%)	0	3 (1.1%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
そう痒性皮疹	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
過角化	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
湿疹	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
斑状皮疹	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
皮膚潰瘍	- Any Grade -	3 (0.5%)	0	3 (1.1%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
皮膚剥脱	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
毛髪成長異常	- Any Grade -	3 (0.5%)	0	3 (1.1%)	0
	1	3 (0.5%)	0	3 (1.1%)	0
ざ瘡様皮膚炎	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
乾癬	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
全身性皮疹	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
多形紅斑	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
爪破損	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
皮膚炎	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
皮膚腫瘤	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
扁平苔癬	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
褥瘡性潰瘍	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
ざ瘡	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
アレルギー性そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
アレルギー性皮膚炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
乾皮症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
顔面腫脹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
紅斑性皮疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
脂漏性皮膚炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
尋常性白斑	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
水疱	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
前癌性皮膚病変	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
全身性そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
苔癬様角化症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
中毒性皮疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
爪の障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
爪ジストロフィー	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
爪甲脱落症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
爪変色	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
日光角化症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
斑状出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
皮膚亀裂	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
皮膚筋炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
皮膚刺激	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
皮膚色素過剰	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚色素減少	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚線維症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚反応	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚病変	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
皮膚疼痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
無汗症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
毛質異常	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
毛髪変色	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
網状皮斑	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
冷汗	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
痂皮	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
瘢痕痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
神経系障害					
- Overall -	- Any Grade -	174 (26.4%)	36 (25.9%)	70 (26.2%)	68 (26.9%)
	1	114 (17.3%)	22 (15.8%)	46 (17.2%)	46 (18.2%)
	2	40 (6.1%)	8 (5.8%)	17 (6.4%)	15 (5.9%)
	3	16 (2.4%)	5 (3.6%)	5 (1.9%)	6 (2.4%)
	4	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	5	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
頭痛	- Any Grade -	59 (9.0%)	12 (8.6%)	19 (7.1%)	28 (11.1%)
	1	48 (7.3%)	9 (6.5%)	17 (6.4%)	22 (8.7%)
	2	9 (1.4%)	3 (2.2%)	1 (0.4%)	5 (2.0%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
浮動性めまい	- Any Grade -	42 (6.4%)	6 (4.3%)	16 (6.0%)	20 (7.9%)
	1	34 (5.2%)	6 (4.3%)	12 (4.5%)	16 (6.3%)
	2	7 (1.1%)	0	3 (1.1%)	4 (1.6%)
	3	1 (0.2%)	0	1 (0.4%)	0
味覚異常	- Any Grade -	15 (2.3%)	2 (1.4%)	7 (2.6%)	6 (2.4%)
	1	13 (2.0%)	2 (1.4%)	5 (1.9%)	6 (2.4%)
	2	2 (0.3%)	0	2 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
末梢性ニューロパチー	- Any Grade -	14 (2.1%)	3 (2.2%)	4 (1.5%)	7 (2.8%)
	1	13 (2.0%)	2 (1.4%)	4 (1.5%)	7 (2.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
感覚鈍麻	- Any Grade -	11 (1.7%)	2 (1.4%)	5 (1.9%)	4 (1.6%)
	1	8 (1.2%)	1 (0.7%)	3 (1.1%)	4 (1.6%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
錯感覚	- Any Grade -	11 (1.7%)	1 (0.7%)	4 (1.5%)	6 (2.4%)
	1	11 (1.7%)	1 (0.7%)	4 (1.5%)	6 (2.4%)
末梢性感覚ニューロパチー	- Any Grade -	9 (1.4%)	3 (2.2%)	4 (1.5%)	2 (0.8%)
	1	9 (1.4%)	3 (2.2%)	4 (1.5%)	2 (0.8%)
振戦	- Any Grade -	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	1	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
脳血管発作	- Any Grade -	5 (0.8%)	0	1 (0.4%)	4 (1.6%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	2 (0.3%)	0	0	2 (0.8%)
	3	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	1 (0.4%)	0
構語障害	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
神経痛	- Any Grade -	4 (0.6%)	2 (1.4%)	2 (0.7%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
多発ニューロパチー	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
一過性脳虚血発作	- Any Grade -	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	0	0	1 (0.4%)
運動失調	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
下肢静止不能症候群	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
傾眠	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	0	1 (0.4%)
健忘	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
坐骨神経痛	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	3	1 (0.2%)	1 (0.7%)	0	0
失神	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
失神寸前の状態	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
声帯麻痺	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
嗜眠	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	1 (0.7%)	0	0
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
アカシジア	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
ヘルペス後神経痛	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
協調運動異常	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
手根管症候群	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
知覚過敏	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
注意力障害	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	1 (0.4%)	0
末梢性運動ニューロパチー	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
嗅覚錯誤	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0

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事象名 : MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
くも膜下出血	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
ミオクローヌス	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
意識消失	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
異常感覚	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
運動機能障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
会話障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
記憶障害	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
虚血性脳卒中	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
筋痙直	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
血栓性脳卒中	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
三叉神経障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
三叉神経痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
視神経炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
失声症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
灼熱感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
神経毒性	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
脊髄圧迫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
脊髄症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
体位性めまい	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
対麻痺	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
第７脳神経麻痺	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
脳梗塞	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	5	1 (0.2%)	1 (0.7%)	0	0
脳出血	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
副鼻腔炎に伴う頭痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
平衡障害	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
片頭痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
味覚消失	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
臨床検査					
- Overall -	- Any Grade -	136 (20.6%)	20 (14.4%)	61 (22.8%)	55 (21.7%)
	1	69 (10.5%)	12 (8.6%)	32 (12.0%)	25 (9.9%)
	2	45 (6.8%)	6 (4.3%)	20 (7.5%)	19 (7.5%)
	3	22 (3.3%)	2 (1.4%)	9 (3.4%)	11 (4.3%)
体重減少	- Any Grade -	46 (7.0%)	6 (4.3%)	17 (6.4%)	23 (9.1%)
	1	32 (4.9%)	4 (2.9%)	13 (4.9%)	15 (5.9%)
	2	12 (1.8%)	2 (1.4%)	3 (1.1%)	7 (2.8%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	24 (3.6%)	2 (1.4%)	10 (3.7%)	12 (4.7%)
	1	14 (2.1%)	2 (1.4%)	4 (1.5%)	8 (3.2%)
	2	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	3	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	21 (3.2%)	1 (0.7%)	9 (3.4%)	11 (4.3%)
	1	15 (2.3%)	1 (0.7%)	7 (2.6%)	7 (2.8%)
	2	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
血中クレアチニン増加	- Any Grade -	14 (2.1%)	3 (2.2%)	9 (3.4%)	2 (0.8%)
	1	13 (2.0%)	2 (1.4%)	9 (3.4%)	2 (0.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	10 (1.5%)	1 (0.7%)	4 (1.5%)	5 (2.0%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	3	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
血中アルカリホスファターゼ増加	- Any Grade -	8 (1.2%)	2 (1.4%)	2 (0.7%)	4 (1.6%)
	1	5 (0.8%)	2 (1.4%)	1 (0.4%)	2 (0.8%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
体重増加	- Any Grade -	8 (1.2%)	1 (0.7%)	5 (1.9%)	2 (0.8%)
	1	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
リンパ球数減少	- Any Grade -	6 (0.9%)	3 (2.2%)	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
血小板数減少	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
血中ビリルビン増加	- Any Grade -	5 (0.8%)	2 (1.4%)	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	0	0	1 (0.4%)
血中リン減少	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
Ｃ－反応性蛋白増加	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
肝機能検査異常	- Any Grade -	3 (0.5%)	0	3 (1.1%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
白血球数減少	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
トランスアミナーゼ上昇	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
リパーゼ増加	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
肝酵素上昇	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
胸部コンピュータ断層撮影異常	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
血小板数増加	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
血中アルブミン減少	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
血中カルシウム減少	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
血中マグネシウム減少	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
血中甲状腺刺激ホルモン増加	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
心拍数不整	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
ＰＯ２低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
アミラーゼ増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
カテーテル培養陽性	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
ヘモグロビン減少	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
ヘモグロビン増加	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
胃内ｐＨ低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
駆出率減少	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
血中カリウム	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血中カリウム減少	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
血中クレアチンホスホキナーゼ増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
血中クロール減少	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
血中クロール増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
血中ナトリウム減少	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
血中ブドウ糖増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
血中乳酸脱水素酵素増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血中尿酸増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血中尿素増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
好中球数増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
糸球体濾過率減少	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
心拍出量低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
体温上昇	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
二酸化炭素増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
尿中蛋白陽性	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
白血球数増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
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Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
精神障害					
- Overall -	- Any Grade -	93 (14.1%)	19 (13.7%)	44 (16.5%)	30 (11.9%)
	1	62 (9.4%)	13 (9.4%)	33 (12.4%)	16 (6.3%)
	2	23 (3.5%)	5 (3.6%)	7 (2.6%)	11 (4.3%)
	3	8 (1.2%)	1 (0.7%)	4 (1.5%)	3 (1.2%)
不眠症	- Any Grade -	38 (5.8%)	9 (6.5%)	13 (4.9%)	16 (6.3%)
	1	25 (3.8%)	7 (5.0%)	8 (3.0%)	10 (4.0%)
	2	13 (2.0%)	2 (1.4%)	5 (1.9%)	6 (2.4%)
不安	- Any Grade -	32 (4.9%)	4 (2.9%)	16 (6.0%)	12 (4.7%)
	1	20 (3.0%)	2 (1.4%)	13 (4.9%)	5 (2.0%)
	2	10 (1.5%)	2 (1.4%)	3 (1.1%)	5 (2.0%)
	3	2 (0.3%)	0	0	2 (0.8%)
うつ病	- Any Grade -	20 (3.0%)	5 (3.6%)	10 (3.7%)	5 (2.0%)
	1	15 (2.3%)	4 (2.9%)	8 (3.0%)	3 (1.2%)
	2	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
錯乱状態	- Any Grade -	10 (1.5%)	1 (0.7%)	5 (1.9%)	4 (1.6%)
	1	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
激越	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
ストレス	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
感情不安定	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
気分変化	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
失見当識	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	3	2 (0.3%)	0	2 (0.7%)	0
抑うつ気分	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
易刺激性	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
睡眠時驚愕	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
睡眠障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
精神状態変化	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
落ち着きのなさ	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血液およびリンパ系障害					
- Overall -	- Any Grade -	78 (11.8%)	17 (12.2%)	32 (12.0%)	29 (11.5%)
	1	23 (3.5%)	10 (7.2%)	6 (2.2%)	7 (2.8%)
	2	32 (4.9%)	4 (2.9%)	15 (5.6%)	13 (5.1%)
	3	20 (3.0%)	2 (1.4%)	10 (3.7%)	8 (3.2%)
	4	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
貧血	- Any Grade -	50 (7.6%)	11 (7.9%)	22 (8.2%)	17 (6.7%)
	1	11 (1.7%)	6 (4.3%)	2 (0.7%)	3 (1.2%)
	2	24 (3.6%)	4 (2.9%)	12 (4.5%)	8 (3.2%)
	3	15 (2.3%)	1 (0.7%)	8 (3.0%)	6 (2.4%)
血小板減少症	- Any Grade -	15 (2.3%)	2 (1.4%)	7 (2.6%)	6 (2.4%)
	1	8 (1.2%)	1 (0.7%)	4 (1.5%)	3 (1.2%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	4	1 (0.2%)	1 (0.7%)	0	0
リンパ球減少症	- Any Grade -	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
リンパ節症	- Any Grade -	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	1	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
好中球減少症	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
白血球増加症	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
リンパ節痛	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
白血球減少症	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
リンパ節炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
血小板減少性紫斑病	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
内出血発生の増加傾向	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
脾臓梗塞	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
血管障害					
- Overall -	- Any Grade -	69 (10.5%)	13 (9.4%)	38 (14.2%)	18 (7.1%)
	1	24 (3.6%)	3 (2.2%)	15 (5.6%)	6 (2.4%)
	2	22 (3.3%)	5 (3.6%)	10 (3.7%)	7 (2.8%)
	3	22 (3.3%)	5 (3.6%)	13 (4.9%)	4 (1.6%)
	5	1 (0.2%)	0	0	1 (0.4%)
高血圧	- Any Grade -	18 (2.7%)	3 (2.2%)	9 (3.4%)	6 (2.4%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	2	7 (1.1%)	2 (1.4%)	3 (1.1%)	2 (0.8%)
	3	7 (1.1%)	1 (0.7%)	4 (1.5%)	2 (0.8%)
ほてり	- Any Grade -	12 (1.8%)	3 (2.2%)	7 (2.6%)	2 (0.8%)
	1	11 (1.7%)	3 (2.2%)	6 (2.2%)	2 (0.8%)
	2	1 (0.2%)	0	1 (0.4%)	0
低血圧	- Any Grade -	12 (1.8%)	2 (1.4%)	7 (2.6%)	3 (1.2%)
	1	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
深部静脈血栓症	- Any Grade -	5 (0.8%)	1 (0.7%)	4 (1.5%)	0
	2	3 (0.5%)	0	3 (1.1%)	0
	3	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
血腫	- Any Grade -	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
塞栓症	- Any Grade -	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
潮紅	- Any Grade -	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
	1	3 (0.5%)	0	3 (1.1%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
起立性低血圧	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
上大静脈症候群	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	3	2 (0.3%)	0	2 (0.7%)	0
表在性血栓性静脈炎	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
末梢動脈閉塞性疾患	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	1 (0.7%)	0	0
リンパ浮腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
レイノー現象	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
頚静脈血栓症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
上大静脈閉塞	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
静脈炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
静脈瘤	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
大動脈狭窄	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
内出血	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	0	1 (0.4%)
末梢冷感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
傷害、中毒および処置合併症					
- Overall -	- Any Grade -	50 (7.6%)	12 (8.6%)	20 (7.5%)	18 (7.1%)
	1	30 (4.6%)	7 (5.0%)	10 (3.7%)	13 (5.1%)
	2	12 (1.8%)	3 (2.2%)	6 (2.2%)	3 (1.2%)
	3	7 (1.1%)	2 (1.4%)	3 (1.1%)	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
注入に伴う反応	- Any Grade -	12 (1.8%)	2 (1.4%)	8 (3.0%)	2 (0.8%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	4 (0.6%)	2 (1.4%)	2 (0.7%)	0
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
転倒	- Any Grade -	10 (1.5%)	2 (1.4%)	2 (0.7%)	6 (2.4%)
	1	6 (0.9%)	2 (1.4%)	1 (0.4%)	3 (1.2%)
	2	2 (0.3%)	0	0	2 (0.8%)
	3	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	1 (0.4%)	0
挫傷	- Any Grade -	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
熱傷	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
皮膚擦過傷	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
アレルギー性輸血反応	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
ストーマ部紅斑	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
外傷性血胸	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
胸部損傷	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
骨挫傷	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
骨折	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
擦過傷	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
歯肉損傷	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
事故	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
処置による疼痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
処置後不快感	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
焼痂	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
腎血腫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
脊椎骨折	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
切開部位痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
節足動物咬傷	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
大腿骨骨折	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
肉離れ	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
脳振盪	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
皮膚創傷	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
放射線性食道炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
放射線性肺臓炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
放射線皮膚損傷	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
肋骨骨折	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
瘢痕ヘルニア	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
靱帯捻挫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
心臓障害					
- Overall -	- Any Grade -	50 (7.6%)	7 (5.0%)	23 (8.6%)	20 (7.9%)
	1	19 (2.9%)	3 (2.2%)	11 (4.1%)	5 (2.0%)
	2	15 (2.3%)	1 (0.7%)	3 (1.1%)	11 (4.3%)
	3	9 (1.4%)	1 (0.7%)	6 (2.2%)	2 (0.8%)
	4	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	5	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
頻脈	- Any Grade -	11 (1.7%)	1 (0.7%)	6 (2.2%)	4 (1.6%)
	1	7 (1.1%)	0	5 (1.9%)	2 (0.8%)
	2	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
心嚢液貯留	- Any Grade -	10 (1.5%)	0	5 (1.9%)	5 (2.0%)
	1	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	2	6 (0.9%)	0	2 (0.7%)	4 (1.6%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
心房細動	- Any Grade -	8 (1.2%)	0	2 (0.7%)	6 (2.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	4 (0.6%)	0	0	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
洞性頻脈	- Any Grade -	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
心タンポナーデ	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
	4	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
動悸	- Any Grade -	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
	1	3 (0.5%)	2 (1.4%)	0	1 (0.4%)
うっ血性心不全	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
急性冠動脈症候群	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
	5	1 (0.2%)	0	0	1 (0.4%)
急性心筋梗塞	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	1 (0.7%)	0	0
狭心症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
心停止	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
	5	1 (0.2%)	0	1 (0.4%)	0
心不全	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
心房粗動	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
冠動脈疾患	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
完全房室ブロック	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
心筋梗塞	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
心肺不全	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	5	1 (0.2%)	0	1 (0.4%)	0
心房血栓症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
不整脈	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼障害					
- Overall -	- Any Grade -	48 (7.3%)	11 (7.9%)	18 (6.7%)	19 (7.5%)
	1	37 (5.6%)	7 (5.0%)	15 (5.6%)	15 (5.9%)
	2	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)
	3	2 (0.3%)	2 (1.4%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
眼乾燥	- Any Grade -	11 (1.7%)	1 (0.7%)	5 (1.9%)	5 (2.0%)
	1	9 (1.4%)	1 (0.7%)	4 (1.5%)	4 (1.6%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
霧視	- Any Grade -	9 (1.4%)	3 (2.2%)	4 (1.5%)	2 (0.8%)
	1	8 (1.2%)	2 (1.4%)	4 (1.5%)	2 (0.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
白内障	- Any Grade -	5 (0.8%)	3 (2.2%)	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	3	2 (0.3%)	2 (1.4%)	0	0
複視	- Any Grade -	5 (0.8%)	0	1 (0.4%)	4 (1.6%)
	1	5 (0.8%)	0	1 (0.4%)	4 (1.6%)
流涙増加	- Any Grade -	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
視力障害	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	1 (0.7%)	0	0
眼部腫脹	- Any Grade -	2 (0.3%)	2 (1.4%)	0	0
	1	2 (0.3%)	2 (1.4%)	0	0
眼窩周囲浮腫	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
結膜出血	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
硝子体浮遊物	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
アレルギー性結膜炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
眼そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼刺激	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼充血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼出血	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
眼痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼そう痒症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
眼瞼下垂	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼瞼紅斑	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼発疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼瞼浮腫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
結膜充血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
後嚢部混濁	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
視神経乳頭ドルーゼン	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
視力低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
上強膜炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
乱視	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
老視	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
羞明	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
腎および尿路障害					
- Overall -	- Any Grade -	41 (6.2%)	4 (2.9%)	21 (7.9%)	16 (6.3%)
	1	28 (4.2%)	1 (0.7%)	15 (5.6%)	12 (4.7%)
	2	9 (1.4%)	3 (2.2%)	4 (1.5%)	2 (0.8%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
血尿	- Any Grade -	8 (1.2%)	3 (2.2%)	3 (1.1%)	2 (0.8%)
	1	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	2	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
排尿困難	- Any Grade -	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	1	5 (0.8%)	0	2 (0.7%)	3 (1.2%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
急性腎不全	- Any Grade -	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
頻尿	- Any Grade -	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	1	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
腎結石症	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
蛋白尿	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
尿閉	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
夜間頻尿	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
腎臓痛	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
腎不全	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
尿失禁	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
ミクロアルブミン尿	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
腎梗塞	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
腎嚢胞出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
尿意切迫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
尿臭異常	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
尿路閉塞	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
慢性腎臓病	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
膀胱痙縮	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
内分泌障害					
- Overall -	- Any Grade -	27 (4.1%)	6 (4.3%)	11 (4.1%)	10 (4.0%)
	1	12 (1.8%)	2 (1.4%)	5 (1.9%)	5 (2.0%)
	2	13 (2.0%)	4 (2.9%)	5 (1.9%)	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
甲状腺機能低下症	- Any Grade -	24 (3.6%)	5 (3.6%)	9 (3.4%)	10 (4.0%)
	1	10 (1.5%)	1 (0.7%)	4 (1.5%)	5 (2.0%)
	2	12 (1.8%)	4 (2.9%)	4 (1.5%)	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
甲状腺機能亢進症	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
副腎機能不全	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	1 (0.4%)	0
粘液水腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
生殖系および乳房障害					
- Overall -	- Any Grade -	23 (3.5%)	4 (2.9%)	7 (2.6%)	12 (4.7%)
	1	14 (2.1%)	3 (2.2%)	3 (1.1%)	8 (3.2%)
	2	6 (0.9%)	1 (0.7%)	2 (0.7%)	3 (1.2%)
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
骨盤痛	- Any Grade -	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	1	5 (0.8%)	1 (0.7%)	1 (0.4%)	3 (1.2%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
乳房痛	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
勃起不全	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
良性前立腺肥大症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
陰茎痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
会陰痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
外陰腟そう痒症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
外陰腟乾燥	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
外陰腟灼熱感	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
亀頭包皮炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
子宮出血	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
子宮痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
女性化乳房	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
前立腺閉塞	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
乳頭障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
乳房腫脹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
不規則月経	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
腟部異臭	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
耳および迷路障害					
- Overall -	- Any Grade -	22 (3.3%)	4 (2.9%)	9 (3.4%)	9 (3.6%)
	1	18 (2.7%)	4 (2.9%)	8 (3.0%)	6 (2.4%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	3	1 (0.2%)	0	0	1 (0.4%)
回転性めまい	- Any Grade -	10 (1.5%)	2 (1.4%)	2 (0.7%)	6 (2.4%)
	1	7 (1.1%)	2 (1.4%)	1 (0.4%)	4 (1.6%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
耳痛	- Any Grade -	6 (0.9%)	0	6 (2.2%)	0
	1	6 (0.9%)	0	6 (2.2%)	0
耳鳴	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	3 (0.5%)	0	0	3 (1.2%)
外耳の炎症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
耳そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
耳不快感	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
聴覚障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
聴力低下	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
頭位性回転性めまい	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
難聴	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
両耳難聴	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
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）					
- Overall -	- Any Grade -	18 (2.7%)	4 (2.9%)	8 (3.0%)	6 (2.4%)
	1	7 (1.1%)	3 (2.2%)	2 (0.7%)	2 (0.8%)
	2	7 (1.1%)	1 (0.7%)	4 (1.5%)	2 (0.8%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
腫瘍疼痛	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
メラノサイト性母斑	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
ボーエン病	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
悪性胸水	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
悪性心嚢液貯留	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
癌性リンパ管症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
基底細胞癌	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
脂漏性角化症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
新生物	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
真珠腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
多形性神経膠芽細胞腫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
皮膚乳頭腫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
皮膚有棘細胞癌	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
表皮内悪性黒色腫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
膀胱癌	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
免疫系障害					
- Overall -	- Any Grade -	16 (2.4%)	3 (2.2%)	8 (3.0%)	5 (2.0%)
	1	11 (1.7%)	2 (1.4%)	5 (1.9%)	4 (1.6%)
	2	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
過敏症	- Any Grade -	13 (2.0%)	3 (2.2%)	6 (2.2%)	4 (1.6%)
	1	8 (1.2%)	2 (1.4%)	3 (1.1%)	3 (1.2%)
	2	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
季節性アレルギー	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
サイトカイン放出症候群	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肝胆道系障害					
- Overall -	- Any Grade -	9 (1.4%)	1 (0.7%)	4 (1.5%)	4 (1.6%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	4	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	5	1 (0.2%)	0	1 (0.4%)	0
胆嚢炎	- Any Grade -	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	1 (0.7%)	0	0
肝機能異常	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
肝腫大	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
肝出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
肝不全	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	5	1 (0.2%)	0	1 (0.4%)	0
胆石症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
薬物性肝障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
外科および内科処置					
- Overall -	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
アルコールの解毒	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
股関節形成	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
抜歯	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚新生物切除	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
No Coding available					
- Overall -	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
No Coding available	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
先天性、家族性および遺伝性障害					
- Overall -	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
気管食道瘻	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas / Output: /opt/BIOSTAT/prod/cdt7692j/j28754a/reports/aet04_GO28754_SE.out
09NOV2016 10:22

［5.3.5.3-1 aet04_GO28754_SE を再掲］

表 2.7.6.2.1.5-2 すべての副作用（BIRCH 試験）

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
- Any adverse events -	- Any Grade -	422 (64.0%)	79 (56.8%)	169 (63.3%)	174 (68.8%)
	1	188 (28.5%)	33 (23.7%)	80 (30.0%)	75 (29.6%)
	2	159 (24.1%)	33 (23.7%)	56 (21.0%)	70 (27.7%)
	3	66 (10.0%)	11 (7.9%)	29 (10.9%)	26 (10.3%)
	4	8 (1.2%)	2 (1.4%)	4 (1.5%)	2 (0.8%)
	5	1 (0.2%)	0	0	1 (0.4%)
一般・全身障害および投与部位の状態					
- Overall -	- Any Grade -	236 (35.8%)	45 (32.4%)	93 (34.8%)	98 (38.7%)
	1	144 (21.9%)	26 (18.7%)	58 (21.7%)	60 (23.7%)
	2	80 (12.1%)	17 (12.2%)	27 (10.1%)	36 (14.2%)
	3	12 (1.8%)	2 (1.4%)	8 (3.0%)	2 (0.8%)
疲労	- Any Grade -	117 (17.8%)	22 (15.8%)	49 (18.4%)	46 (18.2%)
	1	64 (9.7%)	11 (7.9%)	25 (9.4%)	28 (11.1%)
	2	46 (7.0%)	10 (7.2%)	19 (7.1%)	17 (6.7%)
	3	7 (1.1%)	1 (0.7%)	5 (1.9%)	1 (0.4%)
発熱	- Any Grade -	52 (7.9%)	9 (6.5%)	19 (7.1%)	24 (9.5%)
	1	39 (5.9%)	6 (4.3%)	15 (5.6%)	18 (7.1%)
	2	12 (1.8%)	3 (2.2%)	3 (1.1%)	6 (2.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
無力症	- Any Grade -	44 (6.7%)	8 (5.8%)	13 (4.9%)	23 (9.1%)
	1	26 (3.9%)	5 (3.6%)	7 (2.6%)	14 (5.5%)
	2	15 (2.3%)	2 (1.4%)	5 (1.9%)	8 (3.2%)
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
インフルエンザ様疾患	- Any Grade -	25 (3.8%)	5 (3.6%)	13 (4.9%)	7 (2.8%)
	1	17 (2.6%)	3 (2.2%)	9 (3.4%)	5 (2.0%)
	2	8 (1.2%)	2 (1.4%)	4 (1.5%)	2 (0.8%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
悪寒	- Any Grade -	17 (2.6%)	3 (2.2%)	8 (3.0%)	6 (2.4%)
	1	17 (2.6%)	3 (2.2%)	8 (3.0%)	6 (2.4%)
倦怠感	- Any Grade -	16 (2.4%)	5 (3.6%)	5 (1.9%)	6 (2.4%)
	1	12 (1.8%)	4 (2.9%)	4 (1.5%)	4 (1.6%)
	2	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
	3	1 (0.2%)	0	1 (0.4%)	0
末梢性浮腫	- Any Grade -	15 (2.3%)	2 (1.4%)	7 (2.6%)	6 (2.4%)
	1	13 (2.0%)	2 (1.4%)	5 (1.9%)	6 (2.4%)
	2	2 (0.3%)	0	2 (0.7%)	0
粘膜の炎症	- Any Grade -	14 (2.1%)	3 (2.2%)	5 (1.9%)	6 (2.4%)
	1	12 (1.8%)	3 (2.2%)	4 (1.5%)	5 (2.0%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
乾燥症	- Any Grade -	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
疼痛	- Any Grade -	4 (0.6%)	3 (2.2%)	0	1 (0.4%)
	1	3 (0.5%)	3 (2.2%)	0	0
	2	1 (0.2%)	0	0	1 (0.4%)
胸部不快感	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
胸痛	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
高熱	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
圧痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
医薬品副作用	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
温度変化不耐症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
泣き	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
限局性浮腫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
注射部位血管炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
注入部位腫脹	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
熱感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
浮腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
末梢腫脹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
胃腸障害					
- Overall -	- Any Grade -	163 (24.7%)	31 (22.3%)	67 (25.1%)	65 (25.7%)
	1	118 (17.9%)	23 (16.5%)	47 (17.6%)	48 (19.0%)
	2	35 (5.3%)	6 (4.3%)	16 (6.0%)	13 (5.1%)
	3	10 (1.5%)	2 (1.4%)	4 (1.5%)	4 (1.6%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
悪心	- Any Grade -	68 (10.3%)	12 (8.6%)	27 (10.1%)	29 (11.5%)
	1	56 (8.5%)	10 (7.2%)	23 (8.6%)	23 (9.1%)
	2	8 (1.2%)	2 (1.4%)	2 (0.7%)	4 (1.6%)
	3	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
下痢	- Any Grade -	64 (9.7%)	10 (7.2%)	29 (10.9%)	25 (9.9%)
	1	52 (7.9%)	8 (5.8%)	24 (9.0%)	20 (7.9%)
	2	10 (1.5%)	1 (0.7%)	5 (1.9%)	4 (1.6%)
	3	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
嘔吐	- Any Grade -	26 (3.9%)	3 (2.2%)	9 (3.4%)	14 (5.5%)
	1	23 (3.5%)	3 (2.2%)	7 (2.6%)	13 (5.1%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
便秘	- Any Grade -	25 (3.8%)	6 (4.3%)	7 (2.6%)	12 (4.7%)
	1	20 (3.0%)	4 (2.9%)	5 (1.9%)	11 (4.3%)
	2	5 (0.8%)	2 (1.4%)	2 (0.7%)	1 (0.4%)
口内乾燥	- Any Grade -	22 (3.3%)	5 (3.6%)	9 (3.4%)	8 (3.2%)
	1	17 (2.6%)	5 (3.6%)	6 (2.2%)	6 (2.4%)
	2	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
口内炎	- Any Grade -	13 (2.0%)	4 (2.9%)	6 (2.2%)	3 (1.2%)
	1	10 (1.5%)	3 (2.2%)	5 (1.9%)	2 (0.8%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
腹痛	- Any Grade -	11 (1.7%)	1 (0.7%)	5 (1.9%)	5 (2.0%)
	1	8 (1.2%)	1 (0.7%)	3 (1.1%)	4 (1.6%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
大腸炎	- Any Grade -	6 (0.9%)	3 (2.2%)	2 (0.7%)	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
	3	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
消化不良	- Any Grade -	5 (0.8%)	2 (1.4%)	2 (0.7%)	1 (0.4%)
	1	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
胃炎	- Any Grade -	3 (0.5%)	0	3 (1.1%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
上腹部痛	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
放屁	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
肛門そう痒症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
おくび	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
アフタ性口内炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
胃食道逆流性疾患	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
血便排泄	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
口腔知覚不全	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
口腔内潰瘍形成	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
歯肉痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
食道炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
直腸潰瘍	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
膵炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
皮膚および皮下組織障害					
- Overall -	- Any Grade -	150 (22.8%)	26 (18.7%)	63 (23.6%)	61 (24.1%)
	1	122 (18.5%)	23 (16.5%)	52 (19.5%)	47 (18.6%)
	2	24 (3.6%)	3 (2.2%)	10 (3.7%)	11 (4.3%)
	3	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
そう痒症	- Any Grade -	60 (9.1%)	10 (7.2%)	25 (9.4%)	25 (9.9%)
	1	54 (8.2%)	10 (7.2%)	22 (8.2%)	22 (8.7%)
	2	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
発疹	- Any Grade -	43 (6.5%)	6 (4.3%)	21 (7.9%)	16 (6.3%)
	1	36 (5.5%)	6 (4.3%)	19 (7.1%)	11 (4.3%)
	2	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	3	2 (0.3%)	0	0	2 (0.8%)
皮膚乾燥	- Any Grade -	29 (4.4%)	8 (5.8%)	10 (3.7%)	11 (4.3%)
	1	28 (4.2%)	7 (5.0%)	10 (3.7%)	11 (4.3%)
	2	1 (0.2%)	1 (0.7%)	0	0
多汗症	- Any Grade -	12 (1.8%)	4 (2.9%)	7 (2.6%)	1 (0.4%)
	1	10 (1.5%)	4 (2.9%)	5 (1.9%)	1 (0.4%)
	2	2 (0.3%)	0	2 (0.7%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
寝汗	- Any Grade -	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	1	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
斑状丘疹状皮疹	- Any Grade -	7 (1.1%)	2 (1.4%)	3 (1.1%)	2 (0.8%)
	1	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
脱毛症	- Any Grade -	6 (0.9%)	2 (1.4%)	2 (0.7%)	2 (0.8%)
	1	5 (0.8%)	1 (0.7%)	2 (0.7%)	2 (0.8%)
	2	1 (0.2%)	1 (0.7%)	0	0
丘疹性皮疹	- Any Grade -	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
	1	5 (0.8%)	0	2 (0.7%)	3 (1.2%)
皮膚剥脱	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
蕁麻疹	- Any Grade -	3 (0.5%)	0	3 (1.1%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
ざ瘡様皮膚炎	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
そう痒性皮疹	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
乾癬	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
湿疹	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
全身性皮疹	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
多形紅斑	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
爪破損	- Any Grade -	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
斑状皮疹	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	0	1 (0.4%)
毛髪成長異常	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
アレルギー性皮膚炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
過角化	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
乾皮症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
顔面腫脹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
紅斑性皮疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
尋常性白斑	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
水疱	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
全身性そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
苔癬様角化症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
中毒性皮疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
爪ジストロフィー	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
爪甲脱落症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
日光角化症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
皮膚亀裂	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
皮膚筋炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
皮膚色素減少	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
皮膚潰瘍	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
毛髪変色	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
冷汗	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
扁平苔癬	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
瘢痕痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
筋骨格系および結合組織障害					
- Overall -	- Any Grade -	84 (12.7%)	13 (9.4%)	30 (11.2%)	41 (16.2%)
	1	48 (7.3%)	9 (6.5%)	17 (6.4%)	22 (8.7%)
	2	33 (5.0%)	4 (2.9%)	10 (3.7%)	19 (7.5%)
	3	3 (0.5%)	0	3 (1.1%)	0
関節痛	- Any Grade -	35 (5.3%)	7 (5.0%)	13 (4.9%)	15 (5.9%)
	1	21 (3.2%)	4 (2.9%)	9 (3.4%)	8 (3.2%)
	2	12 (1.8%)	3 (2.2%)	2 (0.7%)	7 (2.8%)
	3	2 (0.3%)	0	2 (0.7%)	0
筋肉痛	- Any Grade -	18 (2.7%)	2 (1.4%)	7 (2.6%)	9 (3.6%)
	1	8 (1.2%)	2 (1.4%)	2 (0.7%)	4 (1.6%)
	2	9 (1.4%)	0	4 (1.5%)	5 (2.0%)
	3	1 (0.2%)	0	1 (0.4%)	0
背部痛	- Any Grade -	12 (1.8%)	1 (0.7%)	6 (2.2%)	5 (2.0%)
	1	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	2	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
筋骨格痛	- Any Grade -	9 (1.4%)	0	3 (1.1%)	6 (2.4%)
	1	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
筋痙縮	- Any Grade -	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	1	6 (0.9%)	1 (0.7%)	2 (0.7%)	3 (1.2%)
	2	1 (0.2%)	0	0	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
四肢痛	- Any Grade -	6 (0.9%)	1 (0.7%)	3 (1.1%)	2 (0.8%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
骨痛	- Any Grade -	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	1	4 (0.6%)	0	2 (0.7%)	2 (0.8%)
	3	1 (0.2%)	0	1 (0.4%)	0
関節炎	- Any Grade -	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
筋力低下	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
横紋筋融解症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
関節可動域低下	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
関節硬直	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
関節腫脹	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
関節周囲炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
筋骨格系胸痛	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
筋骨格不快感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
頚部痛	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
側腹部痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
代謝および栄養障害					
- Overall -	- Any Grade -	72 (10.9%)	16 (11.5%)	26 (9.7%)	30 (11.9%)
	1	43 (6.5%)	11 (7.9%)	12 (4.5%)	20 (7.9%)
	2	20 (3.0%)	4 (2.9%)	8 (3.0%)	8 (3.2%)
	3	8 (1.2%)	1 (0.7%)	5 (1.9%)	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
食欲減退	- Any Grade -	53 (8.0%)	13 (9.4%)	16 (6.0%)	24 (9.5%)
	1	36 (5.5%)	9 (6.5%)	9 (3.4%)	18 (7.1%)
	2	16 (2.4%)	4 (2.9%)	6 (2.2%)	6 (2.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
低マグネシウム血症	- Any Grade -	9 (1.4%)	2 (1.4%)	2 (0.7%)	5 (2.0%)
	1	8 (1.2%)	2 (1.4%)	1 (0.4%)	5 (2.0%)
	2	1 (0.2%)	0	1 (0.4%)	0
脱水	- Any Grade -	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
低ナトリウム血症	- Any Grade -	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	3	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
高カリウム血症	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
高カルシウム血症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	1 (0.4%)	0
高血糖	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
１型糖尿病	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
高ナトリウム血症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
低カリウム血症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
低血糖症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害					
- Overall -	- Any Grade -	70 (10.6%)	15 (10.8%)	26 (9.7%)	29 (11.5%)
	1	38 (5.8%)	6 (4.3%)	15 (5.6%)	17 (6.7%)
	2	17 (2.6%)	3 (2.2%)	6 (2.2%)	8 (3.2%)
	3	14 (2.1%)	6 (4.3%)	4 (1.5%)	4 (1.6%)
	4	1 (0.2%)	0	1 (0.4%)	0
呼吸困難	- Any Grade -	24 (3.6%)	5 (3.6%)	9 (3.4%)	10 (4.0%)
	1	11 (1.7%)	1 (0.7%)	2 (0.7%)	8 (3.2%)
	2	9 (1.4%)	3 (2.2%)	5 (1.9%)	1 (0.4%)
	3	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肺臓炎	- Any Grade -	19 (2.9%)	2 (1.4%)	9 (3.4%)	8 (3.2%)
	1	7 (1.1%)	0	5 (1.9%)	2 (0.8%)
	2	5 (0.8%)	0	1 (0.4%)	4 (1.6%)
	3	6 (0.9%)	2 (1.4%)	2 (0.7%)	2 (0.8%)
	4	1 (0.2%)	0	1 (0.4%)	0
咳嗽	- Any Grade -	17 (2.6%)	4 (2.9%)	4 (1.5%)	9 (3.6%)
	1	12 (1.8%)	2 (1.4%)	3 (1.1%)	7 (2.8%)
	2	5 (0.8%)	2 (1.4%)	1 (0.4%)	2 (0.8%)
低酸素症	- Any Grade -	6 (0.9%)	2 (1.4%)	3 (1.1%)	1 (0.4%)
	2	5 (0.8%)	2 (1.4%)	2 (0.7%)	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
胸水	- Any Grade -	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	3	1 (0.2%)	1 (0.7%)	0	0
鼻出血	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
鼻漏	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
湿性咳嗽	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	2 (0.3%)	0	2 (0.7%)	0
上気道咳症候群	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
アレルギー性鼻炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
間質性肺疾患	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
胸膜痛	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
誤嚥性肺炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
口腔咽頭痛	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
肺塞栓症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
肺浸潤	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
肺水腫	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
発声障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
鼻の炎症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
鼻乾燥	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
臨床検査					
- Overall -	- Any Grade -	56 (8.5%)	7 (5.0%)	24 (9.0%)	25 (9.9%)
	1	30 (4.6%)	7 (5.0%)	13 (4.9%)	10 (4.0%)
	2	15 (2.3%)	0	7 (2.6%)	8 (3.2%)
	3	11 (1.7%)	0	4 (1.5%)	7 (2.8%)

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	17 (2.6%)	1 (0.7%)	7 (2.6%)	9 (3.6%)
	1	10 (1.5%)	1 (0.7%)	3 (1.1%)	6 (2.4%)
	2	4 (0.6%)	0	3 (1.1%)	1 (0.4%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	15 (2.3%)	1 (0.7%)	6 (2.2%)	8 (3.2%)
	1	10 (1.5%)	1 (0.7%)	5 (1.9%)	4 (1.6%)
	2	4 (0.6%)	0	1 (0.4%)	3 (1.2%)
	3	1 (0.2%)	0	0	1 (0.4%)
体重減少	- Any Grade -	13 (2.0%)	1 (0.7%)	6 (2.2%)	6 (2.4%)
	1	10 (1.5%)	1 (0.7%)	6 (2.2%)	3 (1.2%)
	2	3 (0.5%)	0	0	3 (1.2%)
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
血中アルカリホスファターゼ増加	- Any Grade -	5 (0.8%)	2 (1.4%)	1 (0.4%)	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	1 (0.4%)	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
リンパ球数減少	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
血小板数減少	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
血中クレアチニン増加	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肝酵素上昇	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0
胸部コンピュータ断層撮影異常	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
血中ビリルビン増加	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
血中甲状腺刺激ホルモン増加	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
体重増加	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
ＰＯ２低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
アミラーゼ増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
リパーゼ増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
肝機能検査異常	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血中カリウム	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血中クレアチンホスホキナーゼ増加	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
血中乳酸脱水素酵素増加	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
心拍数不整	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
白血球数減少	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
神経系障害					
- Overall -	- Any Grade -	55 (8.3%)	11 (7.9%)	25 (9.4%)	19 (7.5%)
	1	39 (5.9%)	8 (5.8%)	17 (6.4%)	14 (5.5%)
	2	14 (2.1%)	2 (1.4%)	7 (2.6%)	5 (2.0%)
	3	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
頭痛	- Any Grade -	22 (3.3%)	6 (4.3%)	7 (2.6%)	9 (3.6%)
	1	16 (2.4%)	4 (2.9%)	6 (2.2%)	6 (2.4%)
	2	6 (0.9%)	2 (1.4%)	1 (0.4%)	3 (1.2%)
浮動性めまい	- Any Grade -	12 (1.8%)	2 (1.4%)	4 (1.5%)	6 (2.4%)
	1	10 (1.5%)	2 (1.4%)	3 (1.1%)	5 (2.0%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
味覚異常	- Any Grade -	11 (1.7%)	2 (1.4%)	5 (1.9%)	4 (1.6%)
	1	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)
	2	2 (0.3%)	0	2 (0.7%)	0
感覚鈍麻	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
	3	1 (0.2%)	0	1 (0.4%)	0
錯感覚	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
末梢性ニューロパチー	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
末梢性感覚ニューロパチー	- Any Grade -	3 (0.5%)	2 (1.4%)	1 (0.4%)	0
	1	3 (0.5%)	2 (1.4%)	1 (0.4%)	0
構語障害	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
嗜眠	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	0	1 (0.4%)	0
運動失調	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
会話障害	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
傾眠	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
健忘	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
視神経炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
灼熱感	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
振戦	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
神経毒性	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
対麻痺	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
知覚過敏	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
注意力障害	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
末梢性運動ニューロパチー	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
味覚消失	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
嗅覚錯誤	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
感染症および寄生虫症					
- Overall -	- Any Grade -	38 (5.8%)	7 (5.0%)	9 (3.4%)	22 (8.7%)
	1	12 (1.8%)	1 (0.7%)	3 (1.1%)	8 (3.2%)
	2	20 (3.0%)	6 (4.3%)	4 (1.5%)	10 (4.0%)
	3	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	4	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	5	1 (0.2%)	0	0	1 (0.4%)
上気道感染	- Any Grade -	7 (1.1%)	1 (0.7%)	2 (0.7%)	4 (1.6%)
	1	1 (0.2%)	0	1 (0.4%)	0
	2	6 (0.9%)	1 (0.7%)	1 (0.4%)	4 (1.6%)
結膜炎	- Any Grade -	5 (0.8%)	1 (0.7%)	3 (1.1%)	1 (0.4%)
	1	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
尿路感染	- Any Grade -	5 (0.8%)	2 (1.4%)	1 (0.4%)	2 (0.8%)
	1	1 (0.2%)	0	0	1 (0.4%)
	2	3 (0.5%)	2 (1.4%)	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
肺炎	- Any Grade -	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
	5	1 (0.2%)	0	0	1 (0.4%)
副鼻腔炎	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	2	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
肺感染	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	2 (0.3%)	0	0	2 (0.8%)
鼻咽頭炎	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	1	2 (0.3%)	0	0	2 (0.8%)
インフルエンザ	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
カンジダ感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
咽頭炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
気管支炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
憩室炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
口唇感染	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
脊髄炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

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Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
前庭神経炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
唾液腺炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
帯状疱疹	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
爪囲炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
敗血症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
敗血症性ショック	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
鼻炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
慢性副鼻腔炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
血液およびリンパ系障害					
- Overall -	- Any Grade -	33 (5.0%)	5 (3.6%)	15 (5.6%)	13 (5.1%)
	1	8 (1.2%)	2 (1.4%)	5 (1.9%)	1 (0.4%)
	2	16 (2.4%)	2 (1.4%)	7 (2.6%)	7 (2.8%)
	3	7 (1.1%)	0	3 (1.1%)	4 (1.6%)
	4	2 (0.3%)	1 (0.7%)	0	1 (0.4%)
貧血	- Any Grade -	22 (3.3%)	3 (2.2%)	8 (3.0%)	11 (4.3%)
	1	4 (0.6%)	1 (0.7%)	1 (0.4%)	2 (0.8%)
	2	12 (1.8%)	2 (1.4%)	4 (1.5%)	6 (2.4%)
	3	6 (0.9%)	0	3 (1.1%)	3 (1.2%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
血小板減少症	- Any Grade -	7 (1.1%)	1 (0.7%)	5 (1.9%)	1 (0.4%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	1 (0.7%)	0	0
リンパ球減少症	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
リンパ節症	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
好中球減少症	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	0	1 (0.4%)
リンパ節痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
血小板減少性紫斑病	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	4	1 (0.2%)	0	0	1 (0.4%)
眼障害					
- Overall -	- Any Grade -	24 (3.6%)	5 (3.6%)	8 (3.0%)	11 (4.3%)
	1	21 (3.2%)	4 (2.9%)	8 (3.0%)	9 (3.6%)
	2	3 (0.5%)	1 (0.7%)	0	2 (0.8%)
眼乾燥	- Any Grade -	7 (1.1%)	0	2 (0.7%)	5 (2.0%)
	1	6 (0.9%)	0	2 (0.7%)	4 (1.6%)
	2	1 (0.2%)	0	0	1 (0.4%)
流涙増加	- Any Grade -	4 (0.6%)	2 (1.4%)	0	2 (0.8%)
	1	4 (0.6%)	2 (1.4%)	0	2 (0.8%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
複視	- Any Grade -	3 (0.5%)	0	0	3 (1.2%)
	1	3 (0.5%)	0	0	3 (1.2%)
霧視	- Any Grade -	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
	1	3 (0.5%)	1 (0.7%)	2 (0.7%)	0
眼刺激	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼部腫脹	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼そう痒症	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼下垂	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼瞼紅斑	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼痛	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
眼瞼発疹	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
眼瞼浮腫	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
視力障害	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
視力低下	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
上強膜炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
羞明	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
内分泌障害					
- Overall -	- Any Grade -	21 (3.2%)	5 (3.6%)	8 (3.0%)	8 (3.2%)
	1	6 (0.9%)	1 (0.7%)	2 (0.7%)	3 (1.2%)
	2	13 (2.0%)	4 (2.9%)	5 (1.9%)	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
甲状腺機能低下症	- Any Grade -	20 (3.0%)	5 (3.6%)	7 (2.6%)	8 (3.2%)
	1	6 (0.9%)	1 (0.7%)	2 (0.7%)	3 (1.2%)
	2	12 (1.8%)	4 (2.9%)	4 (1.5%)	4 (1.6%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
甲状腺機能亢進症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
粘液水腫	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
副腎機能不全	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
血管障害					
- Overall -	- Any Grade -	16 (2.4%)	4 (2.9%)	10 (3.7%)	2 (0.8%)
	1	11 (1.7%)	1 (0.7%)	8 (3.0%)	2 (0.8%)
	2	4 (0.6%)	3 (2.2%)	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
ほてり	- Any Grade -	8 (1.2%)	2 (1.4%)	4 (1.5%)	2 (0.8%)
	1	8 (1.2%)	2 (1.4%)	4 (1.5%)	2 (0.8%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
潮紅	- Any Grade -	4 (0.6%)	1 (0.7%)	3 (1.1%)	0
	1	3 (0.5%)	0	3 (1.1%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
高血圧	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	1 (0.7%)	0	0
低血圧	- Any Grade -	2 (0.3%)	0	2 (0.7%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
レイノー現象	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	2	1 (0.2%)	1 (0.7%)	0	0
傷害、中毒および処置合併症					
- Overall -	- Any Grade -	13 (2.0%)	2 (1.4%)	8 (3.0%)	3 (1.2%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	5 (0.8%)	2 (1.4%)	2 (0.7%)	1 (0.4%)
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
注入に伴う反応	- Any Grade -	12 (1.8%)	2 (1.4%)	8 (3.0%)	2 (0.8%)
	1	5 (0.8%)	0	4 (1.5%)	1 (0.4%)
	2	4 (0.6%)	2 (1.4%)	2 (0.7%)	0
	3	3 (0.5%)	0	2 (0.7%)	1 (0.4%)
放射線性肺臓炎	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
免疫系障害					
- Overall -	- Any Grade -	12 (1.8%)	2 (1.4%)	5 (1.9%)	5 (2.0%)
	1	8 (1.2%)	1 (0.7%)	3 (1.1%)	4 (1.6%)
	2	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
過敏症	- Any Grade -	11 (1.7%)	2 (1.4%)	5 (1.9%)	4 (1.6%)
	1	7 (1.1%)	1 (0.7%)	3 (1.1%)	3 (1.2%)
	2	4 (0.6%)	1 (0.7%)	2 (0.7%)	1 (0.4%)
サイトカイン放出症候群	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
精神障害					
- Overall -	- Any Grade -	11 (1.7%)	3 (2.2%)	6 (2.2%)	2 (0.8%)
	1	6 (0.9%)	2 (1.4%)	4 (1.5%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	3	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
不眠症	- Any Grade -	6 (0.9%)	2 (1.4%)	2 (0.7%)	2 (0.8%)
	1	3 (0.5%)	2 (1.4%)	1 (0.4%)	0
	2	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
激越	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
錯乱状態	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	3	1 (0.2%)	1 (0.7%)	0	0
失見当識	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
不安	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
落ち着きのなさ	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
心臓障害					
- Overall -	- Any Grade -	6 (0.9%)	0	3 (1.1%)	3 (1.2%)
	1	2 (0.3%)	0	2 (0.7%)	0
	2	2 (0.3%)	0	0	2 (0.8%)
	3	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
心房細動	- Any Grade -	2 (0.3%)	0	0	2 (0.8%)
	2	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	0	1 (0.4%)
心タンポナーデ	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
心嚢液貯留	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
洞性頻脈	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
頻脈	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
耳および迷路障害					
- Overall -	- Any Grade -	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
	1	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)
外耳の炎症	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	2	1 (0.2%)	0	0	1 (0.4%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
耳そう痒症	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
耳鳴	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
腎および尿路障害					
- Overall -	- Any Grade -	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
	1	3 (0.5%)	1 (0.7%)	1 (0.4%)	1 (0.4%)
ミクロアルブミン尿	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
血尿	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	1	1 (0.2%)	1 (0.7%)	0	0
尿失禁	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
肝胆道系障害					
- Overall -	- Any Grade -	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
	4	2 (0.3%)	1 (0.7%)	1 (0.4%)	0
肝出血	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	4	1 (0.2%)	0	1 (0.4%)	0
胆嚢炎	- Any Grade -	1 (0.2%)	1 (0.7%)	0	0
	4	1 (0.2%)	1 (0.7%)	0	0
生殖系および乳房障害					
- Overall -	- Any Grade -	2 (0.3%)	0	1 (0.4%)	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
	3	1 (0.2%)	0	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28754:BIRCH)
Protocol: GO28754
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=659)	atezolizumab Cohort 1 (N=139)	atezolizumab Cohort 2 (N=267)	atezolizumab Cohort 3 (N=253)
亀頭包皮炎	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	3	1 (0.2%)	0	1 (0.4%)	0
乳頭障害	- Any Grade -	1 (0.2%)	0	0	1 (0.4%)
	1	1 (0.2%)	0	0	1 (0.4%)
No Coding available					
- Overall -	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
No Coding available	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	1	1 (0.2%)	0	1 (0.4%)	0
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）					
- Overall -	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0
腫瘍疼痛	- Any Grade -	1 (0.2%)	0	1 (0.4%)	0
	2	1 (0.2%)	0	1 (0.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

2.7.6.2.1.6　FIR 試験

表 2.7.6.2.1.6-1　すべての有害事象（FIR 試験）

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
- Any adverse events -	- Any Grade -	136 (99.3%)	31 (100.0%)	92 (98.9%)	13 (100.0%)
	1	14 (10.2%)	5 (16.1%)	8 (8.6%)	1 (7.7%)
	2	51 (37.2%)	11 (35.5%)	35 (37.6%)	5 (38.5%)
	3	59 (43.1%)	12 (38.7%)	40 (43.0%)	7 (53.8%)
	4	7 (5.1%)	1 (3.2%)	6 (6.5%)	0
	5	5 (3.6%)	2 (6.5%)	3 (3.2%)	0
一般・全身障害および投与部位の状態					
- Overall -	- Any Grade -	94 (68.6%)	22 (71.0%)	62 (66.7%)	10 (76.9%)
	1	46 (33.6%)	12 (38.7%)	32 (34.4%)	2 (15.4%)
	2	40 (29.2%)	10 (32.3%)	25 (26.9%)	5 (38.5%)
	3	8 (5.8%)	0	5 (5.4%)	3 (23.1%)
疲労	- Any Grade -	56 (40.9%)	15 (48.4%)	36 (38.7%)	5 (38.5%)
	1	33 (24.1%)	10 (32.3%)	20 (21.5%)	3 (23.1%)
	2	21 (15.3%)	5 (16.1%)	14 (15.1%)	2 (15.4%)
	3	2 (1.5%)	0	2 (2.2%)	0
発熱	- Any Grade -	25 (18.2%)	6 (19.4%)	17 (18.3%)	2 (15.4%)
	1	20 (14.6%)	4 (12.9%)	15 (16.1%)	1 (7.7%)
	2	5 (3.6%)	2 (6.5%)	2 (2.2%)	1 (7.7%)
胸痛	- Any Grade -	12 (8.8%)	1 (3.2%)	9 (9.7%)	2 (15.4%)
	1	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	2	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
	3	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
末梢性浮腫	- Any Grade -	12 (8.8%)	3 (9.7%)	7 (7.5%)	2 (15.4%)
	1	7 (5.1%)	2 (6.5%)	5 (5.4%)	0
	2	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	3	1 (0.7%)	0	0	1 (7.7%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas / Output: /opt/BIOSTAT/prod/cdt7692j/j28625a/reports/aet04_GO28625_SE.out
09NOV2016 10:23

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
疼痛	- Any Grade -	11 (8.0%)	5 (16.1%)	4 (4.3%)	2 (15.4%)
	1	6 (4.4%)	3 (9.7%)	1 (1.1%)	2 (15.4%)
	2	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	3	2 (1.5%)	0	2 (2.2%)	0
無力症	- Any Grade -	8 (5.8%)	1 (3.2%)	7 (7.5%)	0
	1	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	2	4 (2.9%)	0	4 (4.3%)	0
悪寒	- Any Grade -	7 (5.1%)	1 (3.2%)	5 (5.4%)	1 (7.7%)
	1	7 (5.1%)	1 (3.2%)	5 (5.4%)	1 (7.7%)
インフルエンザ様疾患	- Any Grade -	6 (4.4%)	3 (9.7%)	2 (2.2%)	1 (7.7%)
	1	4 (2.9%)	2 (6.5%)	1 (1.1%)	1 (7.7%)
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
倦怠感	- Any Grade -	6 (4.4%)	0	6 (6.5%)	0
	1	3 (2.2%)	0	3 (3.2%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
粘膜の炎症	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
非心臓性胸痛	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
浮腫	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
カテーテル留置部位出血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
カテーテル留置部位疼痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
顔面浮腫	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
全身健康状態低下	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	3	1 (0.7%)	0	0	1 (7.7%)
歩行障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
冷感	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
呼吸器、胸郭および縦隔障害					
- Overall -	- Any Grade -	92 (67.2%)	19 (61.3%)	66 (71.0%)	7 (53.8%)
	1	39 (28.5%)	8 (25.8%)	25 (26.9%)	6 (46.2%)
	2	35 (25.5%)	9 (29.0%)	25 (26.9%)	1 (7.7%)
	3	16 (11.7%)	2 (6.5%)	14 (15.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
呼吸困難	- Any Grade -	38 (27.7%)	8 (25.8%)	28 (30.1%)	2 (15.4%)
	1	12 (8.8%)	2 (6.5%)	8 (8.6%)	2 (15.4%)
	2	22 (16.1%)	6 (19.4%)	16 (17.2%)	0
	3	4 (2.9%)	0	4 (4.3%)	0
咳嗽	- Any Grade -	37 (27.0%)	4 (12.9%)	31 (33.3%)	2 (15.4%)
	1	20 (14.6%)	2 (6.5%)	17 (18.3%)	1 (7.7%)
	2	16 (11.7%)	2 (6.5%)	13 (14.0%)	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
喀血	- Any Grade -	12 (8.8%)	5 (16.1%)	6 (6.5%)	1 (7.7%)
	1	9 (6.6%)	4 (12.9%)	4 (4.3%)	1 (7.7%)
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
湿性咳嗽	- Any Grade -	11 (8.0%)	1 (3.2%)	10 (10.8%)	0
	1	6 (4.4%)	0	6 (6.5%)	0
	2	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
喘鳴	- Any Grade -	9 (6.6%)	1 (3.2%)	7 (7.5%)	1 (7.7%)
	1	5 (3.6%)	0	4 (4.3%)	1 (7.7%)
	2	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
胸水	- Any Grade -	8 (5.8%)	2 (6.5%)	5 (5.4%)	1 (7.7%)
	1	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
	3	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
発声障害	- Any Grade -	8 (5.8%)	1 (3.2%)	6 (6.5%)	1 (7.7%)
	1	7 (5.1%)	1 (3.2%)	5 (5.4%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
肺塞栓症	- Any Grade -	7 (5.1%)	0	7 (7.5%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	6 (4.4%)	0	6 (6.5%)	0
鼻閉	- Any Grade -	7 (5.1%)	1 (3.2%)	6 (6.5%)	0
	1	4 (2.9%)	0	4 (4.3%)	0
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
口腔咽頭痛	- Any Grade -	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	1	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
鼻漏	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	4 (2.9%)	1 (3.2%)	3 (3.2%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
低酸素症	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
鼻出血	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	1	3 (2.2%)	0	3 (3.2%)	0
上気道咳症候群	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
肺出血	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
肺臓炎	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	1 (1.1%)	0
労作性呼吸困難	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
気管支狭窄	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	1 (3.2%)	0	0
気管支分泌増加	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
気管支閉塞	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
気胸	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
気道うっ血	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
呼吸障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
誤嚥	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
肺高血圧症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
肺浸潤	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
肺水腫	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
肺痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
鼻乾燥	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
副鼻腔うっ血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
慢性閉塞性肺疾患	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
胃腸障害					
- Overall -	- Any Grade -	85 (62.0%)	22 (71.0%)	55 (59.1%)	8 (61.5%)
	1	44 (32.1%)	12 (38.7%)	28 (30.1%)	4 (30.8%)
	2	34 (24.8%)	7 (22.6%)	25 (26.9%)	2 (15.4%)
	3	7 (5.1%)	3 (9.7%)	2 (2.2%)	2 (15.4%)
悪心	- Any Grade -	36 (26.3%)	9 (29.0%)	23 (24.7%)	4 (30.8%)
	1	27 (19.7%)	7 (22.6%)	17 (18.3%)	3 (23.1%)
	2	8 (5.8%)	1 (3.2%)	6 (6.5%)	1 (7.7%)
	3	1 (0.7%)	1 (3.2%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
下痢	- Any Grade -	28 (20.4%)	8 (25.8%)	16 (17.2%)	4 (30.8%)
	1	20 (14.6%)	6 (19.4%)	12 (12.9%)	2 (15.4%)
	2	6 (4.4%)	1 (3.2%)	4 (4.3%)	1 (7.7%)
	3	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
便秘	- Any Grade -	26 (19.0%)	8 (25.8%)	14 (15.1%)	4 (30.8%)
	1	17 (12.4%)	6 (19.4%)	9 (9.7%)	2 (15.4%)
	2	8 (5.8%)	2 (6.5%)	5 (5.4%)	1 (7.7%)
	3	1 (0.7%)	0	0	1 (7.7%)
嘔吐	- Any Grade -	20 (14.6%)	4 (12.9%)	13 (14.0%)	3 (23.1%)
	1	16 (11.7%)	1 (3.2%)	12 (12.9%)	3 (23.1%)
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	3	2 (1.5%)	2 (6.5%)	0	0
嚥下障害	- Any Grade -	10 (7.3%)	1 (3.2%)	8 (8.6%)	1 (7.7%)
	1	8 (5.8%)	1 (3.2%)	6 (6.5%)	1 (7.7%)
	2	2 (1.5%)	0	2 (2.2%)	0
胃食道逆流性疾患	- Any Grade -	8 (5.8%)	1 (3.2%)	7 (7.5%)	0
	1	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
腹痛	- Any Grade -	8 (5.8%)	1 (3.2%)	7 (7.5%)	0
	1	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
口内炎	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
口内乾燥	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
消化不良	- Any Grade -	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
	1	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
下腹部痛	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
上腹部痛	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	1 (0.7%)	0	1 (1.1%)	0
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
舌痛	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
口唇炎	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
嚥下痛	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
レッチング	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
胃炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
下部消化管出血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
憩室	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
口腔腫脹	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
好酸球性食道炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
歯肉痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
痔核	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
食道炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
舌変色	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
大腸炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
直腸出血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
腹水	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
腹壁血腫	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
筋骨格系および結合組織障害					
- Overall -	- Any Grade -	75 (54.7%)	16 (51.6%)	52 (55.9%)	7 (53.8%)
	1	32 (23.4%)	9 (29.0%)	20 (21.5%)	3 (23.1%)
	2	34 (24.8%)	7 (22.6%)	25 (26.9%)	2 (15.4%)
	3	9 (6.6%)	0	7 (7.5%)	2 (15.4%)
関節痛	- Any Grade -	26 (19.0%)	6 (19.4%)	18 (19.4%)	2 (15.4%)
	1	12 (8.8%)	3 (9.7%)	7 (7.5%)	2 (15.4%)
	2	13 (9.5%)	3 (9.7%)	10 (10.8%)	0
	3	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
背部痛	- Any Grade -	26 (19.0%)	5 (16.1%)	19 (20.4%)	2 (15.4%)
	1	12 (8.8%)	4 (12.9%)	7 (7.5%)	1 (7.7%)
	2	10 (7.3%)	1 (3.2%)	8 (8.6%)	1 (7.7%)
	3	4 (2.9%)	0	4 (4.3%)	0
四肢痛	- Any Grade -	11 (8.0%)	2 (6.5%)	8 (8.6%)	1 (7.7%)
	1	5 (3.6%)	2 (6.5%)	3 (3.2%)	0
	2	5 (3.6%)	0	4 (4.3%)	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0
筋骨格痛	- Any Grade -	10 (7.3%)	3 (9.7%)	6 (6.5%)	1 (7.7%)
	1	6 (4.4%)	3 (9.7%)	3 (3.2%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
筋骨格系胸痛	- Any Grade -	8 (5.8%)	0	8 (8.6%)	0
	1	5 (3.6%)	0	5 (5.4%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
筋肉痛	- Any Grade -	8 (5.8%)	3 (9.7%)	4 (4.3%)	1 (7.7%)
	1	7 (5.1%)	2 (6.5%)	4 (4.3%)	1 (7.7%)
	2	1 (0.7%)	1 (3.2%)	0	0
筋力低下	- Any Grade -	6 (4.4%)	2 (6.5%)	4 (4.3%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	5 (3.6%)	2 (6.5%)	3 (3.2%)	0
頚部痛	- Any Grade -	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	2	3 (2.2%)	0	3 (3.2%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
骨痛	- Any Grade -	5 (3.6%)	0	3 (3.2%)	2 (15.4%)
	1	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
筋痙縮	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
側腹部痛	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
関節炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
リウマチ性多発筋痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
顎痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
滑液包炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
関節硬直	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
筋骨格硬直	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
筋骨格不快感	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
肩回旋筋腱板症候群	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
尾骨痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
感染症および寄生虫症					
- Overall -	- Any Grade -	64 (46.7%)	14 (45.2%)	45 (48.4%)	5 (38.5%)
	1	16 (11.7%)	3 (9.7%)	12 (12.9%)	1 (7.7%)
	2	33 (24.1%)	5 (16.1%)	24 (25.8%)	4 (30.8%)
	3	14 (10.2%)	6 (19.4%)	8 (8.6%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
上気道感染	- Any Grade -	17 (12.4%)	4 (12.9%)	13 (14.0%)	0
	1	6 (4.4%)	0	6 (6.5%)	0
	2	9 (6.6%)	2 (6.5%)	7 (7.5%)	0
	3	2 (1.5%)	2 (6.5%)	0	0
肺炎	- Any Grade -	14 (10.2%)	3 (9.7%)	11 (11.8%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	3	6 (4.4%)	2 (6.5%)	4 (4.3%)	0
尿路感染	- Any Grade -	7 (5.1%)	3 (9.7%)	2 (2.2%)	2 (15.4%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	6 (4.4%)	2 (6.5%)	2 (2.2%)	2 (15.4%)
下気道感染	- Any Grade -	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	2 (1.5%)	0	2 (2.2%)	0
気管支炎	- Any Grade -	4 (2.9%)	2 (6.5%)	2 (2.2%)	0
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	3	1 (0.7%)	1 (3.2%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
口腔カンジダ症	- Any Grade -	4 (2.9%)	0	4 (4.3%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	3 (2.2%)	0	3 (3.2%)	0
カンジダ感染	- Any Grade -	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	1	2 (1.5%)	2 (6.5%)	0	0
	2	1 (0.7%)	0	1 (1.1%)	0
鼻咽頭炎	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
インフルエンザ	- Any Grade -	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	3	1 (0.7%)	1 (3.2%)	0	0
咽頭炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
感染	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
食道カンジダ症	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
帯状疱疹	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
皮膚感染	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
副鼻腔炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
膀胱炎	- Any Grade -	2 (1.5%)	2 (6.5%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
ウイルス感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
ウイルス性上気道感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
ブドウ球菌感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
ヘルペスウイルス感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
リンパ管炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
レンサ球菌性菌血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
外耳炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
気道感染	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
頚部膿瘍	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
結膜炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
細菌性副鼻腔炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
歯感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
単純ヘルペス	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
軟部組織感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
播種性帯状疱疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
敗血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
皮膚真菌感染	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
鼻炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
蜂巣炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
毛包炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
肛径部膿瘍	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
代謝および栄養障害					
- Overall -	- Any Grade -	60 (43.8%)	12 (38.7%)	42 (45.2%)	6 (46.2%)
	1	25 (18.2%)	6 (19.4%)	17 (18.3%)	2 (15.4%)
	2	18 (13.1%)	4 (12.9%)	12 (12.9%)	2 (15.4%)
	3	16 (11.7%)	2 (6.5%)	12 (12.9%)	2 (15.4%)
	4	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
食欲減退	- Any Grade -	28 (20.4%)	6 (19.4%)	20 (21.5%)	2 (15.4%)
	1	17 (12.4%)	5 (16.1%)	11 (11.8%)	1 (7.7%)
	2	11 (8.0%)	1 (3.2%)	9 (9.7%)	1 (7.7%)
低カリウム血症	- Any Grade -	18 (13.1%)	2 (6.5%)	12 (12.9%)	4 (30.8%)
	1	10 (7.3%)	1 (3.2%)	7 (7.5%)	2 (15.4%)
	2	3 (2.2%)	0	3 (3.2%)	0
	3	4 (2.9%)	1 (3.2%)	1 (1.1%)	2 (15.4%)
	4	1 (0.7%)	0	1 (1.1%)	0
低ナトリウム血症	- Any Grade -	11 (8.0%)	1 (3.2%)	10 (10.8%)	0
	1	5 (3.6%)	0	5 (5.4%)	0
	3	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
脱水	- Any Grade -	9 (6.6%)	2 (6.5%)	6 (6.5%)	1 (7.7%)
	1	1 (0.7%)	0	1 (1.1%)	0
	2	6 (4.4%)	2 (6.5%)	3 (3.2%)	1 (7.7%)
	3	2 (1.5%)	0	2 (2.2%)	0
低マグネシウム血症	- Any Grade -	7 (5.1%)	0	7 (7.5%)	0
	1	4 (2.9%)	0	4 (4.3%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
高カルシウム血症	- Any Grade -	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
低アルブミン血症	- Any Grade -	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	4 (2.9%)	0	4 (4.3%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
高カリウム血症	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	0	1 (1.1%)	0
低カルシウム血症	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
低血糖症	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
ビタミンD欠乏	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
食欲亢進	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
耐糖能障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
低リン酸血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
糖尿病	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
皮膚および皮下組織障害					
- Overall -	- Any Grade -	48 (35.0%)	10 (32.3%)	35 (37.6%)	3 (23.1%)
	1	43 (31.4%)	9 (29.0%)	32 (34.4%)	2 (15.4%)
	2	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
そう痒症	- Any Grade -	12 (8.8%)	4 (12.9%)	7 (7.5%)	1 (7.7%)
	1	10 (7.3%)	4 (12.9%)	5 (5.4%)	1 (7.7%)
	2	2 (1.5%)	0	2 (2.2%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
皮膚乾燥	- Any Grade -	11 (8.0%)	1 (3.2%)	10 (10.8%)	0
	1	11 (8.0%)	1 (3.2%)	10 (10.8%)	0
寝汗	- Any Grade -	10 (7.3%)	2 (6.5%)	7 (7.5%)	1 (7.7%)
	1	10 (7.3%)	2 (6.5%)	7 (7.5%)	1 (7.7%)
発疹	- Any Grade -	9 (6.6%)	0	8 (8.6%)	1 (7.7%)
	1	9 (6.6%)	0	8 (8.6%)	1 (7.7%)
斑状丘疹状皮疹	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	3 (2.2%)	0	3 (3.2%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
紅斑性皮疹	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
湿疹	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
水疱性皮膚炎	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
多汗症	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
斑状出血	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
褥瘡性潰瘍	- Any Grade -	2 (1.5%)	2 (6.5%)	0	0
	1	2 (1.5%)	2 (6.5%)	0	0
ざ瘡	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
ざ瘡様皮膚炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
そう痒性皮疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
丘疹性皮疹	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
紫斑	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
前癌性皮膚病変	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
全身性そう痒症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
脱毛症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
爪の障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
斑状皮疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
皮膚炎	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	3	1 (0.7%)	0	0	1 (7.7%)
皮膚潰瘍	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
蕁麻疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
神経系障害					
- Overall -	- Any Grade -	45 (32.8%)	8 (25.8%)	29 (31.2%)	8 (61.5%)
	1	25 (18.2%)	7 (22.6%)	15 (16.1%)	3 (23.1%)
	2	14 (10.2%)	1 (3.2%)	8 (8.6%)	5 (38.5%)
	3	6 (4.4%)	0	6 (6.5%)	0
頭痛	- Any Grade -	13 (9.5%)	2 (6.5%)	8 (8.6%)	3 (23.1%)
	1	9 (6.6%)	1 (3.2%)	6 (6.5%)	2 (15.4%)
	2	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
浮動性めまい	- Any Grade -	8 (5.8%)	1 (3.2%)	6 (6.5%)	1 (7.7%)
	1	7 (5.1%)	1 (3.2%)	6 (6.5%)	0
	2	1 (0.7%)	0	0	1 (7.7%)
味覚異常	- Any Grade -	7 (5.1%)	3 (9.7%)	4 (4.3%)	0
	1	6 (4.4%)	3 (9.7%)	3 (3.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
末梢性ニューロパチー	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
傾眠	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
錯感覚	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
失神	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0
末梢性感覚ニューロパチー	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
ギラン・バレー症候群	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
意識消失	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
異常感覚	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
眼振	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
記憶障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
坐骨神経痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
神経系障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
神経痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
声帯麻痺	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
頭蓋内静脈洞血栓症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
認知障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
脳症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
不全単麻痺	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
不全片麻痺	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
平衡障害	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
片頭痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
末梢性運動ニューロパチー	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
痙攣発作	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
臨床検査					
- Overall -	- Any Grade -	36 (26.3%)	10 (32.3%)	22 (23.7%)	4 (30.8%)
	1	16 (11.7%)	4 (12.9%)	12 (12.9%)	0
	2	13 (9.5%)	4 (12.9%)	6 (6.5%)	3 (23.1%)
	3	5 (3.6%)	2 (6.5%)	2 (2.2%)	1 (7.7%)
	4	2 (1.5%)	0	2 (2.2%)	0
体重減少	- Any Grade -	15 (10.9%)	6 (19.4%)	8 (8.6%)	1 (7.7%)
	1	9 (6.6%)	4 (12.9%)	5 (5.4%)	0
	2	6 (4.4%)	2 (6.5%)	3 (3.2%)	1 (7.7%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	6 (4.4%)	2 (6.5%)	2 (2.2%)	2 (15.4%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	0	0	2 (15.4%)
	3	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	6 (4.4%)	2 (6.5%)	2 (2.2%)	2 (15.4%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	0	0	2 (15.4%)
	3	1 (0.7%)	1 (3.2%)	0	0
	4	2 (1.5%)	0	2 (2.2%)	0
リンパ球数減少	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
血中クレアチニン増加	- Any Grade -	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	1	1 (0.7%)	0	1 (1.1%)	0
	2	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
体重増加	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
ヘモグロビン減少	- Any Grade -	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	1	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	0	1 (7.7%)
血中アルカリホスファターゼ増加	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
白血球数増加	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	1 (1.1%)	0
ヘリコバクター検査陽性	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
活性化部分トロンボプラスチン時間延長	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
血圧異常	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
血中アルカリホスファターゼ	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	1 (3.2%)	0	0
血中甲状腺刺激ホルモン増加	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
血中乳酸脱水素酵素増加	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
国際標準比増加	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
腎クレアチニン・クリアランス減少	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
精神障害					
- Overall -	- Any Grade -	35 (25.5%)	4 (12.9%)	25 (26.9%)	6 (46.2%)
	1	20 (14.6%)	4 (12.9%)	13 (14.0%)	3 (23.1%)
	2	13 (9.5%)	0	11 (11.8%)	2 (15.4%)
	3	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
不眠症	- Any Grade -	13 (9.5%)	3 (9.7%)	9 (9.7%)	1 (7.7%)
	1	8 (5.8%)	3 (9.7%)	5 (5.4%)	0
	2	5 (3.6%)	0	4 (4.3%)	1 (7.7%)
不安	- Any Grade -	11 (8.0%)	0	9 (9.7%)	2 (15.4%)
	1	4 (2.9%)	0	2 (2.2%)	2 (15.4%)
	2	7 (5.1%)	0	7 (7.5%)	0
うつ病	- Any Grade -	9 (6.6%)	1 (3.2%)	7 (7.5%)	1 (7.7%)
	1	9 (6.6%)	1 (3.2%)	7 (7.5%)	1 (7.7%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
錯乱状態	- Any Grade -	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0
易刺激性	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
幻覚	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
感情的苦悩	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
激越	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
精神状態変化	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	3	1 (0.7%)	0	0	1 (7.7%)
血液およびリンパ系障害					
- Overall -	- Any Grade -	33 (24.1%)	8 (25.8%)	21 (22.6%)	4 (30.8%)
	1	14 (10.2%)	4 (12.9%)	7 (7.5%)	3 (23.1%)
	2	12 (8.8%)	3 (9.7%)	8 (8.6%)	1 (7.7%)
	3	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
貧血	- Any Grade -	24 (17.5%)	6 (19.4%)	17 (18.3%)	1 (7.7%)
	1	8 (5.8%)	3 (9.7%)	5 (5.4%)	0
	2	11 (8.0%)	2 (6.5%)	8 (8.6%)	1 (7.7%)
	3	5 (3.6%)	1 (3.2%)	4 (4.3%)	0

Percentages are based on N in the column headings.
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
好中球減少症	- Any Grade -	4 (2.9%)	2 (6.5%)	2 (2.2%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	1 (1.1%)	0
血小板減少症	- Any Grade -	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	1 (3.2%)	0	0
リンパ球減少症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
リンパ節症	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
リンパ節痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
播種性血管内凝固	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
発熱性好中球減少症	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
血管障害					
- Overall -	- Any Grade -	28 (20.4%)	6 (19.4%)	19 (20.4%)	3 (23.1%)
	1	10 (7.3%)	3 (9.7%)	4 (4.3%)	3 (23.1%)
	2	13 (9.5%)	2 (6.5%)	11 (11.8%)	0
	3	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
低血圧	- Any Grade -	11 (8.0%)	3 (9.7%)	8 (8.6%)	0
	1	5 (3.6%)	3 (9.7%)	2 (2.2%)	0
	2	6 (4.4%)	0	6 (6.5%)	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
高血圧	- Any Grade -	6 (4.4%)	1 (3.2%)	4 (4.3%)	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	2 (1.5%)	0	2 (2.2%)	0
	3	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
ほてり	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
出血	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
深部静脈血栓症	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
潮紅	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
頚静脈血栓症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
血腫	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
塞栓症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
静脈炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
静脈血栓症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
大静脈塞栓症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
心臓障害					
- Overall -	- Any Grade -	22 (16.1%)	7 (22.6%)	12 (12.9%)	3 (23.1%)
	1	5 (3.6%)	2 (6.5%)	1 (1.1%)	2 (15.4%)
	2	10 (7.3%)	2 (6.5%)	7 (7.5%)	1 (7.7%)
	3	2 (1.5%)	0	2 (2.2%)	0
	4	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	5	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
心嚢液貯留	- Any Grade -	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0
	4	1 (0.7%)	1 (3.2%)	0	0
頻脈	- Any Grade -	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	3 (2.2%)	0	3 (3.2%)	0
心房細動	- Any Grade -	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
心タンポナーデ	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	1 (3.2%)	0	0
心房粗動	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	1 (1.1%)	0
冠動脈疾患	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
狭心症	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
収縮性心膜炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
徐脈	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
上室性頻脈	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
心筋梗塞	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
心停止	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	5	1 (0.7%)	1 (3.2%)	0	0
大動脈弁疾患	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
第二度房室ブロック	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
動悸	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
洞性頻脈	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
眼障害					
- Overall -	- Any Grade -	19 (13.9%)	4 (12.9%)	12 (12.9%)	3 (23.1%)
	1	8 (5.8%)	0	6 (6.5%)	2 (15.4%)
	2	8 (5.8%)	4 (12.9%)	3 (3.2%)	1 (7.7%)
	3	3 (2.2%)	0	3 (3.2%)	0
視力低下	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	2 (1.5%)	0	2 (2.2%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
複視	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
霧視	- Any Grade -	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	1 (3.2%)	0	0
流涙増加	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
眼乾燥	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
眼精疲労	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
眼瞼炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
ぶどう膜炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
一過性黒内障	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
眼の障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
眼刺激	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
眼窩周囲浮腫	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
光視症	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
視力障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
網膜動脈塞栓症	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
網膜剥離	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
羞明	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
傷害、中毒および処置合併症					
- Overall -	- Any Grade -	12 (8.8%)	4 (12.9%)	6 (6.5%)	2 (15.4%)
	1	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	2	5 (3.6%)	1 (3.2%)	2 (2.2%)	2 (15.4%)
	3	2 (1.5%)	2 (6.5%)	0	0
転倒	- Any Grade -	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	0	0	1 (7.7%)
顔面骨骨折	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
股関節部骨折	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	1 (3.2%)	0	0
挫傷	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
手骨折	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
処置による疼痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
上肢骨折	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
脊椎圧迫骨折	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	1 (3.2%)	0	0
創傷	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
創傷出血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
熱傷	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
剥離骨折	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
皮膚擦過傷	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
放射線性食道炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
裂傷	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
靱帯捻挫	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
耳および迷路障害					
- Overall -	- Any Grade -	8 (5.8%)	0	5 (5.4%)	3 (23.1%)
	1	7 (5.1%)	0	5 (5.4%)	2 (15.4%)
	2	1 (0.7%)	0	0	1 (7.7%)
回転性めまい	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
頭位性回転性めまい	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
耳垢栓塞	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
耳痛	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
耳閉	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
耳鳴	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
前庭障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
両耳難聴	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
腎および尿路障害					
- Overall -	- Any Grade -	8 (5.8%)	3 (9.7%)	5 (5.4%)	0
	1	7 (5.1%)	2 (6.5%)	5 (5.4%)	0
	3	1 (0.7%)	1 (3.2%)	0	0
排尿困難	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
夜間頻尿	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
腎機能障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
腎不全	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	1 (3.2%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
多尿	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
頻尿	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
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）					
- Overall -	- Any Grade -	8 (5.8%)	0	6 (6.5%)	2 (15.4%)
	1	2 (1.5%)	0	2 (2.2%)	0
	2	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
	3	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
腫瘍疼痛	- Any Grade -	6 (4.4%)	0	4 (4.3%)	2 (15.4%)
	1	1 (0.7%)	0	1 (1.1%)	0
	2	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	3	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
癌疼痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
基底細胞癌	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
内分泌障害					
- Overall -	- Any Grade -	5 (3.6%)	0	4 (4.3%)	1 (7.7%)
	1	1 (0.7%)	0	1 (1.1%)	0
	2	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
甲状腺機能低下症	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	2	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
急性甲状腺炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
原発性性腺機能低下	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
No Coding available					
- Overall -	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
No Coding available	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
生殖系および乳房障害					
- Overall -	- Any Grade -	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	1	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	2	2 (1.5%)	0	2 (2.2%)	0
乳房腫脹	- Any Grade -	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	1	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
勃起不全	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
乳房痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
免疫系障害					
- Overall -	- Any Grade -	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
	1	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
季節性アレルギー	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
薬物過敏症	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
肝胆道系障害					
- Overall -	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
黄疸	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

表 2.7.6.2.1.6-2　すべての副作用（FIR 試験）

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
- Any adverse events -	- Any Grade -	93 (67.9%)	23 (74.2%)	61 (65.6%)	9 (69.2%)
	1	40 (29.2%)	11 (35.5%)	25 (26.9%)	4 (30.8%)
	2	32 (23.4%)	10 (32.3%)	19 (20.4%)	3 (23.1%)
	3	16 (11.7%)	2 (6.5%)	12 (12.9%)	2 (15.4%)
	4	4 (2.9%)	0	4 (4.3%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
一般・全身障害および投与部位の状態					
- Overall -	- Any Grade -	54 (39.4%)	11 (35.5%)	36 (38.7%)	7 (53.8%)
	1	32 (23.4%)	8 (25.8%)	19 (20.4%)	5 (38.5%)
	2	21 (15.3%)	3 (9.7%)	16 (17.2%)	2 (15.4%)
	3	1 (0.7%)	0	1 (1.1%)	0
疲労	- Any Grade -	35 (25.5%)	6 (19.4%)	25 (26.9%)	4 (30.8%)
	1	24 (17.5%)	5 (16.1%)	16 (17.2%)	3 (23.1%)
	2	10 (7.3%)	1 (3.2%)	8 (8.6%)	1 (7.7%)
	3	1 (0.7%)	0	1 (1.1%)	0
発熱	- Any Grade -	10 (7.3%)	4 (12.9%)	5 (5.4%)	1 (7.7%)
	1	7 (5.1%)	3 (9.7%)	3 (3.2%)	1 (7.7%)
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
インフルエンザ様疾患	- Any Grade -	6 (4.4%)	3 (9.7%)	2 (2.2%)	1 (7.7%)
	1	4 (2.9%)	2 (6.5%)	1 (1.1%)	1 (7.7%)
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
無力症	- Any Grade -	4 (2.9%)	0	4 (4.3%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0
悪寒	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
倦怠感	- Any Grade -	3 (2.2%)	0	3 (3.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
末梢性浮腫	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
胸痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
粘膜の炎症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
歩行障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
疼痛	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
胃腸障害					
- Overall -	- Any Grade -	41 (29.9%)	14 (45.2%)	23 (24.7%)	4 (30.8%)
	1	27 (19.7%)	10 (32.3%)	14 (15.1%)	3 (23.1%)
	2	13 (9.5%)	4 (12.9%)	9 (9.7%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
悪心	- Any Grade -	20 (14.6%)	8 (25.8%)	11 (11.8%)	1 (7.7%)
	1	16 (11.7%)	7 (22.6%)	8 (8.6%)	1 (7.7%)
	2	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
下痢	- Any Grade -	12 (8.8%)	3 (9.7%)	5 (5.4%)	4 (30.8%)
	1	8 (5.8%)	2 (6.5%)	3 (3.2%)	3 (23.1%)
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	3	1 (0.7%)	0	0	1 (7.7%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
嘔吐	- Any Grade -	8 (5.8%)	1 (3.2%)	7 (7.5%)	0
	1	7 (5.1%)	1 (3.2%)	6 (6.5%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
口内乾燥	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
便秘	- Any Grade -	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
胃食道逆流性疾患	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
口内炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
嚥下痛	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
下部消化管出血	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
消化不良	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
食道炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
舌痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
腹痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
嚥下障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
皮膚および皮下組織障害					
- Overall -	- Any Grade -	27 (19.7%)	7 (22.6%)	18 (19.4%)	2 (15.4%)
	1	25 (18.2%)	6 (19.4%)	17 (18.3%)	2 (15.4%)
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
そう痒症	- Any Grade -	9 (6.6%)	4 (12.9%)	4 (4.3%)	1 (7.7%)
	1	9 (6.6%)	4 (12.9%)	4 (4.3%)	1 (7.7%)
発疹	- Any Grade -	6 (4.4%)	0	5 (5.4%)	1 (7.7%)
	1	6 (4.4%)	0	5 (5.4%)	1 (7.7%)
皮膚乾燥	- Any Grade -	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	1	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
寝汗	- Any Grade -	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	1	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
斑状丘疹状皮疹	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
水疱性皮膚炎	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	1 (3.2%)	0	0
ざ瘡	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
ざ瘡様皮膚炎	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
丘疹性皮疹	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
紅斑性皮疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
紫斑	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
湿疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
多汗症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
爪の障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
蕁麻疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
代謝および栄養障害					
- Overall -	- Any Grade -	24 (17.5%)	5 (16.1%)	17 (18.3%)	2 (15.4%)
	1	14 (10.2%)	4 (12.9%)	9 (9.7%)	1 (7.7%)
	2	7 (5.1%)	1 (3.2%)	5 (5.4%)	1 (7.7%)
	3	2 (1.5%)	0	2 (2.2%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
食欲減退	- Any Grade -	19 (13.9%)	5 (16.1%)	12 (12.9%)	2 (15.4%)
	1	12 (8.8%)	4 (12.9%)	7 (7.5%)	1 (7.7%)
	2	7 (5.1%)	1 (3.2%)	5 (5.4%)	1 (7.7%)
低カリウム血症	- Any Grade -	4 (2.9%)	0	4 (4.3%)	0
	1	3 (2.2%)	0	3 (3.2%)	0
	4	1 (0.7%)	0	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
低マグネシウム血症	- Any Grade -	4 (2.9%)	0	4 (4.3%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
脱水	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
低アルブミン血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
低ナトリウム血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
低リン酸血症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
糖尿病	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
筋骨格系および結合組織障害					
- Overall -	- Any Grade -	23 (16.8%)	4 (12.9%)	16 (17.2%)	3 (23.1%)
	1	15 (10.9%)	3 (9.7%)	9 (9.7%)	3 (23.1%)
	2	6 (4.4%)	1 (3.2%)	5 (5.4%)	0
	3	2 (1.5%)	0	2 (2.2%)	0
関節痛	- Any Grade -	8 (5.8%)	2 (6.5%)	5 (5.4%)	1 (7.7%)
	1	6 (4.4%)	2 (6.5%)	3 (3.2%)	1 (7.7%)
	2	2 (1.5%)	0	2 (2.2%)	0
筋肉痛	- Any Grade -	8 (5.8%)	3 (9.7%)	4 (4.3%)	1 (7.7%)
	1	8 (5.8%)	3 (9.7%)	4 (4.3%)	1 (7.7%)
筋力低下	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	2 (1.5%)	0	2 (2.2%)	0

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
筋痙縮	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
骨痛	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
四肢痛	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
リウマチ性多発筋痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
関節炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
筋骨格系胸痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
側腹部痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
背部痛	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
呼吸器、胸郭および縦隔障害					
- Overall -	- Any Grade -	22 (16.1%)	5 (16.1%)	16 (17.2%)	1 (7.7%)
	1	9 (6.6%)	2 (6.5%)	6 (6.5%)	1 (7.7%)
	2	8 (5.8%)	3 (9.7%)	5 (5.4%)	0
	3	5 (3.6%)	0	5 (5.4%)	0
咳嗽	- Any Grade -	5 (3.6%)	1 (3.2%)	4 (4.3%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
呼吸困難	- Any Grade -	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
湿性咳嗽	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
肺塞栓症	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	3	2 (1.5%)	0	2 (2.2%)	0
肺臓炎	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	1	1 (0.7%)	1 (3.2%)	0	0
	3	1 (0.7%)	0	1 (1.1%)	0
鼻出血	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
鼻漏	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
胸水	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
上気道咳症候群	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
肺高血圧症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
発声障害	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
鼻閉	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
労作性呼吸困難	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
喘鳴	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
神経系障害					
- Overall -	- Any Grade -	17 (12.4%)	4 (12.9%)	9 (9.7%)	4 (30.8%)
	1	11 (8.0%)	3 (9.7%)	5 (5.4%)	3 (23.1%)
	2	4 (2.9%)	1 (3.2%)	2 (2.2%)	1 (7.7%)
	3	2 (1.5%)	0	2 (2.2%)	0
味覚異常	- Any Grade -	4 (2.9%)	1 (3.2%)	3 (3.2%)	0
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
頭痛	- Any Grade -	3 (2.2%)	1 (3.2%)	0	2 (15.4%)
	1	2 (1.5%)	0	0	2 (15.4%)
	2	1 (0.7%)	1 (3.2%)	0	0
浮動性めまい	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	1	2 (1.5%)	0	2 (2.2%)	0
	2	1 (0.7%)	0	0	1 (7.7%)
ギラン・バレー症候群	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
意識消失	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
記憶障害	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
傾眠	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
錯感覚	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0

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事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
不全単麻痺	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
片頭痛	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
血液およびリンパ系障害					
- Overall -	- Any Grade -	11 (8.0%)	5 (16.1%)	4 (4.3%)	2 (15.4%)
	1	7 (5.1%)	3 (9.7%)	2 (2.2%)	2 (15.4%)
	2	3 (2.2%)	2 (6.5%)	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
貧血	- Any Grade -	7 (5.1%)	3 (9.7%)	4 (4.3%)	0
	1	4 (2.9%)	2 (6.5%)	2 (2.2%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
血小板減少症	- Any Grade -	2 (1.5%)	1 (3.2%)	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	1 (3.2%)	0	0
好中球減少症	- Any Grade -	2 (1.5%)	2 (6.5%)	0	0
	1	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
発熱性好中球減少症	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
臨床検査					
- Overall -	- Any Grade -	10 (7.3%)	2 (6.5%)	5 (5.4%)	3 (23.1%)
	1	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	2	3 (2.2%)	0	0	3 (23.1%)
	3	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	4	2 (1.5%)	0	2 (2.2%)	0
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	6 (4.4%)	2 (6.5%)	2 (2.2%)	2 (15.4%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	0	0	2 (15.4%)
	3	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
アラニンアミノトランスフェラーゼ増加	- Any Grade -	6 (4.4%)	2 (6.5%)	2 (2.2%)	2 (15.4%)
	1	1 (0.7%)	1 (3.2%)	0	0
	2	2 (1.5%)	0	0	2 (15.4%)
	3	1 (0.7%)	1 (3.2%)	0	0
	4	2 (1.5%)	0	2 (2.2%)	0
体重減少	- Any Grade -	3 (2.2%)	1 (3.2%)	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	1 (0.7%)	0	0	1 (7.7%)
リンパ球数減少	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
血中アルカリホスファターゼ増加	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
血中甲状腺刺激ホルモン増加	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)

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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
感染症および寄生虫症					
- Overall -	- Any Grade -	7 (5.1%)	1 (3.2%)	6 (6.5%)	0
	1	3 (2.2%)	0	3 (3.2%)	0
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
ヘルペスウイルス感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
下気道感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
外耳炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
結膜炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
上気道感染	- Any Grade -	1 (0.7%)	1 (3.2%)	0	0
	2	1 (0.7%)	1 (3.2%)	0	0
播種性帯状疱疹	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	1 (1.1%)	0
皮膚感染	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
血管障害					
- Overall -	- Any Grade -	7 (5.1%)	2 (6.5%)	4 (4.3%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	3	2 (1.5%)	1 (3.2%)	1 (1.1%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
高血圧	- Any Grade -	3 (2.2%)	1 (3.2%)	2 (2.2%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
	3	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
潮紅	- Any Grade -	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
	2	2 (1.5%)	1 (3.2%)	1 (1.1%)	0
低血圧	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
ほてり	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)
眼障害					
- Overall -	- Any Grade -	6 (4.4%)	0	4 (4.3%)	2 (15.4%)
	1	4 (2.9%)	0	3 (3.2%)	1 (7.7%)
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
眼瞼炎	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	2 (1.5%)	0	2 (2.2%)	0
霧視	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	1	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
眼乾燥	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
眼窩周囲浮腫	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	2	1 (0.7%)	0	0	1 (7.7%)
視力低下	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
流涙増加	- Any Grade -	1 (0.7%)	0	0	1 (7.7%)
	1	1 (0.7%)	0	0	1 (7.7%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
内分泌障害					
- Overall -	- Any Grade -	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
	2	3 (2.2%)	0	2 (2.2%)	1 (7.7%)
甲状腺機能低下症	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
急性甲状腺炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
心臓障害					
- Overall -	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
収縮性心膜炎	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	5	1 (0.7%)	0	1 (1.1%)	0
心タンポナーデ	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	4	1 (0.7%)	0	1 (1.1%)	0
精神障害					
- Overall -	- Any Grade -	2 (1.5%)	0	2 (2.2%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0
易刺激性	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
不眠症	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	2	1 (0.7%)	0	1 (1.1%)	0

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事象名：MedDRA ver. 18.0
All counts represent patients. Multiple occurrences of the same AE in one individual are counted once at the highest grade for this patient. To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28625:FIR)
Protocol: GO28625
Population: Treated Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=137)	atezolizumab Cohort 1 (N=31)	atezolizumab Cohort 2 (N=93)	atezolizumab Cohort 3 (N=13)
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）					
- Overall -	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
腫瘍疼痛	- Any Grade -	2 (1.5%)	0	1 (1.1%)	1 (7.7%)
	2	1 (0.7%)	0	1 (1.1%)	0
	3	1 (0.7%)	0	0	1 (7.7%)
腎および尿路障害					
- Overall -	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
頻尿	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
免疫系障害					
- Overall -	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0
季節性アレルギー	- Any Grade -	1 (0.7%)	0	1 (1.1%)	0
	1	1 (0.7%)	0	1 (1.1%)	0

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2.7.6.2.2 個別症例の詳細

本項では，アテゾリズマブの安全性評価に用いた6臨床試験（PCD4989g 試験，JO28944試験，OAK 試験，POPLAR 試験，BIRCH 試験，FIR 試験）の内，国内のみで実施した JO28944試験の死亡及び重篤な有害事象の個別症例の詳細を，治験総括報告書から引用した。

その他の海外で実施した5臨床試験（PCD4989g 試験，OAK 試験，POPLAR 試験，BIRCH 試験，FIR 試験）の個別症例の詳細は，個々の総括報告書（5.3.3.2-1 1.Narratives Page 7721，5.3.5.1-1 Narratives Page 266，5.3.5.1-2 Narratives Page 248，5.3.5.2-1 1.Narratives Page 249及び5.3.5.2-2 Narratives Page 155）に記載した。

2.7.6.2.2.1 個別症例の詳細（JO28944試験）

(1) 死亡例の個別症例の詳細（JO28944試験）

本治験では，治験期間中の死亡は認められなかった。

(2) 重篤な有害事象の個別症例の詳細（JO28944試験）

1) 症例番号：1102 重篤な有害事象：インフルエンザ様疾患

Protocol No. JO28944 Region: Japan	
Age: 4[redacted] Years Height: [redacted] cm	Gender: 女性 Weight: [redacted] kg
Trial Drug: アテゾリズマブ10 mg/kg First Dose: **Day 1	 Last Dose: **Day 72
PT: インフルエンザ様疾患 Event Onset: **Day 12 Serious: はい Drug Discontinuation due to AE: 休薬 Outcome: 回復	Verbatim: インフルエンザ様症状 Drug Relatedness: 多分あり Adverse Event of Special Interest (AESI): Not applicable* Confirmed Date: **Day 51

*本治験では，AESI の判断をしていない。

本4[redacted]歳女性患者は肺癌と診断されている。
ベースライン時の PS は1であった。
前治療は右肺下葉切除（Stop Date: [redacted]），シスプラチン+ タキソテール（Start Date: [redacted]，Stop Date: [redacted]），全脳照射（Start Date: [redacted]，Stop Date: [redacted]），ゲフィチニブ（Start Date: [redacted]，Stop Date: [redacted]），脳照射（Start Date: [redacted]，Stop Date: [redacted]），ペメトレキセドナトリウム水和物（Start Date: [redacted]，Stop Date: [redacted]），脊椎照射（Start Date: [redacted]，Stop Date: [redacted]）であった。
合併症（その治療）は鉄欠乏性貧血（含糖酸化鉄），悪心（アルプラゾラム），便秘（センナ・センナ実，酸化マグネシウム），季節性アレルギー（オロパタジン塩酸塩），薬物過敏症，不眠症（ゾルピデム酒石酸塩，エスタゾラム）であった。
既往症は薬物性肝障害，子宮内膜症であった。

本被験者の詳細な経過を以下に示す。

**Day 1 治験薬アテゾリズマブ（注射剤：10 mg/kg，3週1回投与）を入院にて投与開始（サイクル1 Day 1）。
**Day 10 治験薬投与後，Infusion Reaction もなく問題なく経過，退院。
Day 14 自宅より連絡。「Day 12頃より38°C 台の発熱とリンパ節痛がある」とのこと。アセトアミノフェンとロキソプロフェンナトリウム水和物にて経過観察。
**Day 16 規定の外来（[redacted]）にて，アセトアミノフェンやロキソプロフェンナトリウム水和物を内服せず解熱していたことを確認。
**Day 22 規定の外来（[redacted]）にて，発熱（38°C 台）の継続とリンパ節痛，多型紅斑を確認。多型紅斑に対して，クロベタゾールプロピオン酸エステルとベタ

メタゾン・d-クロルフェニラミンマレイン酸塩3T/3×を追加。

**Day 24 規定の外来（[redacted]，サイクル2開始予定）にて来院。食欲不振，頭痛，吐気により治験薬の投与延期。食欲不振に対して補液（アミノ酸・糖・電解質・ビタミン（4）500 ml × 1本）を実施。

**Day 25 頭痛にて緊急受診。頭痛 Grade 2，脱水 Grade 2，食欲不振 Grade 2にて入院となった。脱水と食欲不振に対して補液（アミノ酸・糖・電解質・ビタミン（4）500 ml），頭痛に対して濃グリセリン・果糖200 ml を実施。

**Day 28 頭痛と脱水は回復，食欲不振も Grade 1へ回復傾向のため，翌日投与再開可能と判断。

**Day 29 治験薬アテゾリズマブ（注射剤：10 mg/kg，3週1回投与）を再開（サイクル2 Day 1）。

**Day 30 治験薬投与後も体調に問題なく，本日退院となった。再考の結果，頭痛，嘔気，食欲不振，発熱をまとめて「インフルエンザ様症状」と判断した。

担当医のコメント
本症例は，本治験薬（アテゾリズマブ）投与後に，頭痛，嘔気，食欲不振，発熱などの症状を発現，対症療法により軽快を得たため，1週間の延期を行ったものの，2サイクル目の投与を実施した。頭痛，嘔気，食欲不振，発熱などは，先行する海外第 I 相試験でも認められている症状であり，本治験薬との因果関係は「否定できない」ものと考えられる。また，再考の結果，頭痛，嘔気，食欲不振，発熱などの一連の症状をまとめて，インフルエンザ様症状と判断した（インフルエンザ様症状についても，本治験薬との因果関係は「否定できない」と判断される）。

本被験者で発現した有害事象（発現日）は頭痛（ **Day 2 ），紅斑（ **Day 4 ），多形紅斑（ **Day 6 ），悪心（**Day 23），嘔吐（**Day 24），疲労（**Day 25）であった。
本被験者の治験期間終了日は**Day 86で，中止理由は「効果不十分」であった。

**新薬承認情報提供時に置き換え