テセントリク点滴静注1200 mg
（アテゾリズマブ（遺伝子組換え））
［非小細胞肺癌］

第2部　（モジュール2）：CTD の概要（サマリー）

2.7.6 個々の試験のまとめ

中外製薬株式会社

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2.7.6 個々の試験のまとめ

表 2.7.6-1 臨床試験一覧表

地域	試験番号	相 (依頼者)	試験デザイン	対象	被験者数	用法・用量[a]	主要評価項目	CTD 番号 <資料区分>
海外	PCD4989g (GO27831)	I (Roche /Genentech)	非盲検 1群	局所進行又は転移性固形癌患者，あるいは造血器腫瘍患者	481[b]	用量漸増ステージ: 0.01，0.03，0.1，0.3，1，3，10 及び20 mg/kg 拡張ステージ: 10，15，20 mg/kg 及び 1200 mg/body	安全性 MTD 及び DLT 第 II 相試験推奨用量	5.3.3.2-1 <評価>
国内	JO28944	I (中外)	非盲検 1群	進行固形癌患者	6[c]	コホート1：10 mg/kg コホート2：20 mg/kg	安全性 （有害事象及び DLT）	5.3.3.2-2 <評価>
国内及び海外	GO28915 (OAK)	III (Roche /Genentech)	ランダム化 非盲検 2群	局所進行又は転移性非小細胞肺癌患者（二次治療及び三次治療）	全体: 1225 日本人: 101	本剤群：1200 mg/body ドセタキセル群：75 mg/m^2	有効性 （OS）	5.3.5.1-1 <評価>
海外	GO28753 (POPLAR)	II (Roche /Genentech)	ランダム化 非盲検 2群	局所進行又は転移性非小細胞肺癌患者（二次治療及び三次治療）	287	本剤群：1200 mg/body ドセタキセル群：75 mg/m^2	有効性 （OS）	5.3.5.1-2 <評価>
国内及び海外	GO28754 (BIRCH)	II (Roche /Genentech)	非盲検 1群	PD-L1陽性局所進行又は転移性非小細胞肺癌（一次治療，二次治療及び三次治療以降）	全体: 667 日本人: 27	1200 mg/body	有効性 （奏効率）	5.3.5.2-1 <評価>
海外	GO28625 (FIR)	II (Roche /Genentech)	非盲検 1群	PD-L1陽性局所進行又は転移性非小細胞肺癌（一次治療及び二次治療以降）	138	1200 mg/body	有効性 （奏効率）	5.3.5.2-2 <評価>

最大耐用量（MTD）
用量制限毒性（DLT）
programmed death-ligand 1（PD-L1）
全生存期間（OS）
[a]: すべての治験で，本剤（及びドセタキセル）は3週間に1回投与した。
[b]: データカットオフ時点で本剤の投与を受けた被験者数。この内，非小細胞肺癌患者は88例。
[c]: この内，非小細胞肺癌患者は3例。

2.7.6.1 概要

2.7.6.1.1 PCD4989g 試験

(1) 試験の標題

A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of MPDL3280A Administered Intravenously as a Single Agent to Patients with Locally Advanced or Metastatic Solid Tumors or Hematologic Malignancies

局所進行又は転移性の固形癌患者，あるいは造血器腫瘍患者に MPDL3280A を単剤で点滴静脈内投与した場合の安全性及び薬物動態を評価する第 I 相非盲検用量漸増試験

(2) 治験依頼者／実施地域

Roche 社／4カ国，20施設（米国15施設，フランス3施設，イギリス1施設，スペイン1施設）

(3) 公表

Cho D, Sosman J, Sznol M, et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with metastatic renal cell carcinoma (mRCC). ASCO 2013.

Gordon M, Hamid O, Powderly J, et al. A phase 1 study of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic tumors. AACR 2013.

Hamid O, Sosman J, Lawrence D, et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic melanoma (mM). ASCO 2013.

Herbst RS, Gordon MS, Fine G, et al. A study of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic tumors. ASCO 2103.

Hodi FS, Powles T, Cassier P, et al. MPDL3280A (anti-PDL1): Clinical activity, safety and biomarkers of an engineered PD-L1 antibody in patients with locally advanced or metastatic tumors. ECC 2013.

Powderly JD, Koeppen H, Hodi FS, et al. Biomarkers and associations with the clinical activity of PD-L1 blockade in a MPDL3280A study. ASCO 2013.

Soria JC, Cruz C, Bahleda R, et al. Clinical activity, safety and biomarkers of PD-L1 blockade in non-small cell lung cancer (NSCLC): Additional analyses from a clinical study of the engineered antibody MPDL3280A (anti-PDL1). ECC 2013.

Spigel DR, Gettinger S, Horn L, et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). ASCO 2013.

(4) 治験実施期間

2011年6月[redacted]日（最初の被験者の登録日）～2014年12月2日（データカットオフ日）

報告書作成時点で本治験の登録は継続中であった。

(5) フェーズ

第 I 相

(6) 目的

1) 主要目的

- 局所進行又は転移性の固形癌患者，あるいは造血器腫瘍患者にアテゾリズマブ（遺伝子組換え）（以下，アテゾリズマブ又は MPDL3280A）を3週間に1回点滴静脈内投与した場合の安全性及び忍容性を評価する。
- アテゾリズマブ単剤を3週間に1回点滴静脈内投与した場合の MTD を決定し，DLT を評価する。

- アテゾリズマブの第 II 相試験推奨用量を決定する。

2) 副次的目的

- 局所進行又は転移性の固形癌患者，あるいは造血器腫瘍患者にアテゾリズマブ単剤を投与した場合の薬物動態を評価する。
- アテゾリズマブに対する抗薬物抗体（ATA）を測定することで，アテゾリズマブが免疫原性となる可能性を調査する。
- 局所進行又は転移性の固形癌患者，あるいは造血器腫瘍患者にアテゾリズマブを投与した場合の抗腫瘍効果を予備的に評価する。

(7) 治験デザイン

本治験は現在も実施中の第 Ia 相多施設共同 first-in-human 非盲検用量漸増試験であり，局所進行又は転移性の固形癌患者，あるいは造血器腫瘍患者にアテゾリズマブ単剤を投与した場合の安全性，忍容性及び薬物動態を評価するために実施された。

(8) 被験者数

目標被験者数：約656～689例
登録被験者数：483例
投与被験者数：481例

(9) 診断及び主な組入基準

組織学的又は細胞学的に治癒不能又は転移性と確認された固形癌患者又は造血器腫瘍患者。

抗悪性腫瘍療法後に悪化し，進行（切除不能）又は再発した，標準的な治癒可能療法が存在しない患者を対象とした。

(10) 被験薬の投与量，投与方法

- 用量漸増

DLT が発現していないことを確認しながら，0.01，0.03，0.1，0.3，1，3，10及び20 mg/kg のアテゾリズマブを，3週間に1回点滴静脈内投与した。アテゾリズマブの中間用量や様々な投与スケジュールを評価した。

- 固定用量

1200 mg/body（15 mg/kg に相当）のアテゾリズマブを，治験責任（分担）医師により臨床的有益性があると判断される限り，忍容できない毒性又は病勢進行に起因する症状悪化が認められるまで若しくは治験実施計画書に規定した投与中止基準に合致するまで，3週間に1回点滴静脈内投与した。

(11) 評価項目

1) 安全性評価項目

有害事象，重篤な有害事象，アテゾリズマブに特徴的な有害事象（AESI），他の明確な要因がなく全身性のステロイドの投与を要した有害事象［免疫介在性の有害事象（imAE）］，DLT，臨床検査値，バイタルサイン，心電図，アテゾリズマブの曝露量，ATA。補正による QT 間隔と曝露量に関する解析については別の報告書に記載した。

2) 薬物動態評価項目

アテゾリズマブ0.01～20 mg/kg を投与した時のサイクル1の薬物動態プロファイルを明らかにするために集中的な薬物動態試料採取を行い，固定用量1200 mg/body 投与時はピーク時及び

トラフ時の試料採取を行った。薬物動態の評価には平均血清中アテゾリズマブ濃度及び適切な薬物動態パラメータ［アテゾリズマブ濃度–時間曲線下面積（AUC），最高血清中アテゾリズマブ濃度（C_{max}），最低血清中アテゾリズマブ濃度（C_{min}），クリアランス（CL），定常状態における分布容積（V_{ss}），消失半減期］を用いることとした。

3) 有効性評価項目

奏効率，奏効期間，最良総合効果，無増悪生存期間（PFS）を，膀胱癌，非小細胞肺癌及び腎細胞癌の被験者では「固形癌の治療効果判定のための規準」（RECIST）v1.1及び免疫関連反応基準（irRC）に基づいて主治医が評価し，10例を超えて登録されたその他の悪性腫瘍の被験者では RECIST v1.1に基づいて主治医が評価した。OS，6カ月 PFS 割合及び1年生存割合も評価した。

(12) 統計的手法

安全性及び有効性の結果は，データカットオフ日までに10例を超えて登録された悪性腫瘍ごとに要約した。安全性の結果はすべての悪性腫瘍を含む全体集団（安全性解析対象集団，481例）でも要約した。薬物動態の結果は，すべての悪性腫瘍を含む全体集団（薬物動態解析対象集団，473例）でも要約した。本治験のデザインは，この被験者集団における安全性，薬物動態及び薬力学の予備的なデータを得るために考えられたもので，検出力や第一種の過誤については考慮していない。

- 安全性：安全性パラメータは記述統計量を用いて要約した。
- 薬物動態：薬物動態パラメータ（AUC，C_{max}，C_{min}，CL，V_{ss}，消失半減期）はノンコンパートメントモデル解析を用いて算出した。また，血清中アテゾリズマブ濃度の平均値，標準偏差及び変動係数を一覧にした。
- 有効性：奏効率及び最良総合効果の推定値及び95%信頼区間（CI）は Clopper-Pearson 法を用いて算出した。悪性腫瘍ごとの奏効期間及び OS の中央値の推定には Kaplan-Meier 法を用い，95%CI の算出には Brookmeyer-Crowley 法を用いた。PFS 及び1年生存割合の推定には Kaplan-Meier 法を用い，95%CI は Greenwood の式を用いて算出した。
- ATA：ATA 分析のための試料は，アテゾリズマブの投与前，投与中及び投与後に採取した。ATA の発現頻度及び ATA 発現状況と薬物動態，有効性及び安全性との潜在的な関連性を評価した。

(13) 試験方法

本報告書は，局所進行又は転移性の固形癌あるいは造血器腫瘍患者にアテゾリズマブを初めて投与した現在実施中の第 Ia 相試験の中間報告書である。本報告書には最初の被験者が登録された日（2011年6月[redacted]日）からデータカットオフ日（2014年12月2日）までに得られたデータの解析結果を記載した。データカットオフ日は，少なくとも12週間の追跡期間が完了した被験者の数が適切な数に達したため選択した。

- 用量漸増ステージ

用量漸増ステージでは，アテゾリズマブの MTD 又は最大許容量（MAD）を決定するために，0.01～20 mg/kg までの8用量（0.01，0.03及び0.1 mg/kg は各1例，0.3，1，3，10及び20 mg/kg は3＋3コホート）について評価した。

- 拡張ステージ

MTD 及び MAD の決定前にアテゾリズマブの忍容性，安全性，薬物動態及び初期有効性等を詳細に評価するために，用量漸増ステージと平行して拡張ステージを実施した。MTD 又は MAD が決定する前の拡張ステージには，アテゾリズマブ10 mg/kg の安全性が最低3例で確認

された後，非小細胞肺癌患者約10例，腎細胞癌患者約10例，悪性黒色腫患者約10例を追加登録し，10 mg/kg 以下のアテゾリズマブを3週間に1回，点滴静脈内投与することとした。

MTD 又は MAD 決定後に，拡張ステージに追加の被験者を登録し，曝露量が MTD 又は MAD の曝露量以下となるように決定した用法用量でアテゾリズマブを投与した。アテゾリズマブの安全性を明らかにし，異なる悪性腫瘍における腫瘍活性のバイオマーカーを評価するため拡張ステージの被験者数を更に増やした。現在進行中の本治験では約656～689例の登録が計画されている。

本治験の用量漸増ステージで固形癌患者に対する安全性及び有効性の予備的な検討結果が得られ，アテゾリズマブ及び他の PD-L1/ programmed death 1（PD-1）抗体で RECIST v1.1に基づく奏効が報告されていることから，対象患者を標準的な治癒可能療法が存在しない転移性又は治癒不能な固形癌患者あるいは造血器腫瘍患者に広げた。

更に，アテゾリズマブ投与によって効果が得られやすい被験者を特定するため，潜在的な腫瘍特性の予測因子［例えば，PD-L1免疫組織化学スコア（IHC スコア）］に基づいて被験者を登録した。

被験者には当初，サイクル1からサイクル16まで又は1年経過するまでのいずれか早い方まで，アテゾリズマブを投与することとしていた。アテゾリズマブの投与は，治験責任（分担）医師により臨床的有益性があると判断される限り，忍容できない毒性又は画像上の病勢進行に起因する症状悪化が認められるまで若しくは治験実施計画書に規定した投与中止基準に合致するまで継続した。

治験実施計画書では，アテゾリズマブの投与終了時点で部分奏効（PR）又は完全奏効（CR）であり，後にサイクル16の終了後2年以内に再発した被験者には，更に16サイクルまでアテゾリズマブの再投与を認めることとしていた。続く治験実施計画書改訂で，投与期間が改訂され，サイクル16を超えても治験責任（分担）医師により臨床的有益性があると判断される限りアテゾリズマブの投与継続を可能とした。

病勢進行（PD）以外の理由（例えば，有害事象）でアテゾリズマブの投与を中止した被験者では，死亡，PD，次の全身的な抗悪性腫瘍療法の開始又は治験終了のいずれかに該当するまで，計画された腫瘍評価を約12週間ごとに継続している。

すべての被験者の生存に関する追跡調査は，同意撤回，追跡不能，死亡又は治験依頼者による治験全体の中止のいずれかに該当するまで実施している。

(14) 結果の要約

1) 安全性

① 全体集団の安全性成績（安全性解析対象集団：481例）

本治験に登録され，いずれかの用量のアテゾリズマブを投与された全被験者（481例）の安全性成績を以下に示す。

- 有害事象は96.9%（466/481例）に認められた。主な事象（発現率20%以上）は，疲労，悪心，食欲減退，発熱，咳嗽，呼吸困難，便秘，下痢及び貧血であった。有害事象の大部分は Grade 1（15.6%）又は Grade 2（34.3%）の事象であった。
- アテゾリズマブの休薬に至った有害事象は18.9%，投与中止に至った有害事象は6.7%に認められた。
- Grade 3の有害事象は38.5%に，Grade 4の有害事象は5.0%に認められた。主な事象（発現率2%以上）は，貧血（4.4%），呼吸困難（3.5%），疲労（2.7%）及び低ナトリウム血症（2.7%）であった。
- Grade 3の副作用は10.8%に，Grade 4の副作用は1.7%に認められた。主な事象（発現率1%以上）は，疲労（1.2%）及び貧血（1.0%）であった。
- 重篤な有害事象は37.8%に認められた。主な事象（発現率1%以上）は，呼吸困難（3.3%），発熱（3.1%），腹痛（1.9%），胸水（1.7%），肺炎（1.7%），疲労（1.5%），低酸素症

（1.2%），疼痛（1.2%），尿路感染（1.2%），背部痛（1.2%），急性腎障害（1.0%）及び貧血（1.0%）であった。

- 重篤な副作用は8.3%に認められた。主な事象（発現率1%以上）は発熱であった。
- AESI は36.2%に認められた。AESI の大部分は Grade 1（20.4%）又は Grade 2（9.8%）の事象であった。主な事象（発現率2%以上）は，発疹（14.8%）及び斑状丘疹状皮疹（3.1%）の皮膚反応，アスパラギン酸アミノトランスフェラーゼ増加（5.6%），アラニンアミノトランスフェラーゼ増加（5.2%），甲状腺機能低下症（4.2%），末梢性ニューロパチー（3.7%），肺臓炎（2.3%），血中ビリルビン増加（2.1%）であった。Grade 3の AESI は4.8%に，Grade 4 の AESI は1.0%に認められた。死亡に至った AESI は1例（0.2%）で認められ，病勢進行に伴うものと考えられる全身性炎症反応症候群であった。
- 死亡は213例（44.3%）で報告され，主なものは，追跡期間中の死亡（例えば，治験実施計画書によるとアテゾリズマブの最終投与から30日を超える死亡は死亡理由を収集しないこととなっているが，死亡日は記録された）（25.2%），病勢進行（14.6%）であった。死亡例の内3例［心肺停止（非小細胞肺癌患者），肺高血圧症（トリプルネガティブ乳癌患者），死亡（トリプルネガティブ乳癌患者）］は治験責任（分担）医師により副作用と判断された。死亡に至った有害事象は3.5%（17/481例）に認められた。

② 非小細胞肺癌コホートの安全性成績（安全性解析対象集団：88例）

非小細胞肺癌コホートに登録され，いずれかの用量のアテゾリズマブを投与された被験者（88例）の安全性成績を以下に示す。

- アテゾリズマブの投与期間の中央値（範囲）は3.47（0.0～32.3）カ月であった。
- 有害事象は98.9%（87/88例）に認められた。主な事象（発現率20%以上）は，悪心，下痢，無力症，便秘，嘔吐，呼吸困難，咳嗽，疲労及び食欲減退であった。有害事象の大部分は Grade 1又は Grade 2の事象であった。
- アテゾリズマブの休薬に至った有害事象は26.1%（23/88例）に認められた。この内1例はサイクル1で骨痛及び低酸素症が認められたが，アテゾリズマブの全予定投与量が投与された。この他に過敏症又は注入に伴う反応によるアテゾリズマブの休薬を要する事象は認められなかった。
- 投与中止に至った有害事象は6.8%（6/88例）に認められ，その内訳は，疲労及び低酸素症，発熱及び倦怠感，心肺停止，突然死，蓄膿，中枢神経系転移が各1例であった。疲労及び低酸素症，発熱及び倦怠感，心肺停止は副作用と考えられた。
- Grade 3の有害事象は30.7%（27/88例）に，Grade 4の有害事象は3.4%（3/88例）に認められた。主な事象は（発現率3%以上）は，呼吸困難（6.8%），疲労（4.5%），低酸素症（3.4%），脱水（3.4%）及び低ナトリウム血症（3.4%）であった。
- Grade 3の副作用は9.1%（8/88例）に，Grade 4の副作用は2.3%（2/88例）に認められた。Grade 3又は4の副作用が認められた主な器官別大分類（SOC）（発現率5%以上）は，「呼吸器，胸郭および縦隔障害」が6.8%（6/88例）であった。
- 重篤な有害事象は40.9%（36/88例）に認められた。主な事象（発現率2%以上）は，呼吸困難（5.7%），低酸素症（3.4%），疲労（3.4%），肺炎（3.4%），胸水，気胸，腹痛，心嚢液貯留，脱水及び大静脈症候群が各2例（2.3%）であった。
- 重篤な副作用は11.4%（10/88例）に認められた。重篤な副作用が認められた主な SOC は，「呼吸器，胸郭および縦隔障害」が8.0%（7/88例）であった。
- AESI は29.5%（26/88例）に認められた。AESI の大部分は Grade 1（18.2%）又は Grade 2（9.1%）であった。主な事象（発現率2%以上）は，発疹（14.8%）及びそう痒性皮疹（4.5%）の皮膚反応，肺臓炎（5.7%），アラニンアミノトランスフェラーゼ増加（2.3%）であった。
- 有害事象発現後30日以内に全身性のステロイドを投与した有害事象は21.6%（19/88例）に認められた。19例の内9例は imAE と考えられ，重症度の内訳は Grade 1が2例（2.3%），Grade

2が3例（3.4%），Grade 3が4例（4.5%）であった。Grade 4又は5の事象は認められなかった。主な事象（発現率2%以上）は，いずれも SOC の「呼吸器，胸郭および縦隔障害」に該当する低酸素症（3.4%）及び肺臓炎（3.4%）であった。

- 死亡は49例（55.7%）で報告された。死亡に至った有害事象は4.5%（4/88例）に認められ，心タンポナーデ，心肺停止，突然死及び肺炎が各1例であった。治験実施計画書によるとアテゾリズマブの最終投与から30日を超える死亡は死亡理由を収集しないこととなっているが，死亡日は記録された。

2) 薬物動態

実投与量で除した $AUC_{0\text{-}21}$/D，C_{max}/D 及び C_{min}/D の幾何平均値は，固定用量の1200 mg（15 mg/kg に相当）を含む1～20 mg/kg の用量範囲で同程度の値であり，線形又は用量依存的な薬物動態を示した。

半減期（投与終了時の試料から算出した）の調和平均は，1～20 mg/kg の各投与群で18.0～26.6日であった。C_{min} 及び C_{max} は徐々に上昇し，サイクル4～8の間に定常状態に到達した。C_{min} 及び C_{max} から算出した蓄積係数の幾何平均の範囲は，それぞれ2.07～2.39と1.21～1.41であった。この蓄積係数の範囲は，推定半減期の幅が同様の薬剤を3週間に1回投与した場合の予測と一致していた。

アテゾリズマブの推定半減期が18.0～26.6日であること及び $AUC_{0\text{-}inf}$ はサイクル1のデータのみから算出した値であることを考慮すると，$AUC_{0\text{-}inf}$，CL 及び V_{ss} の推定値は近似値と考えられる。この点を考慮しても，1～20 mg/kg のアテゾリズマブを投与した時の CL 及び V_{ss} の推定値は，この用量範囲における薬物動態の線形性を示す結果であり，一般的な IgG1抗体の予測値と一致していた。

総合的に考えて，固定用量1200 mg（15 mg/kg に相当）を含む1～20 mg/kg の用量範囲で，アテゾリズマブは線形の薬物動態を示すと考えられた。

3) 有効性

非小細胞肺癌コホートの有効性成績（有効性解析対象集団：88例）を以下に示す。

- OS の追跡期間の中央値は22.5カ月（範囲：0.53*～35.25カ月，*は打切り）であった。
- RECIST v1.1による主治医評価の奏効率は，PD-L1の発現が最も高い，TC スコア（腫瘍細胞の PD-L1発現状況）が3又は IC スコア（腫瘍浸潤免疫細胞の PD-L1発現状況）が3（TC3又は IC3）の被験者集団で50.0%であった。irRC による主治医評価の結果は RECIST v1.1による主治医評価の結果と一致していた。
- PD-L1の発現量が高いほど RECIST v1.1による主治医評価の奏効率が高かった（TC3又は IC3の被験者集団：50.0%，TC3又は IC2/3の被験者集団：37.5%，TC2/3又は IC2/3の被験者集団：33.3%，TC0/1又は IC0/1の被験者集団：12.5%）。
- 未確定を含む最良総合効果での CR + PR の割合は PD-L1の発現状況別に，TC3又は IC3の被験者集団で50.0%，TC3又は IC2/3の被験者集団で40.0%，TC2/3又は IC2/3の被験者集団で35.4%，TC0/1又は IC0/1の被験者集団で15.6%であった。
- RECIST v1.1による主治医評価の奏効期間の中央値は，すべての PD-L1の発現状況別の部分集団で同程度であり（TC3又は IC3の被験者集団：14.6カ月，TC3又は IC2/3の被験者集団：17.3カ月，TC2/3又は IC2/3の被験者集団：17.3カ月，TC0/1又は IC0/1の被験者集団：18.2カ月），持続性があった。
- RECIST v1.1による主治医評価の PFS の中央値は，PD-L1の発現状況別に TC3又は IC3の被験者集団で7.0カ月，TC3又は IC2/3の被験者集団で3.5カ月，TC2/3又は IC2/3の被験者集団で2.8カ月，TC0/1又は IC0/1の被験者集団で4.8カ月であった。
- OS の中央値は，PD-L1の発現状況別に TC3又は IC3の被験者集団で17.9カ月，TC3又は IC2/3の被験者集団で19.5カ月，TC2/3又は IC2/3の被験者集団で17.9カ月，TC0/1又は IC0/1の被験

者集団で14.2カ月であった。1年生存割合は，TC3又は IC3の被験者集団で70.33%（22例），TC3又は IC2/3の被験者集団で72.96%（40例），TC2/3又は IC2/3の被験者集団で66.24%（48例），TC0/1又は IC0/1の被験者集団で56.71%（32例），全体集団で63.1%であった。

4) ATA の結果

ベースライン時に ATA が陽性であった被験者は全体集団の3.1%であった。アテゾリズマブの投与後に，139/439例（31.7%）でアテゾリズマブ投与に関連する ATA が認められた。139例の内136例はアテゾリズマブ投与により ATA が誘発された（ベースライン時には ATA 陰性であったが，アテゾリズマブの投与後に ATA 陽性となった）被験者，3例はアテゾリズマブ投与により ATA が増幅された（ベースライン時も ATA 陽性であったが，アテゾリズマブの投与後に抗体価が0.60以上増幅した）被験者であった。

ATA がアテゾリズマブの薬物動態に与える影響という点では，ATA 陽性例で曝露量が低い傾向が認められたが，10 mg/kg 以上の用量範囲では C_{min} の幾何平均値は一貫して定量下限値及び目標トラフ濃度（6 μg/mL）を超えていた。低用量（0.3，1及び3 mg/kg）群で ATA が陽性の被験者では，アテゾリズマブの3週間に1回反復投与後に C_{min} の定量下限値未満への低下がみられた。

非小細胞肺癌コホートにおいて，ATA 陰性例と ATA 陽性例の人口統計学的特性に不均衡は認められず，dose intensity の中央値も同程度であった。

非小細胞肺癌コホートにおいて，ATA 発現状況による奏効率及び奏効期間の臨床的に意義のある差異は認められなかった。AESI の発現頻度から，ATA 陰性例と ATA 陽性例の安全性プロファイルは同様と考えられた。

(15) 結論

1) 安全性

① 全体集団

いずれのコホートでも疲労が最も高頻度に，続いて食欲減退，悪心，発熱が認められた。MTD には到達せず，DLT は発現しなかった。また，用量依存的な有害事象の発現頻度の増加も認められなかった。アテゾリズマブ投与により発現した免疫介在性有害事象には，発疹，甲状腺機能低下症，インフルエンザ様症候群，肺臓炎，大腸炎及び肝炎／トランスアミナイティスがあった。全体を通して，報告された有害事象は既知のアテゾリズマブの作用機序又は原疾患の癌に起因する事象と一致するものであった。

② 非小細胞肺癌コホート

非小細胞肺癌コホートにおいて，有害事象の大部分は原疾患である癌に関連する事象と考えられ，アテゾリズマブ投与の忍容性は良好であった。アテゾリズマブの投与中止に至った有害事象の発現はわずかであった。免疫介在性有害事象からなる AESI は，大部分が Grade 1又は2の事象であり，管理可能であった。

2) 薬物動態

固定用量1200 mg（15 mg/kg に相当）を含む1～20 mg/kg の用量範囲で，アテゾリズマブの薬物動態は線形であった。固定用量1200 mg を含む1～20 mg/kg の各投与群で，推定半減期は18.0～26.6日であった。1 mg/kg 以上のアテゾリズマブを3週間に1回投与した被験者では，C_{min} はサイクル4までに定常状態に到達していると考えられ，サイクル4～8までの C_{min} から算出した蓄積係数の幾何平均の範囲は2.07～2.39であった。低用量（0.3～3 mg/kg）のアテゾリズマブを3週間に1回投与し ATA が陽性となった被験者では，C_{min} の定量下限値未満への低下がみられたが，固定用量1200 mg を含む10～20 mg/kg のアテゾリズマブを3週間に1回投与した被験者では，C_{min} の幾何平均値は定量下限値及び目標トラフ濃度を超える値で維持された。非臨床試験及びこれまでに得られた本治験の臨床成績から，固定用量1200 mg（15 mg/kg に相当）を第

II 相試験推奨用量と決定した。

3) 有効性

抗悪性腫瘍療法後に進行した治癒不能又は転移性の非小細胞肺癌患者にアテゾリズマブを投与したところ，PD-L1の発現が最も高い，TC3又は IC3の被験者集団で RECIST v1.1による主治医評価の奏効率は50.0%（95%CI：28.22～71.78%，11/22例）であった。奏効期間の中央値はTC3又は IC3の被験者集団で14.6カ月と持続性が認められた。irRC による主治医評価の結果は RECIST v1.1による主治医評価の結果と一致していた。PD-L1の発現が高いほど RECIST v1.1による主治医評価の奏効率は高かった。

前治療数の多いこの対象集団で，PD-L1の発現状況と奏効率との間に関連があり，PD-L1の発現が高いほど RECIST v1.1による主治医評価の奏効率が高かった。irRC による主治医評価の奏効率は RECIST v1.1による主治医評価の奏効率と一致していた。効果は持続性があり，奏効期間の中央値は少なくとも15カ月であった。RECIST v1.1による主治医評価の PFS の中央値は，TC3又は IC3の被験者集団で7.0カ月，TC3又は IC2/3の被験者集団で3.5カ月，TC2/3又は IC2/3の被験者集団で2.8カ月と過去の報告とも遜色のない結果であった。全体集団の OS の中央値は少なくとも18カ月，1年生存割合は63.1%と過去の報告とも遜色のない結果であった。

4) ATA

アテゾリズマブの投与後に ATA 陽性であった被験者は全体集団の31.7%であった。ATA の発現状況はアテゾリズマブの薬物動態に臨床的に意義のある影響を与えなかった。非小細胞肺癌患者において，ATA の発現状況はアテゾリズマブの有効性及び安全性に臨床的に意義のある影響を与えなかった。

(16) 報告書作成日

[redacted]年[redacted]月

2.7.6.1.2 JO28944試験

(1) 試験の標題

MPDL3280A の進行固形癌患者を対象とした第 I 相臨床試験

(2) フェーズ

第 I 相

(3) 治験依頼者／実施地域

中外製薬株式会社／国内2施設

(4) 治験実施期間

2013年[redacted]月[redacted]日（最初の患者の同意日）～2014年11月15日（データカットオフ日）

(5) 目的

進行固形癌患者を対象として，アテゾリズマブの安全性，忍容性及び薬物動態を検討する。

(6) 対象患者

組織学的又は細胞学的に固形癌であることが確認された20歳以上の患者で，Eastern Cooperative Oncology Group（ECOG）Performance Status（PS）が0～1の患者を対象とした。

(7) 被験者数

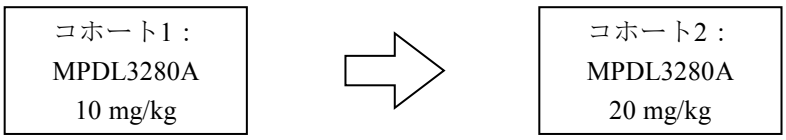
目標被験者数：6～12例（コホート1：アテゾリズマブ10 mg/kg，コホート2：アテゾリズマブ20 mg/kg，各コホート3～6例）
登録被験者数：6例（コホート1：3例，コホート2：3例）
投与被験者数：6例（コホート1：3例，コホート2：3例）

(8) 試験方法

本治験は，アテゾリズマブ単剤による忍容性の検討を行う。本治験の対象は標準的治療法が無効又は標準的治療法が確立していない固形癌患者であるため，DLT 評価期間以降も中止基準に抵触するまで3週間を1サイクルとして投与を継続することができる。サイクル2以降の投与については，サイクル1 Day 15の検査・観察終了後からサイクル2 Day 1の投与開始までに治験継続に関する再同意を取得した上で実施する。

本治験では，図 2.7.6.1.2-1に示すように2つのコホート（コホート1：アテゾリズマブ10 mg/kg，コホート2：アテゾリズマブ20 mg/kg）を設定する。

図 2.7.6.1.2-1 本治験のデザイン



［5.3.3.2-2 図 9.1.2.3-1を再掲］

(9) 治療期間

各被験者の治験期間は，同意取得日から治験薬最終投与後30日までとした。ただし，治験薬最終投与後30日以内に他治療に移行する場合は他治療開始前日まで，転院や被験者都合等の理由により来院が困難になった場合は最終来院日までを治験期間とした。

(10) 被験薬，投与量，投与方法

各被験者のアテゾリズマブの1回投与量は，登録されたコホートごとに決定した。

- コホート1：10 mg/kg
- コホート2：20 mg/kg

アテゾリズマブの初回投与量（サイクル1）は，初回投与前の14日以内に測定された体重に基づき決定した。

3週間を1サイクルとし，各サイクルの Day 1にアテゾリズマブの点滴静注を行った。

(11) 併用薬，投与量，投与方法

該当しない。

(12) 対照治療，投与量，投与方法

該当しない。

(13) 評価基準

1) 主要評価項目

有害事象，DLT の発現プロファイル

2) 副次的評価項目

- MTD
- 薬物動態
- 免疫原性
- 腫瘍縮小効果

(14) 統計的手法

1) 被験者特性

コホートごとに被験者背景を集計し，集計した被験者集団の特徴を示す。

2) 安全性

有害事象を医薬品規制調和国際会議国際医薬用語集（MedDRA）コードを用いて読み替え，SOC と基本語（PT）で定義された事象別に発現者数，発現件数を集計する。この内，治験薬との因果関係が否定できないものについては副作用として別途発現者数，発現件数を集積する。臨床検査値等の推移はデータの要約（記述統計）とともに個別推移を検討する。

3) 薬物動態

コホートごとに血清中アテゾリズマブ濃度の一覧表を作成するとともに要約統計量を算出し，推移図を作成する。アテゾリズマブの薬物動態パラメータ（AUC，C_{max}，C_{min}，CL 等）を算

出する。

4) 有効性

コホートごとに，RECIST ver.1.1に基づく腫瘍縮小効果等の一覧を示す。

5) 免疫原性

ATA 発現頻度に関して一覧表を作成する。

6) 探索的評価

腫瘍組織中 PD-L1発現，血液中の T，B，NK 細胞数及び Fcγ レセプターIII 遺伝子多型について一覧を示し，必要に応じて要約等を行い探索的に検討する。

(15) 結果の要約

1) 薬物動態

- 血清中アテゾリズマブ濃度のサイクル1のトラフ値（平均値 ± 標準偏差）は，コホート1及びコホート2でそれぞれ36.8 ± 1.35及び113 ± 11.3 μg/mL であり，サイクル3以降のトラフ値は，それぞれ84.6～179及び232～292 μg/mL で推移した。
- コホート1及びコホート2の CL，V_d 及び $t_{1/2}$はほぼ同じ値を示した。
- 初回投与時の消失速度定数から求めた累積係数（R_{kel}）と実測の累積係数は大きく異ならなかった。

2) 有効性

- 登録された全6例で RECIST ver.1.1による腫瘍縮小効果の評価が可能であった。
- 最良総合効果が確定した3例の最良総合効果は，いずれも病勢安定（SD）であった。また，治験薬投与継続中である3例の総合効果は，いずれも SD で継続していた。
- PFS が12カ月を超えた被験者は，6例中3例（コホート1で2例，コホート2で1例）であった。

3) 安全性

- 本治験に登録された6例全例に治験薬が投与され，安全性評価対象集団は6例であった。
- 投与期間の中央値（範囲）は，コホート1で53.90（13.1～61.1）週，コホート2で56.10（12.1～56.9）週であった。
- DLT に該当する有害事象は認められず，今回検討した用量では MTD に到達しなかった。
- 有害事象は6例中6例に42件（コホート1：24件，コホート2：18件）発現し，この内30件（コホート1：19件，コホート2：11件）が副作用であった。6例中2例以上に発現した有害事象は，発疹（3例），下痢（2例），アスパラギン酸アミノトランスフェラーゼ増加（2例），アラニン･アミノトランスフェラーゼ増加（2例），血中アルカリホスファターゼ増加（2例），頭痛（2例）であり，これらは下痢の1例を除きすべて副作用であった。Grade 3以上の有害事象は認められなかった。
- 治験期間中の死亡は認められなかった。
- 重篤な有害事象は，6例中1例に認められた。その内訳は，コホート1でインフルエンザ様疾患が1例であり，治験薬との因果関係は否定されなかった。
- 治験薬の投与中止に至った有害事象は認められなかった。
- 治験薬の休薬に至った有害事象は，6例中3例に認められた。その内訳は，コホート1でインフルエンザ様疾患及び血中アルカリホスファターゼ増加が各1例，コホート2で肺炎が1例であった。肺炎以外は治験薬との因果関係が否定されなかった。
- Infusion reaction は6例中3例に認められた。その内訳は，コホート1で頭痛及びそう痒症が各1例，コホート2でリンパ球数減少が1例であった。

(16) 結論

進行固形癌患者において，アテゾリズマブの10 mg/kg 又は20 mg/kg（3週間に1回）投与は忍

容可能であることが確認された。また，用量による CL の変動や異常な蓄積性は認められなかった。最良総合効果が確定した3例はいずれも SD であり，PFS が12カ月を超えた被験者は6例中3例であった。

(17) 報告書作成日
[redacted]年[redacted]月[redacted]日

2.7.6.1.3 OAK 試験

(1) 試験の標題

A Phase III, Open-label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared with Docetaxel in Patients with Non-small Cell Lung Cancer after Failure with Platinum-containing Chemotherapy (OAK)

プラチナ製剤併用化学療法歴を有する非小細胞肺癌患者を対象に，ATEZOLIZUMAB（抗PD-L1抗体）の有効性及び安全性をドセタキセルと比較する，第 III 相多施設共同非盲検ランダム化試験（OAK）

(2) 治験依頼者／実施地域

Roche 社／31カ国，194施設

(3) 公表

Rittmeyer et al. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. Lancet. 2016 Dec 12.

Gadgeel et al. OAK, a randomized Ph III study of atezolizumab vs docetaxel in patients with advanced NSCLC: results from subgroup analyses. Presented at: 17th World Congress of Lung Cancer. Vienna, Austria. December 4−7, 2016.

(4) 治験実施期間

最初の被験者の割付日：2014年3月11日

主要解析対象集団（PP，初めにランダム化された850例と定義）の最後の被験者の割付日：2014年11月28日

副次的解析対象集団（SP，全1225例と定義）の最後の被験者の割付日：2015年4月29日

データカットオフ日：2016年7月7日

(5) フェーズ

第 III 相

(6) 目的

1) 有効性に関する目的

① 有効性に関する主要目的

- プラチナ製剤併用化学療法の施行中又は施行後に増悪した局所進行／転移性非小細胞肺癌患者に対するアテゾリズマブの投与が，ドセタキセルと比較して OS の延長をもたらすかどうかを検討する。

② 有効性に関する副次的目的

- 抗腫瘍効果として RECIST v1.1を用いた PFS（主治医評価）を評価し，アテゾリズマブの有効性をドセタキセルと比較する。
- 抗腫瘍効果として RECIST v1.1を用いた奏効率（主治医評価）を評価し，アテゾリズマブの

有効性をドセタキセルと比較する。
- 抗腫瘍効果として奏効が得られた被験者における RECIST v1.1により判定する奏効期間を評価し，アテゾリズマブの有効性をドセタキセルと比較する。

2) 安全性
- アテゾリズマブの安全性と忍容性をドセタキセルと比較する。
- アテゾリズマブに対する ATA の発現率を評価する。また，免疫原性反応と薬物動態，安全性，有効性との関連性を探索する。

3) 薬物動態
- アテゾリズマブの薬物動態の特性を調べる。

4) 患者報告アウトカム
- EORTC の QOL 質問票 Core 30（QLQ-C30）及び肺癌モジュール（QLQ-LC13）で測定される患者報告に基づく肺癌症状（咳嗽，呼吸困難［単項目及び複数項目の尺度評価］，胸痛，腕／肩痛）において無悪化期間を測定することで，ドセタキセルと比較したアテゾリズマブの効果を測定する。
- 肺癌の症状，被験者の機能，健康関連の生活の質（HRQoL）についての患者報告アウトカムを，EORTC QLQ-C30及び EORTC QLQ-LC13を用いて評価し，治療群間で比較する。

(7) 治験デザイン

第 III 相多施設共同非盲検ランダム化試験。

ランダム化の際，腫瘍浸潤免疫細胞の PD-L1発現（IC0，IC1，IC2及び IC3），過去に受けた化学療法レジメン数（1又は2）及び組織型（非扁平上皮癌又は扁平上皮癌）を割付因子とした。

(8) 被験者数

本治験は当初，850例の被験者を登録する計画であった。後に，TC3又は IC3の被験者集団（20%の割合で存在と仮定）の OS の比較の検出力を上げるため，登録可能な被験者数を1300に増やし，最終的には1225例（ドセタキセル群612例，本剤群613例）の被験者を登録した。

POPLAR 試験の結果に基づき，PP 全体，及び，PP の TC1/2/3又は IC1/2/3の部分集団の OS を検定するため，事前に規定した modification plan に基づき本治験の解析計画を変更した。PP には，ドセタキセル群に425例，本剤群に425例の被験者が割り付けられた。

(9) 診断及び主な組入基準
- 組織学的又は細胞学的に確認された局所進行又は転移性非小細胞肺癌（Stage IIIb，IV 又は再発）
- 局所進行又は転移性非小細胞肺癌に対し，殺細胞性化学療法による治療を1レジメン又は2レジメン受けており，受けた治療に1つ以上プラチナ製剤が含まれる
- PD-L1発現状況は問わない

(10) 被験薬の投与量，投与方法

臨床的有益性が認められなくなるまで，アテゾリズマブ1200 mg を3週間に1回投与した。

(11) 対照薬の投与量，投与方法

病勢進行又は忍容できない毒性が発現するまで，ドセタキセル75 mg/m^{2}を3週間に1回投与した。

(12) 評価項目

1) 有効性

有効性は PP の結果に基づき評価した。

① 主要有効性評価項目

- OS

② 副次的有効性評価項目

- PFS（RECIST v1.1，主治医評価）
- 奏効率（RECIST v1.1，主治医評価）
- 奏効期間（RECIST v1.1，主治医評価）

2) 薬物動態

- 血清中アテゾリズマブ濃度（スパースサンプリング）

3) 安全性

安全性は安全性評価対象集団（少なくとも1回以上治験薬の投与を受けた，すべてのランダム化された被験者）

- 有害事象，臨床検査値，AESI，imAE

(13) 統計的手法

Kaplan-Meier 法を使用して各治療群の OS 中央値を推定し，生存曲線を作成して治療群間の差を視覚的に比較した。Brookmeyer-Crowley 法を使用して，各治療群の OS 中央値の95%CI を算出した。層化調整ハザード比（HR）及び非調整 HR（95%CI 含む）は Cox 回帰モデルを用いて推定した。

第1種の過誤を調整するため，主要評価項目では，PP 全体集団と TC1/2/3又は IC1/2/3で，α を分割した。

(14) 試験方法

同意取得後，適格患者はドセタキセル群又は本剤群のいずれかに，1：1の割合でランダム化された。ランダム化の際，腫瘍浸潤免疫細胞の PD-L1発現（IC0，IC1，IC2及び IC3），過去に受けた化学療法レジメン数（1又は2）及び組織型（非扁平上皮癌又は扁平上皮癌）を割付因子とした。被験者は，病勢進行又は忍容不可能な毒性発現まで（ドセタキセル群），若しくは臨床的利益の消失まで（本剤群），ないしは治験依頼者による治験中止まで，本剤又はドセタキセル群の投与を受けた。

RECIST v1.1による腫瘍評価を，ベースライン時，6週目，及びその後は6週ごとに（約2サイクルに1回），ランダム化の36週間後まで実施した。ランダム化から36週間後にも病勢進行が認められなかった被験者には，9（±1）週ごとに，死亡又は追跡不能まで，腫瘍評価を実施した。

ドセタキセル群の被験者に対しては，ドセタキセルの継続/中止に関わらず，評価を RECIST v1.1に基づく病勢進行まで継続した。本剤群の被験者に対しては，病勢進行（本剤を中止した被験者）又は治療中止（病勢進行後も本剤を継続した被験者）まで，評価を継続した。病勢進行が認められない場合は，被験者が次の抗腫瘍治療を開始したかに関わらず，同意撤回まで腫瘍評価を継続した。

次の抗腫瘍治療を含むフォローアップデータの収集は，被験者の死亡，追跡不能，同意撤回，治験依頼者による治験中止のいずれか早い時期まで継続した。

有害事象の収集は，治験薬最終投与後30日又は次の抗腫瘍治療の開始のいずれか早い時期ま

で行った。その後は，死亡，重篤な有害事象，治験薬との因果関係があると考えられた有害事象を記録した。

(15) 結果の要約

1) 人口統計学的特徴及び患者背景

PP850例では，人口統計学的特徴及び疾患背景は両群で均衡していた。主だった被験者は白人（70.4%），男性（61.2%）であり，年齢の中央値は64歳であった。多くの被験者は非扁平上皮癌（73.9%）であり，前化学療法数は1（75.3%），ECOG PS は1（62.9%），喫煙歴あり（66.8%）で，ベースライン時に脳転移巣を有しなかった（90.0%）。

2) 有効性

主要解析時（PAT）のデータカットオフは，PP で569の死亡イベントが発生した2016年7月7日に行った。

有効性の結果の概要を表 2.7.6.1.3-1に示す。

本治験では，PP 全体及び PP の TC1/2/3又は IC1/2/3の部分集団の両方で，主要評価項目である OS が，ドセタキセル群に対し本剤群で統計学的に有意かつ臨床的に意義のある改善を示した。いずれの PD-L1発現別の部分集団でも（TC0及び IC0を含む）臨床的に意義のある治療効果が認められた（最も明白な治療効果は TC3又は IC3でみられた）。本剤による OS の改善は，非扁平上皮癌，扁平上皮癌，ベースライン時に脳転移巣あり，喫煙歴なしの集団を含む，多くの部分集団で認められた。EGFR 遺伝子変異を有する被験者集団では，ドセタキセルと比較した本剤での OS 改善はみられなかった。

PFS 及び奏効率は PP の両群で同様であったが，本剤群の奏効期間はドセタキセル群と比較して十分に長かった。

表 2.7.6.1.3-1 OAK 試験の有効性成績の概要（PP）

項目	ドセタキセル群	本剤群
主要評価項目: OS		
ITT 集団	n = 425	n = 425
OS イベント（%）	298 (70.1%)	271 (63.8%)
OS 中央値（月）	9.6	13.8
95%CI	(8.6～1.2)	(11.8～15.7)
Stratified HR（95%CI）	0.73 (0.62～0.87)	
P 値（層別 log-rank 検定）	0.0003	
TC1/2/3又は IC1/2/3の被験者集団	n = 222	n = 241
OS イベント（%）	149 (67.1%)	151 (62.7%)
OS 中央値（月）	10.3	15.7
95%CI	(8.8～12.0)	(12.6～18.0)
Stratified HR（95%CI）	0.74 (0.58～0.93)	
P 値（層別 log-rank 検定）	0.0102	
副次的評価項目		
PFS		
ITT 集団	n = 425	n = 425
PFS イベント（%）	375 (88.2%)	380 (89.4%)
PFS 中央値（月）	4.0	2.8
95%CI	(3.3～4.2)	(2.6～3.0)
Stratified HR（95%CI）	0.95 (0.82～1.10)	
TC1/2/3又は IC1/2/3の被験者集団	n = 222	n = 241
PFS イベント（%）	193 (86.9%)	216 (89.6%)
PFS 中央値（月）	4.1	2.8
95%CI	(2.9～4.3)	(2.6～4.0)
Stratified HR（95%CI）	0.91 (0.74～1.12)	

項目	ドセタキセル群	本剤群
奏効率		
ITT 集団	n = 425	n = 425
奏効被験者数（%）	57 (13.4%)	58 (13.6%)
95%CI（Clopper-Pearson）	(10.32～17.02)	(10.53～17.28)
TC1/2/3又は IC1/2/3の被験者集団	n = 222	n = 241
奏効被験者数（%）	36 (16.2%)	43 (17.8%)
95%CI（Clopper-Pearson）	(11.62～21.74)	(13.22～23.27)
奏効期間		
ITT 集団	n = 57	n = 58
奏効期間中央値（月）	6.2	16.3
95%CI	(4.9～7.6)	(10.0～推定不能)
Unstratified HR（95%CI）	0.34 (0.21～0.55)	
TC1/2/3又は IC1/2/3の被験者集団	n = 36	n = 43
奏効期間中央値（月）	6.2	16.0
95%CI	(4.9～9.2)	(9.7～推定不能)
Unstratified HR（95%CI）	0.38 (0.22～0.65)	

［5.3.5.1-1 Table 23を改変］

3) 薬物動態

アテゾリズマブ1200 mg/body の3週間に1回投与で，C_{min} の平均値は4～8サイクルの間に定常状態に到達することが明らかとなった。C_{min} の幾何平均値は，サイクル1の74.9 μg/mL からサイクル8の183 μg/mL まで上昇した。

4) 安全性

本治験の本剤群の安全性の結果は，既知の安全性プロファイルと一致しており，いずれのPD-L1発現別の部分集団でも，組織型別の部分集団でも同様であった。新たな安全性のシグナルは特定されなかった。有害事象と AESI の概要を表 2.7.6.1.3-2及び表 2.7.6.1.3-3に示す。

治験薬の投与中止に至った有害事象の発現率が低かったことから，アテゾリズマブの忍容性はドセタキセルよりも良好であった。重症な（Grade 3～4の）有害事象は本剤群よりもドセタキセル群の患者で多かった。Grade 5の有害事象の発現率（治験薬最終投与後30日まで）は両群で同様であった。本剤群でみられたすべての Grade 5の有害事象は，本剤との因果関係はないと考えられた。ドセタキセル群と比較して本剤群では AESI が多くみられたが，両群の大部分の AESI の重症度は軽度～中等度であった。imAE の発現率は両群で同等であった。大部分の imAE の重症度は軽度～中等度であった。

表 2.7.6.1.3-2 OAK 試験の有害事象の概要

Safety Summary, Adverse Event Profile Table
All Safety Evaluable Patients
Protocol: GO28915 (Data Cut: 7JUL2016)

	Docetaxel (Actual) (N=578)	Atezolizumab (Actual) (N=609)	All Patients (N=1187)
Total number of patients with at least one adverse event	555 (96.0%)	573 (94.1%)	1128 (95.0%)
Total number of events	5905	5225	11130
Total number of patients with at least one			
Treatment-related AE	496 (85.8%)	390 (64.0%)	886 (74.6%)
Grade 3-4 AE	310 (53.6%)	227 (37.3%)	537 (45.2%)
Treatment-related Grade 3-4 AE	247 (42.7%)	90 (14.8%)	337 (28.4%)
Grade 5 AE	14 (2.4%)	10 (1.6%)	24 (2.0%)
Treatment-related Grade 5 AE	1 (0.2%)	0	1 (<0.1%)
Serious Adverse Event	181 (31.3%)	194 (31.9%)	375 (31.6%)
AE leading to withdrawal from treatment	108 (18.7%)	46 (7.6%)	154 (13.0%)
AE leading to dose modification/interruption	210 (36.3%)	152 (25.0%)	362 (30.5%)

Only events reported in the Adverse Events Form are included.
Investigator text for AEs encoded using MedDRA v19.0. Percentages are based on N in the column headings. Multiple occurrences of the same AE in one individual are counted only once except for "Total number of events" row in which multiple occurrences of the same AE are counted separately.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692h/s28915g/t_aet01.sas / Output:
/opt/BIOSTAT/prod/cdt7692h/s28915g/reports/t_aet01_SE.out
25SEP2016 1:24

[5.3.5.1-1 Table 54 (a)を再掲]

表 2.7.6.1.3-3 OAK 試験の AESI の概要

Safety Summary, Adverse Event Profile Table Without 30-day Window
All Safety Evaluable Patients
Protocol: GO28915 (Data Cut: 7JUL2016)

	Docetaxel (Actual) (N=578)	Atezolizumab (Actual) (N=609)	All Patients (N=1187)
Total number of patients with at least one adverse event	555 (96.0%)	575 (94.4%)	1130 (95.2%)
Total number of events	5950	5278	11228
Total number of patients with at least one			
Treatment-related Serious Adverse Event	102 (17.6%)	63 (10.3%)	165 (13.9%)
Adverse Event of Special Interest of Any Grade	132 (22.8%)	184 (30.2%)	316 (26.6%)
Adverse Event of Special Interest of Grade 3-4	14 (2.4%)	31 (5.1%)	45 (3.8%)
AE of Special Interest Medical Concepts: patients with at least one			
Dermatologic	60 (10.4%)	88 (14.4%)	148 (12.5%)
Neurologic	68 (11.8%)	28 (4.6%)	96 (8.1%)
Hepatic	15 (2.6%)	50 (8.2%)	65 (5.5%)
Endocrine	2 (0.3%)	34 (5.6%)	36 (3.0%)
Pulmonary	4 (0.7%)	11 (1.8%)	15 (1.3%)
Gastrointestinal	2 (0.3%)	2 (0.3%)	4 (0.3%)
Ocular	0	4 (0.7%)	4 (0.3%)
Musculoskeletal and Joint	0	4 (0.7%)	4 (0.3%)
Cardiac	0	2 (0.3%)	2 (0.2%)
Other Non-specific Immune	0	2 (0.3%)	2 (0.2%)
Renal	0	1 (0.2%)	1 (<0.1%)

Only events reported in the Adverse Events Form are included.
Investigator text for AEs encoded using MedDRA v19.0. Percentages are based on N in the column headings. Multiple occurrences of the ame AE in one individual are counted only once except for "Total number of events" row in which multiple occurrences of the same AE are counted separately.
AEs collected after first treatment dose are included.
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692h/s28915g/t_aet01_trtem.sas
Output: /opt/BIOSTAT/prod/cdt7692h/s28915g/reports/t_aet01_trtem_SE.out
12OCT2016 2:37

[5.3.5.1-1 Table 54 (b)を再掲]

5) 免疫原性

薬剤投与により出現する ATA の発現割合は本剤投与を受けた被験者の30.4%であった。ATA

の存在は，薬物動態に対し臨床的に関連する影響を及ぼさなかったが，ATA 陰性の被験者集団と比較して ATA 陽性の被験者集団では C_{min} の値は数字上は低かった。しかし，ATA 陽性の被験者集団でも C_{min} は目標血清中濃度を上回っていた。OS，PFS，奏効率及び奏効期間の ATA 別の部分集団の結果から，ATA の発現は有効性に対し臨床的に関連する影響を及びさなかった。有害事象及び AESI の結果から，ATA 陽性集団と ATA 陰性集団の安全性プロファイルも同様であった。

6) 患者報告アウトカム

EORTC QLQ-C30によって計測された全般的な健康状態と機能スコア（肉体，役割，社会，感情及び認知）は，両群ともに，臨床的に意義のある経時的な悪化を示さなかった。このことから，治験治療中の被験者の HRQoL と患者報告機能スコアは維持されていたことが示唆された。

本剤群の被験者では，抗腫瘍治療に伴う一般的な症状（疲労，悪心/嘔吐，下痢，便秘，脱毛，末梢性ニューロパチー及び口内炎）の臨床的に意義のある悪化はみられず，ドセタキセル群の被験者では，治療期間中に，脱毛と末梢性ニューロパチーに臨床的に意義のある悪化が認められた。

患者報告による胸痛の，悪化するまでの期間は，ドセタキセル群と比較して本剤群で著しく長かった。他の肺癌関連症状（EORTC QLQ-LC13で計測される咳嗽，呼吸困難，腕/肩痛）の，悪化するまでの時間は，両群で同様であった。

(16) 結論

- 本治験では，PP 全体及び PP の TC1/2/3又は IC1/2/3の部分集団の両方で，主要評価項目である OS が，二次治療及び三次治療の非小細胞肺癌患者のドセタキセル群に対し本剤群で統計学的に有意かつ臨床的に意義のある改善を示した。
- いずれの PD-L1発現別の部分集団でも（TC0及び IC0を含む）臨床的に意義のある OS の改善が認められた（最も明白な治療効果は TC3又は IC3でみられた）。
- 本剤による OS の改善は，年齢，性別，人種，ECOG PS，前治療数，脳転移巣の有無，喫煙歴及び肺癌の組織型を含む，多くの部分集団で認められた。EGFR 遺伝子変異を有する被験者集団では，ドセタキセルと比較して本剤での OS 改善はみられなかった。
- PFS 及び奏効率は PP の両群で同様であった。TC3又は IC3の部分集団では，ドセタキセル群と比較して，本剤群で PFS と奏効率の改善がみられたが，他の閾値での PD-L1発現別の集団では PFS と奏効率の改善はみられなかった。
- 本剤群の奏効期間はドセタキセル群と比較して二倍以上長く，いずれの PD-L1発現別の部分集団でも奏効期間の改善が認められた。
- アテゾリズマブの C_{min} は経時的に上昇し，1200 mg を3週間に1回静脈内投与した場合，アテゾリズマブの C_{min} はサイクル4～8の間に定常状態に達した。
- 薬剤投与により出現する ATA の発現割合は本剤投与を受けた被験者の30.4%であった。ATA の発現は薬物動態，有効性及び安全性に臨床的に関連する影響を及ぼさなかった。
- 本剤群の安全性の結果は，既知のアテゾリズマブの安全性プロファイルと一致していた。新たな安全性シグナルは認められなかった。アテゾリズマブの忍容性はドセタキセルより良好であった。免疫関連毒性は一般的に頻度は少なく重症度も低かった。いずれの PD-L1発現別の部分集団でも，組織型別の部分集団でも，安全性プロファイルは同様であった。
- 患者報告による胸痛の，悪化するまでの期間は，ドセタキセル群と比較して本剤群で長かった。他の肺癌関連症状（EORTC QLQ-LC13で計測される咳嗽，呼吸困難，腕/肩痛）の，悪化するまでの時間は，両群で同様であった。
- 病勢進行後も本剤の投与を継続することは，安全性リスクを増加させず，利益をもたらした。
- 二次治療以降の非小細胞肺癌に対する本剤の単剤治療は，PD-L1発現レベルに関わらずすべ

ての患者に臨床的に意義のあるベネフィットをもたらし，リスク・ベネフィット比はドセタキセルよりも良好であった。

(17) 報告書作成日
[redacted]年[redacted]月

2.7.6.1.4 POPLAR 試験

(1) 試験の標題

A Phase II, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of MPDL3280A (Anti-PD-L1Antibody) Compared with Docetaxel in Patients with Non-Small Cell Lung Cancer after Platinum Failure

プラチナ化学療法に不応となった非小細胞肺癌患者を対象に，MPDL3280A（抗 PD-L1抗体）の有効性及び安全性をドセタキセルと比較した非盲検多施設共同ランダム化第 II 相臨床試験

(2) 治験依頼者／実施地域

Roche 社／13カ国，61施設（米国26施設，フランス5施設，ポーランド4施設，ドイツ4施設，スペイン4施設，イギリス4施設，韓国3施設，タイ3施設，トルコ2施設，カナダ2施設，イタリア2施設，ベルギー1施設，スウェーデン1施設）

(3) 治験実施期間

最初の被験者の割付日：2013年8月5日
最後の被験者の割付日：2014年3月31日
データカットオフ日：2015年5月8日（主要解析）

(4) フェーズ

第 II 相

(5) 目的

1) 有効性

① 主要目的

- OS により，ドセタキセルと比較したアテゾリズマブの有効性を推定する。

② 副次的目的

- RECIST v1.1に基づく総合効果，奏効期間及び PFS により測定される抗腫瘍効果について，ドセタキセルと比較したアテゾリズマブの有効性を評価する。
- Modified RECIST に基づく総合効果，奏効期間及び PFS により測定される抗腫瘍効果について，アテゾリズマブの有効性を評価する。

2) 安全性

- ドセタキセルと比較したアテゾリズマブの安全性及び忍容性を評価する。
- アテゾリズマブに対する ATA の発現率を評価し，免疫原性反応と薬物動態，安全性及び有効性との潜在的な関連性を探索する。

3) 薬物動態

- アテゾリズマブの薬物動態を評価する。

4) 患者報告アウトカム

- European Organization for Research and Treatment of Cancer（EORTC）QLQ-C30及び QLQ-LC13で測定される，肺癌症状，患者の機能及び health-related quality of life（HRQoL）の患者報告アウトカムを治療群間で比較する。

(6) 治験デザイン

非盲検国際多施設共同ランダム化比較第 II 相臨床試験。適格被験者は腫瘍組織の PD-L1発現状況（IC0，IC1，IC2及び IC3までの4カテゴリ），前治療数（1又は2），組織型（非扁平上皮癌又は扁平上皮癌）を層別因子として，1：1の割合で本剤群又はドセタキセル群に割り付けた。

(7) 被験者数

目標被験者数：IC2又は IC3の被験者が約54例以上になるまで被験者を登録するデザインとした。IC2/3の被験者の割合が全被験者の18%を下回る場合は，治験全体で最大約300例まで登録可能とした。

割付被験者数：287例（ドセタキセル群：143例，本剤群：144例）
治験全体の IC2又は3の被験者数は55例

投与被験者数：277例（ドセタキセル群：135例，本剤群：142例）

(8) 診断及び主な組入基準

組織学的又は細胞学的に局所進行又は転移性の非小細胞肺癌と確認されており，プラチナ製剤を含む化学療法の施行中又は施行後に病勢進行した患者。

(9) 被験薬の投与量，投与方法

臨床的有益性が認められなくなるまで，アテゾリズマブ1200 mg を3週間に1回投与した。

(10) 対照薬の投与量，投与方法

病勢進行又は忍容できない毒性が発現するまで，ドセタキセル75 mg/m^2を3週間に1回投与した。

(11) 評価項目

1) 有効性

- 主要評価項目：OS
- 副次的評価項目：RECIST v1.1及び modified RECIST に基づく PFS，奏効率，奏効期間

2) 薬物動態

血清中アテゾリズマブ濃度（スパースサンプリング）

3) 安全性

有害事象，臨床検査値，AESI，imAE

4) 免疫原性

ATA の発現状況，ATA が薬物動態，有効性及び安全性に与える影響

(12) 統計的手法

Kaplan-Meier 法を用いて各群の OS 中央値を推定するとともに，両群の差を視覚的に描写するため生存曲線を作成した。各群の OS 中央値の95%CI は Brookmeyer-Crowley 法を用いて算出した。

Intent-to-treat（ITT）集団の HR 及び95%CI は，層化調整した Cox 回帰モデル及び log-rank 検

定を用いて算出した。ITT 集団及び PD-L1発現状況別の各部分集団について層化調整しない HR も算出した。

主要評価項目（OS）は，順序［①TC2/3又は IC2/3，②TC1/2/3又は IC1/2/3，③ITT 集団（TC0/1/2/3又は IC0/1/2/3），④TC3又は IC3］を固定した階層的な閉手順に従って評価した。

(13) 試験方法

被験者を1：1の割合で本剤群又はドセタキセル群に割り付けた。被験者は病勢進行（ドセタキセル群の場合），臨床的有益性の消失（本剤群の場合），忍容できない毒性の発現又は治験依頼者による治験全体の中止のいずれかに該当するまで治験薬を投与した。

RECIST v1.1に基づく腫瘍評価はベースライン時，ランダム化から36週目までは6週間（約2サイクル）ごとに行った。ランダム化から36週目以降は，病勢進行が認められない被験者では9（± 1）週ごとに腫瘍評価を行った。ドセタキセル群の被験者は，治療を中止したか否かに関わらず RECIST v1.1に基づく病勢進行まで腫瘍評価を行った。本剤群の被験者は，modified RECIST に基づく病勢進行又は治療中止（病勢進行後もアテゾリズマブの投与を継続している被験者の場合）まで腫瘍評価を行った。病勢進行が認められない場合は，腫瘍に対する新たな治療を行うか否かに関わらず，同意撤回，被験者の死亡又は治験依頼者による治験全体の中止のいずれかに該当するまで腫瘍評価を継続した。腫瘍に対する新たな治療を含む追跡調査データの収集は，被験者の死亡，追跡不能，同意撤回又は治験依頼者による治験全体の中止のいずれかに該当するまで継続した。

(14) 結果の要約

1) 有効性

主要解析は，ITT 集団で死亡が173件集積した2015年5月8日にカットオフしたデータを用いて行った。主要解析時の有効性成績の要約を表 2.7.6.1.4-1に示す。

- ITT 集団において，ドセタキセル群と比較し，本剤群で臨床的に意義がある統計学的に有意な OS の延長が認められた（HR = 0.73，95%CI：0.53～0.99；log-rank 検定：P = 0.0404）。OS 中央値は，ドセタキセル群で9.7カ月，本剤群で12.6カ月であった。
- ドセタキセル群と比較した本剤群での OS の延長は，TC1又は IC1以上のいずれの PD-L1発現状況別部分集団でも認められた。
- 主要評価項目（OS）については，順序を固定した階層的な閉手順に従って評価した。TC2/3又は IC2/3の被験者集団（P = 0.0146），TC1/2/3又は IC1/2/3の被験者集団（P = 0.0050）及び ITT 集団（P = 0.0404）ではドセタキセル群に対して本剤群で，統計学的に有意な OS の延長が認められた。最後の仮説検定である TC3又は IC3の被験者集団では，OS の HR は0.49であったものの，両群間に統計学的に有意な差は認められなかった（P = 0.0684）。
- ITT 集団において，両群間で PFS 及び奏効率に差は認められなかった。PFS 及び奏効率は TC3又は IC3の被験者集団で良好であった。
- ITT 集団における奏効期間の中央値は，本剤群でドセタキセル群の約2倍であった（ドセタキセル群：7.2カ月，本剤群：14.3カ月）。
- 相互排他的な部分集団解析の結果から，PD-L1発現状況が TC1又は IC1以上の被験者集団でアテゾリズマブの有効性（OS の延長）が期待できることが示された。TC1/2/3又は IC1/2/3の被験者集団から TC2/3又は IC2/3の被験者を除いても，ドセタキセル群と比較して本剤群で OS の延長が認められた。TC2/3又は IC2/3の被験者集団から TC3又は IC3の被験者を除いてもドセタキセル群と比較して本剤群で OS の延長が認められた。
- 部分集団解析によって，TC 及び IC 上の PD-L1発現状況はいずれも，OS で測られるアテゾリズマブの有効性の独立した予測因子であることが示された。
- ドセタキセル群と比較した本剤群での OS の延長傾向は，非小細胞肺癌の非扁平上皮癌及び扁平上皮癌のいずれの被験者でも認められた。

表 2.7.6.1.4-1 POPLAR 試験の有効性成績の概要（主要解析時）

	ドセタキセル群	本剤群
主要評価項目（OS）		
ITT 集団（TC0/1/2/3又は IC0/1/2/3の被験者集団）	n = 143	n = 144
イベント数	95 (66.4%)	78 (54.2%)
OS 中央値	9.7カ月	12.6カ月
95%CI	（8.6～12.0カ月）	（9.7～16.4カ月）
P 値（層別 log-rank 検定）	P = 0.0404	
Stratified HR（95%CI）	0.73（0.53～0.99）	
TC3又は IC3の被験者集団	n = 23	n = 24
イベント数	16 (69.6%)	10 (41.7%)
OS 中央値	11.1カ月	15.5カ月
95%CI	（6.7～14.4カ月）	（9.8カ月～推定不能）
P 値（log-rank 検定）	P = 0.0684	
Unstratified HR（95%CI）	0.49 (0.22～1.07)	
TC2/3又は IC2/3の被験者集団	n = 55	n = 50
イベント数（%）	41 (74.5%)	25 (50.0%)
OS 中央値	7.4カ月	15.1カ月
95%CI	（6.0～12.5カ月）	（8.4カ月～推定不能）
P 値（log-rank 検定）	P = 0.0146	
Unstratified HR（95%CI）	0.54（0.33～0.89）	
TC1/2/3又は IC1/2/3の被験者集団	n = 102	n = 93
イベント数	69 (67.6%)	45 (48.4%)
OS 中央値	9.2カ月	15.5カ月
95%CI	（7.3～12.8カ月）	（11.0カ月～推定不能）
P 値（log-rank 検定）	P = 0.0050	
Unstratified HR（95%CI）	0.59 (0.40～0.85)	
副次的評価項目		
PFS	n = 143	n = 144
イベント数	121 (84.6%)	124 (86.1%)
PFS 中央値	3.0カ月	2.7カ月
95%CI	（2.8～4.1カ月）	（2.0～4.1カ月）
Stratified HR（95%CI）	0.94 (0.72～1.23)	
奏効率	n = 143	n = 144
奏効例（%）	21 (14.7%)	21 (14.6%)
95%CI	(9.33～21.57%)	(9.26～21.42%)
奏効期間	n = 21	n = 21
奏効期間中央値	7.2カ月	14.3カ月
95%CI	（5.6～12.5カ月）	（11.6カ月～推定不能）
Stratified HR（95%CI）	0.41 (0.18～0.96)	

［5.3.5.1-2 Table 21を改変］

2) 薬物動態

アテゾリズマブ1200 mg/body の3週間に1回投与で，C_{min} の平均値は4～8サイクルの間に定常状態に到達することが明らかとなった。C_{min} の幾何平均値は，サイクル1の58.8 μg/mL からサイクル8の161 μg/mL まで上昇した。

3) 安全性

アテゾリズマブの安全性プロファイルは，既知の作用機序と一致するものであった。Grade 3

又は4の有害事象，治験薬の投与中止に至った有害事象及び治験薬の減量（ドセタキセル群のみ）又は休薬に至った有害事象の発現率が低いという点で，アテゾリズマブの忍容性はドセタキセルよりも良好であった。

- 治験薬の投与期間は，ドセタキセル群よりも本剤群で長かった（投与期間の中央値，ドセタキセル群：2.1カ月，本剤群：3.7カ月）。また治験薬を12カ月以上投与した被験者の割合は，本剤群で高かった（ドセタキセル群：3.7%，本剤群：21.1%）。
- ドセタキセル群で本剤群よりも10%以上発現率が高かった事象は，脱毛症，悪心，下痢，好中球減少症及び末梢性ニューロパチーであった。一方，本剤群でドセタキセル群よりも10%以上発現率が高かった事象は，食欲減退であった。
- Grade 3又は4の有害事象の発現率は，ドセタキセル群よりも本剤群で低かった（ドセタキセル群：52.6%，本剤群：40.1%）。Grade 3又は4の副作用の発現率も本剤群で低かった（ドセタキセル群：38.5%，本剤群：11.3%）。
- 死亡に至った有害事象は，ドセタキセル群で5例（敗血症2例，死亡2例，急性呼吸窮迫症候群1例），本剤群で6例（心不全，肺塞栓症，肺炎，塞栓症，潰瘍性出血及び気胸が各1例）に認められた。
- 重篤な有害事象の発現率は，両群で同程度であった（ドセタキセル群：34.1%，本剤群：35.2%）。
- 治験薬の投与中止に至った有害事象の発現率は，ドセタキセル群よりも本剤群で低かった（ドセタキセル群：22.2%，本剤群：7.7%）。
- 治験薬の減量（ドセタキセル群のみ）又は休薬に至った有害事象の発現率は，ドセタキセル群よりも本剤群で低かった（ドセタキセル群：32.6%，本剤群：23.9%）。
- AESI は治験依頼者が定義した分類に基づいて評価した。AESI はドセタキセル群で29.6%，本剤群で28.9%に認められ，主なものは皮膚反応（発疹）であった。Grade 3の AESI は11例（4.0%）に認められ（ドセタキセル群：3.0%，本剤群：4.9%），主なものは発疹，アスパラギン酸アミノトランスフェラーゼ増加及びアラニンアミノトランスフェラーゼ増加であった。Grade 4の AESI は，本剤群で1例にアスパラギン酸アミノトランスフェラーゼ増加及びアラニンアミノトランスフェラーゼ増加が認められた。
- imAE は，ドセタキセル群で7.4%，本剤群で7.7%に認められた。

表 2.7.6.1.4-2 POPLAR 試験の安全性成績の概要

Safety Summary, Adverse Event Profile Table
Safety-Evaluable Patients
Protocol: GO28753 (Data Cut: 8May2015)

	Docetaxel (N=135)	Atezolizumab (N=142)	All Patients (N=277)
Total number of patients with at least one adverse event	130 (96.3%)	136 (95.8%)	266 (96.0%)
Total number of events	1325	1354	2679
Total number of patients with at least one			
Grade 5 AE	5 (3.7%)	6 (4.2%)	11 (4.0%)
Serious AE	46 (34.1%)	50 (35.2%)	96 (34.7%)
AE leading to withdrawal from treatment	30 (22.2%)	11 (7.7%)	41 (14.8%)
AE leading to dose modification/interruption	44 (32.6%)	34 (23.9%)	78 (28.2%)
Related AE	119 (88.1%)	95 (66.9%)	214 (77.3%)
Related AE leading to withdrawal from treatment	24 (17.8%)	2 (1.4%)	26 (9.4%)
Related AE leading to dose modification/interruption	32 (23.7%)	15 (10.6%)	47 (17.0%)

Only events reported in the Adverse Events Form are included.
Investigator text for AEs encoded using MedDRA v18.0. Percentages are based on N in the column headings. Multiple occurrences of the same AE in one individual are counted only once except for "Total number of AEs" row in which multiple occurrences of the same AE are counted separately. AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Program: /opt/BIOSTAT/prod/cdt7692c/s28753j/t_aet01.sas / Output:
/opt/BIOSTAT/prod/cdt7692c/s28753j/reports/t_aet01_SE_dc8May2015.out
23JUL2015 23:54

[5.3.5.1-2 Table 62を再掲]

4) 免疫原性

アテゾリズマブの投与後に ATA 陽性を示した被験者は54.1%であった。ATA 陽性例でも C_{min} は目標トラフ濃度（6 μg/mL）を超えており，ATA の発現は，アテゾリズマブの血清中濃度や C_{min} で評価した薬物動態に大きな影響を与えなかった。ATA の発現は有効性に悪い影響を与えなかった。全有害事象及び AESI の発現率や種類を比較した結果，ATA 陽性例と ATA 陰性例におけるアテゾリズマブの安全性プロファイルに明確な差異は認められなかった。

5) 患者報告アウトカム

両群で患者報告アウトカムの結果に差異はみられなかった。本剤群の被験者ではいずれのサブスケール評価でも臨床的に重要な変化（改善及び低下）は認められなかった。一方，ドセタキセル群の被験者では，脱毛症で重要な増加が認められた。肺癌症状の悪化までの期間については，両群間で差異はみられなかった。

(15) 結論

- 二次治療以降の非小細胞肺癌患者を対象とした本治験で，TC2/3又は IC2/3，TC1/2/3又は IC1/2/3，ITT の被験者集団では，主要評価項目である OS について，ドセタキセル群と比較して本剤群でいずれも統計学的に有意であり，臨床的に意義のある延長が認められた。PD-L1の高発現とアテゾリズマブによる OS の延長には関連性がみられた。
- TC3又は IC3の被験者集団では，ドセタキセル群と比較して本剤群で OS，PFS 及び奏効率の改善がみられた。
- 奏効が認められた被験者の奏効期間及び OS から，奏効の質はドセタキセル群よりも本剤群で高かった。
- アテゾリズマブの有効性は非扁平上皮癌及び扁平上皮癌のいずれの被験者でも認められた。
- アテゾリズマブ1200 mg/body の3週間隔反復静脈内投与により，C_{min} は徐々に上昇していき，4～8サイクルの間に定常状態に到達することが明らかとなった。
- アテゾリズマブ投与後の ATA 発現率は54.1%であった。ATA の発現による薬物動態，有効性

及び安全性への臨床的に重要な影響は認められなかった。
- アテゾリズマブの忍容性は概ね良好であり，ドセタキセルと比較しても，より許容可能な安全性であった。免疫関連の有害事象のほとんどは発現頻度が低い，重症度が低い及び管理可能な事象であった。PD-L1発現状況別のすべての部分集団で安全性プロファイルは一致していた。
- 患者報告アウトカムの結果から，アテゾリズマブは忍容可能であり，被験者の HRQoL 及び機能を低下させるような影響は与えないことが示された。

(16) 報告書作成日
[redacted]年[redacted]月

2.7.6.1.5 BIRCH 試験

(1) 試験の標題

A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with PD-L1-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer

局所進行又は転移性の PD-L1陽性非小細胞肺癌患者を対象に，MPDL3280A を投与する第 II 相多施設共同単群試験

(2) 治験依頼者／実施地域

Roche 社／19カ国，106施設（米国34施設，日本11施設，フランス8施設，オーストラリア5施設，カナダ5施設，ベルギー4施設，ジョージア4施設，ドイツ4施設，スイス4施設，ボスニア・ヘルツェゴビナ3施設，香港3施設，オランダ3施設，スペイン3施設，トルコ3施設，ブルガリア2施設，イタリア2施設，シンガポール2施設，イギリス2施設，スロベニア1施設）

(3) 公表

Besse B, Johnson M, Jänne PA, et al. Phase II, single-arm trial (BIRCH) of atezolizumab as first-line or subsequent therapy for locally advanced or metastatic PD-L1-selected non-small cell lung cancer (NSCLC). Presented at: 2015 European Cancer Congress; September 25-29, 2015; Vienna, Austria. Abstract 16LBA.

(4) 治験実施期間

2014年1月[redacted]日（最初の被験者の登録日）～2015年5月28日（データカットオフ日）

(5) フェーズ

第 II 相

(6) 目的

1) 主要目的

本治験の主要目的は，PD-L1陽性の局所進行又は転移性非小細胞肺癌患者におけるアテゾリズマブの有効性を，奏効率（RECIST v1.1，委員会評価）によって評価することである。

2) 副次的目的

本治験の副次的目的は以下のとおりである。
- 委員会が RECIST v1.1を用いて，また主治医が modified RECIST を用いて判定する PFS，奏効期間及び Time in response を評価する。
- 主治医が RECIST v1.1を用いて判定する奏効率，奏効期間，Time in response 及び PFS を評価する。

- 主治医が modified RECIST を用いて判定する奏効率を評価する。
- OS 及び1年 OS を評価する。
- 委員会が RECIST v1.1を用いて，また主治医が RECIST v1.1及び modified RECIST を用いて判定する1年 PFS を評価する。
- アテゾリズマブの安全性と忍容性を評価する。
- アテゾリズマブの薬物動態の特性を調べる。
- アテゾリズマブに対する ATA の発現率と力価を評価する。また，免疫原性反応と薬物動態，安全性，有効性との潜在的な関連性を探索する。

(7) 治験デザイン

本治験は現在も実施中の第 II 相国際多施設共同単群試験で，PD-L1陽性の局所進行又は転移性非小細胞肺癌患者を対象として，アテゾリズマブの有効性及び安全性を評価するために実施された。

(8) 被験者数

目標被験者数：635例以上
登録被験者数：667例（コホート1：142例，コホート2：271例，コホート3：254例）
投与被験者数：659例（コホート1：139例，コホート2：267例，コホート3：253例）

(9) 診断及び主な組入基準

適格基準に合致する患者から採取された腫瘍組織検体は，中央測定機関によって PD-L1発現状況が確認された。IHC スコアに基づいて PD-L1発現（TC2又は3，IC2又は3）が確認された患者のみを登録した。患者は以下の3つのコホートのいずれか1つに登録された。

- コホート1（一次治療）：非小細胞肺癌に対する前治療歴のない患者（目標被験者数：約127例）。
- コホート2（二次治療）：プラチナ製剤併用の化学療法施行中又は施行後に病勢進行した患者（目標被験者数：約254例）。
- コホート3（三次治療）：プラチナ製剤併用の化学療法施行中又は施行後に病勢進行し，更に1つ以上の追加レジメンの施行中又は施行後に病勢進行した患者（目標被験者数：少なくとも254例）。なお，前治療の最大レジメン数は規定しなかった。また，コホート3には TC3 又は IC3の被験者を約100例登録することとした。

いずれのコホートにおいても，感受性の Epidermal growth factor receptor（EGFR）遺伝子変異又は Anaplastic lymphoma kinase（ALK）融合遺伝子を有する被験者は，既承認の EGFR チロシンキナーゼ阻害剤又は ALK 阻害剤での治療（治療中又は治療後に）で，病勢進行又は忍容ではないことが確認されていることとした。

(10) 被験薬，投与量，投与方法

アテゾリズマブ1200 mg を点滴静脈内投与にて3週間に1回投与した。

(11) 評価項目

1) 有効性評価項目

本治験の有効性に関する主要評価項目は，委員会が RECIST v1.1を用いて判定する奏効率である。本治験の副次的有効性評価項目は以下のとおりである。

- 主治医が RECIST v1.1を用いて判定する奏効率
- 主治医が modified RECIST を用いて判定する奏効率
- 委員会が RECIST v1.1を用いて判定する奏効期間

- 主治医が RECIST v1.1を用いて判定する奏効期間
- 主治医が modified RECIST を用いて判定する奏効期間
- 委員会が RECIST v1.1を用いて判定する PFS
- 主治医が RECIST v1.1を用いて判定する PFS
- 主治医が modified RECIST を用いて判定する PFS
- 6カ月 PFS 割合及び1年 PFS 割合
- OS
- 6カ月 OS 割合及び1年 OS 割合
- 委員会が RECIST v1.1を用いて判定する Time in response
- 主治医が RECIST v1.1を用いて判定する Time in response
- 主治医が modified RECIST を用いて判定する Time in response

感度分析及び部分集団解析は，委員会が RECIST v1.1を用いて判定する奏効率，また，部分的に治験責任（分担）医師が RECIST v1.1を用いて判定する奏効率及び奏効期間についても実施した。

肺癌症状，患者の機能及び HRQoL の患者報告アウトカムは，2つの指標（EORTC QLQ-C30 及び QLQ-LC13）を用いて評価した。

2) 薬物動態に関する評価項目

薬物動態解析対象集団（アテゾリズマブが投与され，薬物動態パラメータの算出に十分なデータポイントで薬物動態データが採取された被験者）において，アテゾリズマブの血清中濃度（C_{min} 及び C_{max}）を，それぞれの測定時期（C_{max}：サイクル1のみ，C_{min}：サイクル1，2，3，4，8，16及びその後8サイクルごとの投与前，治験薬投与中止時）について算出し，要約した。

3) 安全性評価項目

安全性評価項目は，有害事象，標準的な臨床検査値及びバイタルサインであった。また，ベースライン時及びアテゾリズマブ投与後に ATA 検査を行った被験者で，ATA 発現例数と発現率を要約した。免疫原性反応と薬物動態，安全性及び有効性との関連性について評価した。

(12) 統計的手法

重要な有効性パラメータの解析に用いた解析方法（該当する場合は，打切り方法も含む）の概要を(13) 試験方法の表 2.7.6.1.5-1に示した。

(13) 試験方法

21日を1サイクルとし，各サイクルの1日目にアテゾリズマブ（固定用量1200 mg）を投与した。アテゾリズマブの投与は，治験責任（分担）医師により臨床的有益性があると判断される限り継続可能とした。すなわち，画像データ，生検結果（ある場合）及び臨床状態の総合的評価を通じ，忍容できない毒性若しくは病勢進行に起因する症状悪化が発現しない限りは，継続することができるとした。

被験者にはベースライン時と，その後は6週ごとに，サイクル1の1日目から数えて12カ月後まで腫瘍評価を実施した。12カ月経過後は，9週ごとに腫瘍評価を病勢進行，死亡，同意の撤回若しくは治験依頼者が治験終了を決定するまでの，いずれか短い期間にわたって実施した。

全被験者に対して委員会による治療効果の独立した審査［コンピュータ断層撮影（CT）画像の盲検下での評価を含む］を実施した。委員会による評価は最終有効性解析の前に実施した。

全被験者に対して，生存及び新たに開始する抗癌療法に関する追跡調査を投与中止から約3カ月ごとに，被験者の死亡，追跡不能，同意の撤回若しくは治験依頼者が治験終了を決定するまでの，いずれか短い期間にわたって継続した。

安全性の評価では，有害事象，バイタルサイン，及び臨床検査異常の発現率，種類，重症度を，CTCAE v4.0の Grade 分類に基づき，評価した。アテゾリズマブの薬物動態をモニタリングし，アテゾリズマブに対する抗体の有無を調べる目的で，血清検体を採取した。被験者の保管腫瘍組織及び血清，血漿検体を，将来の探索的バイオマーカー評価に使用する目的で採取した。

有効性の重要な評価項目及び解析方法を以下に示した。

表 2.7.6.1.5-1 有効性の主要評価項目及び主な副次的評価項目の解析方法の要約

評価項目	定義	打切り	解析方法
主要評価項目			
奏効率（RECIST v1.1，委員会評価）	最良総合効果で CR 又は PR が確定した被験者の割合	該当しない	95%CI の算出：Clopper-Pearson 法 歴史対照の奏効率との比較：直接確率検定
主な副次的評価項目			
奏効率（RECIST v1.1及び modified RECIST，主治医評価）	最良総合効果で CR 又は PR が確定した被験者の割合	該当しない	95%CI の算出：Clopper-Pearson 法
奏効期間*	CR 又は PR（いずれか早い方）が最初に発生した日から，病勢進行又は死亡（いずれか早い方）まで	最後の腫瘍評価日	中央値の推定：Kaplan-Meier 法 95%CI の算出：Brookmeyer-Crowley 法
PFS*	アテゾリズマブの初回投与日から，病勢進行又は理由を問わない死亡（いずれか早い方）まで	最後の腫瘍評価日又はベースライン後のデータがない被験者の場合はアテゾリズマブの初回投与日の翌日	奏効期間と同様
OS	アテゾリズマブの初回投与日から，理由を問わない死亡まで	最後の治験に関連する評価日又は最後に生存が確認された日	PFS と同様
6カ月又は1年 PFS 割合 6カ月又は1年 OS 割合	アテゾリズマブの初回投与日から6カ月又は1年時点で，イベントが発生していない被験者の割合	PFS 又は OS と同様	割合の推定：Kaplan-Meier 法 標準誤差及び95%CI の算出：Greenwood の式
Time in response*	奏効例：Time in response は奏効期間と同様 非奏効例：アテゾリズマブの初回投与日の翌日にイベントが発生したと定義	最後の腫瘍評価日又はアテゾリズマブの初回投与日の翌日	PFS と同様

*: RECIST v1.1による委員会評価又は主治医評価，あるいは modified RECIST による主治医評価
［5.3.5.2-1 Table 6を改変］

(14) 結果の要約

1) 有効性

主解析は最後の被験者の登録から約6カ月後に実施した。最後の被験者はコホート3に2014年12月に登録された。

主要評価項目及び主な副次的評価項目の要約は表 2.7.6.1.5-2に，また，主な結果を以下に示す。

- 奏効率（RECIST v1.1，委員会評価）は，7つすべての被験者集団で，事前に治験実施計画書で定めた歴史対照の奏効率を有意水準5%で統計学的に有意に上回り（P < 0.0001），臨床的に意義のある改善が認められ，本治験の主要目的を達成した。いずれのコホートにおいても，最も PD-L1の発現レベルが高い被験者集団（TC3又は IC3）で奏効率が最も高かった（範

囲：23.8%～27.0%）。

- データカットオフ（2015年5月28日）時点で，いずれのコホート及びいずれの PD-L1発現レベルにおいても奏効例（RECIST v1.1，委員会評価）の58.7%以上の被験者で，奏効が継続していた（死亡や PD が認められていない）。三次治療以降（コホート3）及び二次治療以降（コホート2 + 3）ではいずれの PD-L1発現レベルにおいても奏効期間は中央値に達し，それぞれ7.2～8.4カ月の範囲にあったが，フォローアップ期間が限定的であること及び奏効が認められるまでの中央値が約2カ月であることから，この推定値は不安定であると考えられた。
- 二次治療以降（コホート2 + 3）の TC3の被験者集団では委員会評価による奏効率は32.4%（95%CI：24.7～40.8%）であった。この内，30.2%は PR，2.2%は CR であった。この被験者集団の奏効期間の中央値は7.2カ月（95%CI：5.7カ月～推定不能）であった。しかし，この奏効期間の推定値は，95%CI の上限が推定不能であったこと，フォローアップ期間が短いことから，暫定的であると考えられた。
- データカットオフ（2015年5月28日）時点で，すべての被験者集団の内60.5%以上の被験者が生存していた。三次治療以降（コホート3），二次治療以降（コホート2 + 3）及び二次治療（コホート2）のいずれの PD-L1発現レベルにおいても OS の中央値は推定不能であった。各コホートの6カ月生存割合は，TC3又は IC3の被験者で75.1～79.7%，TC2/3又は IC2/3の被験者で70.5～81.7%であった。
- 三次治療以降（コホート3），二次治療以降（コホート2 + 3）及び二次治療（コホート2）では，PD-L1の高発現（TC3又は IC3）と長い PFS の中央値（委員会評価）には関連が認められ，この集団の PFS 中央値は4.1～4.2カ月であった。また，三次治療以降（コホート3），二次治療以降（コホート2 + 3）及び二次治療（コホート2）の TC3又は IC3の被験者集団の6カ月 PFS 割合は，34.5～38.9%であった。
- RECIST v1.1に基づく主治医評価の奏効率，奏効期間及び PFS は，数値的には高いが，全体的に RECIST v1.1に基づく委員会評価と一致していた。modified RECIST v1.1に基づく主治医評価の奏効率及び奏効期間は，RECIST v1.1に基づく主治医評価と全体的に同様であった。
- 委員会評価及び主治医評価の奏効率に関する部分集団解析では，喫煙歴及び ECOG PS を除いて，人口統計学的特性及びベースライン時の特性に関わらずアテゾリズマブの効果が認められた。現在喫煙又は過去に喫煙歴ありの患者と比べて喫煙歴なしの患者で，ECOG PS 0の患者と比べて ECOG PS 1の患者で奏効率が低い傾向がみられたが，95%CI は重なっていた。更に三次治療以降（コホート3）ではいずれの PD-L1発現レベルにおいても女性と比べて男性で奏効率が高く，二次治療以降（コホート2 + 3）ではいずれの PD-L1発現レベルにおいても扁平上皮癌の患者と比べて非扁平上皮癌の患者で奏効率が高かったが，95%CI は重なっていた。
- 三次治療以降（コホート3）の奏効率（委員会評価）は，いずれの PD-L1発現レベルにおいても非扁平上皮癌の被験者と扁平上皮癌の被験者で同様であった。三次治療以降（コホート3）の TC2/3又は IC2/3の被験者集団では，扁平上皮癌の被験者の奏効率は16%，非扁平上皮癌の被験者の奏効率は18%であった。二次治療以降（コホート2 + 3）の扁平上皮癌の被験者の奏効率は11%，非扁平上皮癌の被験者の奏効率は20%であったが，95%CI は重なっていた。

表 2.7.6.1.5-2 主要評価項目及び主な副次的評価項目の要約

評価項目	コホート1 （一次治療） N=139	コホート2 （二次治療） N=267	コホート3 （三次治療以降） N=253	コホート2＋3 （二次治療以降） N=520
主要評価項目				
TC3又はIC3の被験者	n = 65	n = 122	n = 115	n = 237
奏効例（%）*	17（26.2%）	29（23.8%）	31（27.0%）	60（25.3%）
95%CI	16.0～38.5	16.5～32.3	19.1～36.0	19.9～31.4
TC2/3又はIC2/3の被験者	n = 139	n = 267	n = 253	n = 520
奏効例（%）*	27（19.4%）	46（17.2%）	44（17.4%）	90（17.3%）
95%CI	13.2～27.0	12.9～22.3	12.9～22.6	14.2～20.8
副次的評価項目				
TC3又はIC3の奏効例	n = 17	n = 29	n = 31	n = 60
イベント数（%）**	5（29.4%）	11（37.9%）	12（38.7%）	23（38.3%）
奏効期間の中央値（カ月）	推定不能	推定不能	7.2	7.2
95%CI	5.8～推定不能	4.9～推定不能	5.6～推定不能	5.7～推定不能
TC2/3又はIC2/3の奏効例	n = 27	n = 46	n = 44	n = 90
イベント数（%）**	10（37.0%）	19（41.3%）	14（31.8%）	33（36.7%）
奏効期間の中央値（カ月）	8.5	8.4	8.4	8.3
95%CI	5.6～推定不能	6.9～推定不能	5.7～推定不能	6.9～推定不能

*: RECIST v1.1に基づく委員会評価
**:死亡又はPD
［5.3.5.2-1 Table 17を改変］

2) 薬物動態

アテゾリズマブ1200 mg/bodyの3週間に1回投与で，C_{min}の平均値は4～8サイクルの間に定常状態に到達することが明らかとなった。C_{min}の幾何平均値は，サイクル1の78.9 μg/mLからサイクル8の193 μg/mLまで上昇した。本治験でアテゾリズマブ1200 mg/bodyの3週に1回投与を選択した根拠の一部として，目標トラフ濃度は6 μg/mLとされたが，サイクル8のC_{min}の幾何平均値はこの目標トラフ濃度6 μg/mLを超えていた。アテゾリズマブ1200 mg/bodyを3週間隔で反復投与した後のサイクル8のC_{min}の幾何平均値は，ATA陽性例及びATA陰性例でそれぞれ168 μg/mL及び208 μg/mLであった。ATA陽性例及びATA陰性例のいずれでもC_{min}は目標トラフ濃度を十分に超えていた。この投与量においては，ATAの発現はアテゾリズマブの血清中濃度に臨床的に意味のある影響を与えないと考えられた。

3) 安全性

アテゾリズマブは概ね忍容であり，安全性プロファイルは，現在までに得られているアテゾリズマブを対象とした臨床試験結果と同様であった。

- アテゾリズマブの投与期間の中央値（範囲）は4.2（0～15）カ月，投与回数の中央値（範囲）は7（1～21）回であった。
- アテゾリズマブの安全性プロファイルはいずれの治療ライン（一次治療，二次治療，三次治療以降及び二次治療以降）においても，いずれのPD-L1発現レベルにおいても概ね同様であった。
- 有害事象は93.6%に認められた。主な事象は，疲労，食欲減退，咳嗽，呼吸困難及び悪心であった。有害事象の大部分はGrade 1又はGrade 2の事象であった。
- 副作用は64.0%に認められた。主な事象は，疲労及び悪心であった。
- Grade 3又は4の有害事象は38.2%に認められた。主な事象は，呼吸困難，肺炎，低ナトリウム血症，疲労及び貧血であった。Grade 3又は4の副作用は11.2%に認められた。

- Grade 5の有害事象は2.9%に認められた。1事象（肺炎）は治験責任（分担）医師により副作用と判断された。
- 重篤な有害事象は35.4%に認められた。主な事象は，肺炎（3.3%）などの感染症と呼吸困難（2.7%），発熱（2.3%），肺臓炎（2.3%）などの呼吸器系の事象であった。
- AESI は26.3%に認められた。AESI の大部分は Grade 1又は2の事象であった。主な事象は，発疹などの皮膚反応，アラニンアミノトランスフェラーゼ増加やアスパラギン酸アミノトランスフェラーゼ増加などの肝機能検査値異常，甲状腺機能低下症及び肺臓炎であった。Grade 3又は4の AESI は5%で認められ，1例（0.2%）で Grade 5の AESI（肺臓炎）が認められた。
- imAE は7.3%に認められ，主な事象は，肺臓炎（1.8%），呼吸困難（0.8%）及びアスパラギン酸アミノトランスフェラーゼ増加（0.8%）であった。
- アテゾリズマブの投与中止に至った有害事象は5.2%に認められた。
- アテゾリズマブの休薬に至った有害事象は26.1%に認められた。主な事象は，肺臓炎（2.7%），呼吸困難（2.6%），疲労（2.1%）及び肺炎（1.4%）であった。
- PD-L1発現状況別の被験者集団（TC3又は IC3，TC3）の安全性プロファイルは，全体集団の安全性プロファイルと同様であった。同じく，二次治療以降の TC3の被験者集団と全体集団の有害事象，重篤な有害事象及び Grade 5の有害事象の発現率は同程度であった。
- 全体的に本治験で得られた安全性プロファイルは，アテゾリズマブの作用機序又は非小細胞肺癌の起因する症状を反映したものであった。本治験の結果からは予期せぬ安全性上の兆候は認められなかった。

(15) 結論

- 奏効率（RECIST v1.1，委員会評価）は，7つすべての被験者集団で，事前に治験実施計画書で定めた歴史対照の奏効率を有意水準5%で統計学的に有意に上回り（$P < 0.0001$），臨床的に意義のある改善が認められ，本治験の主要目的を達成した。
- PD-L1の高発現（例えば，TC3又は IC3）と高い奏効率及び長い PFS 中央値には関連が認められた。
- 二次治療以降の被験者では，TC3の被験者集団で最も奏効率が高かった。
- 委員会評価及び主治医評価の有効性評価（奏効率及び奏効期間など）は一致していた。
- modified RECIST に基づく主治医評価及び RECIST v1.1に基づく主治医評価の奏効率は，一致していた。
- 主要解析のためのデータカットオフ時点では，奏効期間及び OS の結果は暫定的であり，さらなるフォローアップが必要であった。奏効（CR 又は PR）が確定した被験者の大部分では奏効が継続していた（各コホートの各 PD-L1発現状況別部分集団で58.7～70.6%）。
- 患者報告アウトカムの結果は安全性と一致しており，アテゾリズマブによる治療期間中，HRQoL や機能が維持されることが明らかとなった。
- アテゾリズマブ1200 mg/body の3週間に1回投与で，C_{min} の平均値は徐々に上昇していき，4～8サイクルの間に定常状態に到達することが明らかとなった。
- アテゾリズマブ投与後の ATA 発現率は38.5%であった。ATA の発現による薬物動態，有効性及び安全性への臨床的に重要な影響は認められなかった。
- アテゾリズマブの忍容性は概ね良好であり，免疫関連の有害事象は発現頻度が低く，概ね管理可能な事象であった。
- 二次治療以降の TC3の被験者集団と全体集団の安全性は同様であった。
- コホート及び PD-L1発現状況別の各部分集団において，安全性プロファイルに差異は認められなかった。
- アテゾリズマブの忍容性は概ね良好であった。免疫関連の有害事象は発現頻度が低い又は管理可能な事象であった。PD-L1発現状況別の各部分集団において，安全性プロファイルに差

異は認められなかった。

(16) 報告書作成日
[redacted]年[redacted]月

2.7.6.1.6 FIR 試験

(1) 試験の標題
A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with PD-L1-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer
PD-L1陽性の局所進行又は転移性の非小細胞肺癌患者を対象とした MPDL3280A の第 II 相多施設共同単群試験

(2) 治験依頼者／実施地域
Roche 社／5カ国，28施設（米国22施設，イギリス3施設，ベルギー1施設，オランダ1施設，フランス1施設）

(3) 治験実施期間
2013年5月[redacted]日（最初の被験者のスクリーニング日）～2015年1月7日（データカットオフ日）

(4) フェーズ
第 II 相

(5) 目的
1) 主要目的
- PD-L1陽性の局所進行又は転移性の非小細胞肺癌患者に対するアテゾリズマブの有効性を，modified RECIST による主治医評価の奏効率で評価する。

2) 副次的目的
- modified RECIST による PFS 及び奏効期間を評価する。
- MPDL3280A の有効性を，RECIST v1.1による主治医評価の奏効率，奏効期間及び PFS で評価する。
- OS を評価する。
- modified RECIST で CR 又は PR に確定された被験者の PFS を評価する。
- アテゾリズマブの安全性及び忍容性を評価する。
- アテゾリズマブの薬物動態を評価する。
- アテゾリズマブに対する ATA の発現と力価を評価し，免疫原性反応と薬物動態，安全性及び有効性との潜在的な関連性を探索する。

(6) 治験デザイン
PD-L1陽性患者を対象とした第 II 相国際多施設共同単群試験

(7) 被験者数
目標被験者数：130例
登録被験者数：138例
非小細胞肺癌に対する前治療歴のない患者（コホート1）：31例
プラチナ製剤併用の化学療法施行中又は施行後に病勢進行した患者（コホート2）：94例
二次治療以降の患者で，脳転移巣に対し治療歴を有する患者（コホート3）：13例

投与被験者数：137例（コホート1：31例，コホート2：93例，コホート3：13例）

(8) 診断及び主な組入基準

18歳以上で PD-L1陽性（TC2/3又は IC2/3）の局所進行又は転移性の非小細胞肺癌患者

(9) 被験薬の投与量，投与方法

アテゾリズマブ1200 mg を3週間に1回静脈内投与した。アテゾリズマブの初回量は60分（±15分）をかけて投与した。初回投与時に注入関連の有害事象がなく忍容性が良好であれば，2回目以降の点滴は30分（±10分）で行うことを可能とした。

コホート1の被験者は RECIST v1.1による病勢進行が認められるまで，コホート2又はコホート3の被験者は治験責任（分担）医師によってこれ以上臨床的有益性が得られないと判断されるまで各サイクル（1サイクルは21日）の Day 1にアテゾリズマブを投与した。

(10) 対照薬の投与量，投与方法

該当しない。

(11) 評価項目

1) 有効性

- modified RECIST 及び RECIST v1.1に基づく奏効率
- modified RECIST 及び RECIST v1.1に基づく奏効期間
- modified RECIST 及び RECIST v1.1に基づく奏効までの期間
- modified RECIST 及び RECIST v1.1に基づく PFS
- OS
- EORTC QLQ-C30及び QLQ-LC13で測定される患者報告アウトカム

2) 薬力学

T 細胞，B 細胞，NK 細胞，インターフェロン γ，その他の探索的バイオマーカーの変化

3) 薬物動態

サイクル1の C_{max}，サイクル2，4，8及び治験薬投与中止時の C_{min}

4) 安全性

有害事象，重篤な有害事象，死亡，AESI，ATA，血液学的及び生化学的臨床検査値，バイタルサイン，12誘導心電図

(12) 統計的手法

正式な統計的仮説検定は実施しなかった。奏効率の推定値及び95%CI は，Clopper-Pearson 法を用いて算出した。イベント発生までの期間は，中央値及び範囲を用いて要約した。6カ月及び12カ月のイベント発生割合は Kaplan-Meier 法を用いて推定し，95%CI 及び標準誤差は Greenwood の式を用いて算出した。

(13) 試験方法

患者背景，病歴（既往歴，合併症，使用した薬剤），理学的検査，バイタルサイン，ECOG PS，血清学的エプスタイン・バーウイルス検査，血清学的ヒト免疫不全ウイルス検査，B 型肝炎ウイルス血清学的検査，C 型肝炎ウイルス血清学的検査，血清妊娠検査（妊娠可能な女性の場合），脳核磁気共鳴画像法/CT スキャン，12誘導心電図は，スクリーニング時に確認及び実施した。

薬物動態及び ATA 評価のための血清検体は，すべてのサイクルの Day 1（サイクル2以降は±2日を許容）に採取した。

バイオマーカー（T 細胞，B 細胞，NK 細胞，T 細胞分画，その他の探索的バイオマーカー）評価用の血液検体はベースライン，サイクル1，2，3，4及び8の Day 1，病勢進行時，治験薬投与中止時に採取した。

腫瘍評価は，ベースライン，サイクル1の Day 1及び最初の12カ月間は6週ごとに，12カ月経過後は RECIST による病勢進行（コホート2及び3で画像所見上の病勢進行後もアテゾリズマブの投与を継続した被験者は病勢進行以降も），同意撤回，死亡又は治験依頼者による治験中止のいずれかに該当するまで9週ごとに実施した。

患者報告アウトカムの質問票（EORTC QLQ-C30及び QLQ-LC13）は，治験薬投与開始及びベースライン時の評価の前と各サイクルの Day 1に被験者が回答した。

フルオロデオキシグルコース－陽電子放射断層撮影/CT スキャンは，ベースライン，初回腫瘍評価時（サイクル1 Day 1の約6週後），画像所見上の病勢進行時に実施した。

心エコー検査は，心嚢液貯留の既往歴がある被験者又はスクリーニング時の胸部 CT で胸水又は心嚢液貯留が確認された被験者に実施した。心エコーはスクリーニング時，サイクル2の Day 1，更に，その後の治験薬投与期間中は臨床上の必要性又は通常の診療手順に従って実施し，治験薬投与中止時にも実施した。

治験薬投与開始後に発現した有害事象は，治験薬最終投与日から90日間又は次の抗悪性腫瘍療法開始のいずれかに該当するまで収集した。それ以降は，死亡，重篤な有害事象及び治験薬投与又は治験手順と「関連あり」と考えられるその他の有害事象を収集した。

血液学的及び生化学的臨床検査は，治験薬初回投与前14日以内及びサイクル2以降は各サイクルの Day 1（±2日）に実施した。

ECOG PS，簡素化した理学的検査及び各医療機関での臨床検査は，各サイクル Day 1の前96時間以内に実施した。

心電図検査（1時点につき3回）は，スクリーニング時，サイクル1，4の投与前及び投与後，治験薬投与中止時，その他にも臨床上の必要性を認めた時点で実施した。

(14) 結果の要約

1) 有効性

有効性の結果をコホート2，コホート3，コホート1の順に示す。

- プラチナ製剤を含む化学療法の施行中又は施行後に病勢進行した患者93例（二次治療以降，コホート2）の主要評価項目である奏効率（modified RECIST，主治医評価）は，17.2%（95%CI：10.2～26.4%）であった。2例で CR，14例で PR が認められた。
  - 副次的評価項目である奏効率（RECIST v1.1，主治医評価）は，16.1%（95%CI：9.3～25.2%）であり，modified RECIST による奏効率と同程度であった。2例で CR，13例で PR が認められた。
  - このコホートでは，PD-L1の高発現と高い奏効率には関連があり，TC3又は IC3の被験者集団の modified RECIST による奏効率は26.3%（95%CI：13.4～43.1%），RECIST v1.1による奏効率は23.7%（95%CI：11.4～40.2%）と他の被験者集団（TC2/3又は IC2/3，TC3又は IC2/3）と比較して最も高かった。
  - コホート2において，TC3又は IC3の発現は効果を予測させるものであった。TC3の被験者（IC スコアは問わない）22例の modified RECIST による奏効率は27.3%（95%CI：10.7～50.2%），RECIST v1.1による奏効率は22.7%（95%CI：7.8～45.4%）であった。IC3の被験者（TC スコアは問わない）21例の modified RECIST による奏効率は33.3%（95%CI：14.6～57.0%），RECIST v1.1による奏効率は28.6%（95%CI：11.3～52.2%）であった。
- 奏効率は，二次治療以降で既治療の脳転移巣を有する被験者（コホート3）及び非小細胞肺癌に対する前治療歴のない被験者（コホート1）で同程度であった。

– コホート3（二次治療以降で既治療の脳転移巣を有する被験者）の modified RECIST 及び RECIST v1.1による奏効率はいずれも23.1%（95%CI：5.0～53.8%）であった。
– コホート1（非小細胞肺癌に対する前治療歴のない被験者）の modified RECIST による奏効率は29.0%（95%CI：14.2～48.0%），RECIST v1.1による奏効率は25.8%（95%CI：11.9～44.6%）であった。

- 奏効までの期間の中央値は，コホート2，コホート3，コホート1でそれぞれ2.6カ月，1.4カ月，2.0カ月であった。

– コホート2では，有効性解析対象集団全体と比較して，TC3又は IC3の被験者集団及び（奏効までの期間の中央値：1.4カ月），TC3又は IC2/3の被験者（奏効までの期間の中央値：1.5カ月）で，より早く奏効が認められた。

- データカットオフ時点でいずれのコホートでも奏効が認められた。被験者の大部分（66.7%～86.7%）で奏効が継続（範囲：2.3カ月～17.2カ月）しており，奏効期間の中央値は，推定不能であった。コホート2では，奏効が認められた15例中13例（86.7%）で RECIST v1.1による奏効が継続（範囲：4.1カ月～17.2カ月）しており，15例中10例は奏効期間が6カ月以上であった。
- RECIST v1.1による PFS の中央値は，コホート2，コホート3，コホート1でそれぞれ2.7カ月，2.5カ月，4.5カ月であった。

– コホート2では，有効性解析対象集団（TC2/3又は IC2/3）と比較して，TC3又は IC3の被験者集団でより長い PFS（中央値：4.1カ月）が認められ，6カ月 PFS 割合及び1年 PFS 割合も高かった（6カ月 PFS 割合：42.5% vs 32.3%，1年 PFS 割合：34.1% vs 21.5%）。

- OS の中央値は，コホート2で10.6カ月，コホート3で約7カ月，コホート1では推定不能であった。
- 患者報告アウトカムでは，本治験中にアテゾリズマブ投与による全般的健康状態や QoL，機能（身体，役割，心理，認知，社会）及び肺癌症状（咳，呼吸困難，胸痛，腕痛や肩痛）の重要な変化は認められなかった。

2) 薬物動態

アテゾリズマブ1200 mg/body の3週間に1回投与で，C_{min} の平均値は4～8サイクルの間に定常状態に到達することが明らかとなった。C_{min} の幾何平均値は，サイクル1の68.8 μg/mL からサイクル8の206 μg/mL まで上昇した。本治験でアテゾリズマブ1200 mg/body の3週に1回投与を選択した根拠の一部として，目標トラフ濃度は6 μg/mL とされたが，サイクル8の C_{min} の幾何平均値はこの目標トラフ濃度6 μg/mL を超えていた。アテゾリズマブ1200 mg/body を3週間隔で反復投与した後のサイクル8の C_{min} の幾何平均値は，ATA 陽性例及び ATA 陰性例でそれぞれ191 μg/mL 及び220 μg/mL であった。ATA 陽性例と ATA 陰性例で同程度の C_{min} が認められたことから，この投与量では，ATA の発現はアテゾリズマブの血清中濃度にほとんど影響を与えないと考えられた。

3) 安全性

アテゾリズマブ投与の忍容性は良好であり，本治験の安全性成績はこれまでの臨床試験で得られたアテゾリズマブ単独投与時の安全性プロファイルと一致していた。有害事象はほぼ全例（99.3%）に認められ，全 Grade で高頻度に認められた事象は，疲労，呼吸困難，咳嗽，悪心，下痢及び食欲減退であった。これらの高頻度で認められた事象は大部分が Grade 1又は2であった。Grade が3又は4（最悪時）の有害事象は66例（48.2%）に認められた。Grade 3又は4（最悪時）の副作用は14.6%に認められ，2例以上に認められた事象は，アラニンアミノトランスフェラーゼ増加及びアスパラギン酸アミノトランスフェラーゼ増加が各3例（2.2%），肺塞栓症及び高血圧が各2例（1.5%）であった。

アテゾリズマブの最終投与から30日以内に発現した死亡に至った有害事象は5例（播種性血

管内凝固，心停止，心タンポナーデ，収縮性心膜炎，呼吸障害）であった。この内，治験責任（分担）医師により副作用と判断された事象は，収縮性心膜炎のみであった。更に，アテゾリズマブの最終投与から30日より後に発現した死亡に至った有害事象は2例であり，その内訳は安楽死が1例，肺炎が1例であった。

重篤な有害事象は65例（47.4%）に認められ，主なものは肺炎（7例，5.1%），呼吸困難（6例，4.4%），喀血及び背部痛（各4例，2.9%），下痢及び胸痛（各3例，2.2%）であった。重篤な副作用は14例（10.2%）に認められ，2例以上に認められた事象は，下痢が2例（1.5%，いずれも Grade 2），アラニンアミノトランスフェラーゼ増加が2例（1.5%，Grade 3と Grade 4が各1例），アスパラギン酸アミノトランスフェラーゼ増加が2例（1.5%，いずれも Grade 3）であった。

アテゾリズマブの投与中止に至った有害事象は13例（9.5%）で認められ，2例以上に認められた事象は呼吸困難及び体重減少が各2例（1.5%）であった。アテゾリズマブの投与中止に至った副作用は3例で認められ，その内訳はギラン・バレー症候群（Grade 3，回復），糖尿病（Grade 3，回復）及び肺高血圧症（Grade 3，データカットオフ時未回復）が各1例であった。

全 Grade の AESI は31例（22.6%）に認められ，主なものは発疹，湿疹及び皮膚炎のような皮膚に関連する AESI（12.4%），肝酵素の増加（4.4%），末梢性ニューロパチーやギラン・バレー症候群などの神経系の AESI（3.6%），甲状腺機能亢進症や甲状腺機能低下症のような内分泌に分類される AESI（2.9%）であった。AESI の大部分は Grade 1又は2の事象であり，治療やステロイドを要さず管理可能であり，回復した。Grade 3又は4（最悪時）の AESI は6例（4.4%）に認められ，2例以上に認められた事象は，アラニンアミノトランスフェラーゼ増加及びアスパラギン酸アミノトランスフェラーゼ増加が各3例であった。死亡に至った AESI は認められなかった。投与中止に至った AESI は1例で認められ，その事象はギラン・バレー症候群であった。この事象は治験責任（分担）医師により副作用と判断され，治療とアテゾリズマブの中止により回復した。他の明確な要因がなく全身性のステロイド投与を要した有害事象（imAE）は9例（6.6%）に認められた。この内，6例（4.4%）は Grade 1又は2の事象であり，3例（肺臓炎，不全単麻痺，アラニンアミノトランスフェラーゼ増加）は Grade 3の事象であった。imAE の種類，発現率及び重症度に明確な傾向は認められなかった。

表 2.7.6.1.6-1 FIR 試験の安全性成績の概要

Safety Summary, Treated Patients
Protocol: GO28625

	Cohort 1 (N=31)	Cohort 2 (N=93)	Cohort 3 (N=13)	All Patients (N=137)
Total no. of patients with at least one AE	31 (100.0%)	92 (98.9%)	13 (100.0%)	136 (99.3%)
Total no. of events	298	950	146	1394
Total no. of patients with at least one				
Related AE	23 (74.2%)	61 (65.6%)	9 (69.2%)	93 (67.9%)
Grade 5 Adverse Event	2 (6.5%)	3 (3.2%)	0	5 (3.6%)
Related Grade 5 AE	0	1 (1.1%)	0	1 (0.7%)
Serious Adverse Event	16 (51.6%)	43 (46.2%)	6 (46.2%)	65 (47.4%)
AE leading to withdrawal from treatment	2 (6.5%)	9 (9.7%)	2 (15.4%)	13 (9.5%)
Related AE leading to withdrawal from treatment	0	3 (3.2%)	0	3 (2.2%)

Investigator text for AEs encoded using MedDRA version 18.0. Death due to progressive disease is excluded from this summary.
Percentages are based on N in the column headings. Multiple occurrences of the same AE in one individual are counted only once except for "Total number of events" row in which multiple occurrences of the same AE are counted separately.
Clinical cut-off date: 07-JAN-2015; Final RAVE extraction date: 20-MAY-2015

Program: /opt/BIOSTAT/prod/cdpt7692/s28625i/t_ae_summary.sas
Output: /opt/BIOSTAT/prod/cdpt7692/s28625i/reports/t_ae_summary_AENPD_SE.out

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[5.3.5.2-2 Table 32を再掲]

血液学的又は生化学的臨床検査の平均値及び中央値について，臨床的に重要な変化は認められなかった。また，バイタルサイン及び心電図についてもベースラインからの臨床的に重要な変化は認められなかった。

アテゾリズマブの投与後に ATA 陽性を示した被験者は，129例中66例（51.2%）であった。ATA 陽性例でも C_{min} は目標トラフ濃度を超えており，ATA の発現はアテゾリズマブの血清中濃度や薬物動態にほとんど影響を与えないと考えられた。ATA 陽性例と ATA 陰性例の modified RECIST 及び RECIST v1.1による主治医評価の奏効率や奏効期間に臨床的に重要な差異は認められなかった。全有害事象及び AESI の発現率に基づき，ATA 陽性例と ATA 陰性例のアテゾリズマブの安全性プロファイルは同等であった。

(15) 結論

アテゾリズマブ1200 mg/body の3週間隔投与は，前治療歴のない患者及び二次治療以降の非小細胞肺癌患者（脳転移巣を有する患者を含む）のいずれにも臨床的な有効性を示した。

プラチナ製剤を含む化学療法の後に病勢進行した患者（コホート2）では，本治験の主要評価項目である modified RECIST による主治医評価の奏効率は17.2%（95%CI：10.2～26.4%）であり，アテゾリズマブの投与は臨床的に意義があった。副次的評価項目である RECIST v1.1による主治医評価の奏効率（16.1%，95%CI：9.3～25.2%）も同程度であった。最も短いフォローアップ期間は6カ月であり，奏効期間の中央値は推定不能であった。

modified RECIST 及び RECIST v1.1ともに，高い奏効率と PD-L1の高発現には関連が認められた。特に TC3又は IC3の被験者集団では，他の被験者集団（TC2/3又は IC2/3，TC3又は IC2/3）と比較して奏効率が最も高かった［modified RECIST による奏効率：26.3%（95%CI：13.4～43.1%），RECIST v1.1による奏効率：23.7%（95%CI：11.4～40.2%）］。

アテゾリズマブ1200 mg/body を3週間隔で投与した際の安全性プロファイルは忍容可能であり，予期せぬ安全性の懸念もなく忍容性は良好であった。90%超の被験者でアテゾリズマブの投与継続が可能であった。

アテゾリズマブ1200 mg/body の3週間隔反復静脈内投与により，C_{min} は徐々に上昇していき，4～8サイクルの間に定常状態に到達することが明らかとなった。アテゾリズマブ投与後の ATA 発現率は51.2%であった。ATA の発現による薬物動態，有効性及び安全性への臨床的に重要な影響は認められなかった。

(16) 報告書作成日

[redacted]年[redacted]月

2.7.6.2 付録

2.7.6.2.1 有害事象の集計表

本項では，アテゾリズマブの安全性評価に用いた6試験（PCD4989g 試験，JO28944試験，OAK 試験，POPLAR 試験，BIRCH 試験，FIR 試験）について，因果関係を問わない有害事象及び因果関係が否定できない有害事象（副作用）の集計表を提示する。

2.7.6.2.1.1　PCD4989g 試験

表 2.7.6.2.1.1-1　すべての有害事象（PCD4989g 試験）

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
- Any adverse events -	- Any Grade -	466 (96.9%)	9 (100.0%)	3 (100.0%)	35 (97.2%)	231 (97.9%)	145 (99.3%)	43 (84.3%)
	1	75 (15.6%)	2 (22.2%)	0	3 (8.3%)	38 (16.1%)	19 (13.0%)	13 (25.5%)
	2	165 (34.3%)	6 (66.7%)	0	10 (27.8%)	74 (31.4%)	65 (44.5%)	10 (19.6%)
	3	185 (38.5%)	1 (11.1%)	3 (100.0%)	19 (52.8%)	99 (41.9%)	49 (33.6%)	14 (27.5%)
	4	24 (5.0%)	0	0	2 (5.6%)	14 (5.9%)	8 (5.5%)	0
	5	17 (3.5%)	0	0	1 (2.8%)	6 (2.5%)	4 (2.7%)	6 (11.8%)
一般・全身障害および投与部位の状態								
- Overall -	- Any Grade -	338 (70.3%)	9 (100.0%)	3 (100.0%)	27 (75.0%)	169 (71.6%)	102 (69.9%)	28 (54.9%)
	1	155 (32.2%)	6 (66.7%)	1 (33.3%)	13 (36.1%)	78 (33.1%)	49 (33.6%)	8 (15.7%)
	2	147 (30.6%)	2 (22.2%)	2 (66.7%)	12 (33.3%)	74 (31.4%)	41 (28.1%)	16 (31.4%)
	3	32 (6.7%)	1 (11.1%)	0	2 (5.6%)	15 (6.4%)	11 (7.5%)	3 (5.9%)
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	5	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
疲労	- Any Grade -	180 (37.4%)	7 (77.8%)	3 (100.0%)	16 (44.4%)	88 (37.3%)	52 (35.6%)	14 (27.5%)
	1	86 (17.9%)	4 (44.4%)	1 (33.3%)	7 (19.4%)	45 (19.1%)	24 (16.4%)	5 (9.8%)
	2	81 (16.8%)	2 (22.2%)	2 (66.7%)	8 (22.2%)	39 (16.5%)	22 (15.1%)	8 (15.7%)
	3	13 (2.7%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	6 (4.1%)	1 (2.0%)
発熱	- Any Grade -	107 (22.2%)	4 (44.4%)	3 (100.0%)	8 (22.2%)	53 (22.5%)	32 (21.9%)	7 (13.7%)
	1	80 (16.6%)	3 (33.3%)	3 (100.0%)	7 (19.4%)	37 (15.7%)	25 (17.1%)	5 (9.8%)
	2	25 (5.2%)	1 (11.1%)	0	0	16 (6.8%)	7 (4.8%)	1 (2.0%)
	3	2 (0.4%)	0	0	1 (2.8%)	0	0	1 (2.0%)
無力症	- Any Grade -	80 (16.6%)	1 (11.1%)	0	2 (5.6%)	44 (18.6%)	27 (18.5%)	6 (11.8%)
	1	33 (6.9%)	1 (11.1%)	0	1 (2.8%)	20 (8.5%)	10 (6.8%)	1 (2.0%)
	2	39 (8.1%)	0	0	1 (2.8%)	21 (8.9%)	12 (8.2%)	5 (9.8%)
	3	8 (1.7%)	0	0	0	3 (1.3%)	5 (3.4%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
末梢性浮腫	- Any Grade -	57 (11.9%)	1 (11.1%)	1 (33.3%)	8 (22.2%)	24 (10.2%)	17 (11.6%)	6 (11.8%)
	1	40 (8.3%)	1 (11.1%)	1 (33.3%)	7 (19.4%)	14 (5.9%)	12 (8.2%)	5 (9.8%)
	2	17 (3.5%)	0	0	1 (2.8%)	10 (4.2%)	5 (3.4%)	1 (2.0%)
悪寒	- Any Grade -	55 (11.4%)	4 (44.4%)	3 (100.0%)	5 (13.9%)	24 (10.2%)	17 (11.6%)	2 (3.9%)
	1	50 (10.4%)	3 (33.3%)	3 (100.0%)	4 (11.1%)	23 (9.7%)	15 (10.3%)	2 (3.9%)
	2	5 (1.0%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	2 (1.4%)	0
疼痛	- Any Grade -	44 (9.1%)	4 (44.4%)	1 (33.3%)	3 (8.3%)	21 (8.9%)	13 (8.9%)	2 (3.9%)
	1	28 (5.8%)	4 (44.4%)	1 (33.3%)	2 (5.6%)	13 (5.5%)	8 (5.5%)	0
	2	9 (1.9%)	0	0	0	4 (1.7%)	3 (2.1%)	2 (3.9%)
	3	7 (1.5%)	0	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	0
インフルエンザ様疾患	- Any Grade -	36 (7.5%)	0	0	5 (13.9%)	12 (5.1%)	17 (11.6%)	2 (3.9%)
	1	30 (6.2%)	0	0	4 (11.1%)	11 (4.7%)	14 (9.6%)	1 (2.0%)
	2	5 (1.0%)	0	0	1 (2.8%)	0	3 (2.1%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
胸痛	- Any Grade -	24 (5.0%)	1 (11.1%)	1 (33.3%)	4 (11.1%)	6 (2.5%)	8 (5.5%)	4 (7.8%)
	1	14 (2.9%)	0	1 (33.3%)	3 (8.3%)	5 (2.1%)	5 (3.4%)	0
	2	9 (1.9%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	3 (5.9%)
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
粘膜の炎症	- Any Grade -	14 (2.9%)	0	0	3 (8.3%)	7 (3.0%)	4 (2.7%)	0
	1	11 (2.3%)	0	0	2 (5.6%)	6 (2.5%)	3 (2.1%)	0
	2	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
胸部不快感	- Any Grade -	9 (1.9%)	1 (11.1%)	0	2 (5.6%)	3 (1.3%)	3 (2.1%)	0
	1	8 (1.7%)	0	0	2 (5.6%)	3 (1.3%)	3 (2.1%)	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
非心臓性胸痛	- Any Grade -	7 (1.5%)	1 (11.1%)	0	0	1 (0.4%)	5 (3.4%)	0
	1	3 (0.6%)	1 (11.1%)	0	0	0	2 (1.4%)	0
	2	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
倦怠感	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	0	1 (2.0%)
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
顔面浮腫	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	0	1 (2.0%)
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
浮腫	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
歩行障害	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	3 (0.6%)	0	0	0	0	3 (2.1%)	0
末梢腫脹	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	0	1 (2.0%)
	1	2 (0.4%)	0	0	1 (2.8%)	0	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ヘルニア痛	- Any Grade -	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
	1	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
圧痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
医療機器閉塞	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
温度変化不耐症	- Any Grade -	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
	1	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
乾燥症	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
限局性浮腫	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
高熱	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
全身健康状態低下	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
全身性炎症反応症候群	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
早期満腹	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
嚢胞	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
不快感	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
腋窩痛	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
カテーテル留置部位そう痒感	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
カテーテル留置部位紅斑	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
カテーテル留置部位発疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ステントグラフトエンドリーク	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
医療機器位置異常	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
顔面痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
局所腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
死亡	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
治癒不良	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
疾患進行	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
低体温	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
適用部位発疹	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
突然死	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
分泌物分泌	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
薬剤離脱症候群	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胃腸障害								
- Overall -	- Any Grade -	316 (65.7%)	9 (100.0%)	3 (100.0%)	28 (77.8%)	152 (64.4%)	97 (66.4%)	27 (52.9%)
	1	183 (38.0%)	5 (55.6%)	2 (66.7%)	15 (41.7%)	91 (38.6%)	54 (37.0%)	16 (31.4%)
	2	101 (21.0%)	4 (44.4%)	1 (33.3%)	10 (27.8%)	41 (17.4%)	36 (24.7%)	9 (17.6%)
	3	30 (6.2%)	0	0	3 (8.3%)	18 (7.6%)	7 (4.8%)	2 (3.9%)
	4	2 (0.4%)	0	0	0	2 (0.8%)	0	0
悪心	- Any Grade -	126 (26.2%)	7 (77.8%)	2 (66.7%)	9 (25.0%)	51 (21.6%)	44 (30.1%)	13 (25.5%)
	1	93 (19.3%)	7 (77.8%)	2 (66.7%)	7 (19.4%)	40 (16.9%)	28 (19.2%)	9 (17.6%)
	2	28 (5.8%)	0	0	2 (5.6%)	9 (3.8%)	14 (9.6%)	3 (5.9%)
	3	5 (1.0%)	0	0	0	2 (0.8%)	2 (1.4%)	1 (2.0%)
下痢	- Any Grade -	102 (21.2%)	5 (55.6%)	0	16 (44.4%)	43 (18.2%)	30 (20.5%)	8 (15.7%)
	1	76 (15.8%)	2 (22.2%)	0	11 (30.6%)	36 (15.3%)	23 (15.8%)	4 (7.8%)
	2	25 (5.2%)	3 (33.3%)	0	4 (11.1%)	7 (3.0%)	7 (4.8%)	4 (7.8%)
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
便秘	- Any Grade -	102 (21.2%)	2 (22.2%)	0	9 (25.0%)	50 (21.2%)	35 (24.0%)	6 (11.8%)
	1	65 (13.5%)	1 (11.1%)	0	7 (19.4%)	30 (12.7%)	23 (15.8%)	4 (7.8%)
	2	35 (7.3%)	1 (11.1%)	0	2 (5.6%)	19 (8.1%)	11 (7.5%)	2 (3.9%)
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
嘔吐	- Any Grade -	90 (18.7%)	0	1 (33.3%)	6 (16.7%)	42 (17.8%)	33 (22.6%)	8 (15.7%)
	1	74 (15.4%)	0	1 (33.3%)	5 (13.9%)	33 (14.0%)	29 (19.9%)	6 (11.8%)
	2	13 (2.7%)	0	0	1 (2.8%)	8 (3.4%)	3 (2.1%)	1 (2.0%)
	3	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
腹痛	- Any Grade -	60 (12.5%)	3 (33.3%)	0	7 (19.4%)	31 (13.1%)	16 (11.0%)	3 (5.9%)
	1	38 (7.9%)	3 (33.3%)	0	5 (13.9%)	21 (8.9%)	8 (5.5%)	1 (2.0%)
	2	14 (2.9%)	0	0	2 (5.6%)	4 (1.7%)	6 (4.1%)	2 (3.9%)
	3	8 (1.7%)	0	0	0	6 (2.5%)	2 (1.4%)	0
上腹部痛	- Any Grade -	30 (6.2%)	1 (11.1%)	0	4 (11.1%)	12 (5.1%)	12 (8.2%)	1 (2.0%)
	1	21 (4.4%)	1 (11.1%)	0	3 (8.3%)	7 (3.0%)	10 (6.8%)	0
	2	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	1 (2.0%)
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
口内乾燥	- Any Grade -	22 (4.6%)	1 (11.1%)	0	1 (2.8%)	8 (3.4%)	10 (6.8%)	2 (3.9%)
	1	22 (4.6%)	1 (11.1%)	0	1 (2.8%)	8 (3.4%)	10 (6.8%)	2 (3.9%)
嚥下障害	- Any Grade -	20 (4.2%)	1 (11.1%)	0	0	13 (5.5%)	6 (4.1%)	0
	1	9 (1.9%)	1 (11.1%)	0	0	5 (2.1%)	3 (2.1%)	0
	2	6 (1.2%)	0	0	0	3 (1.3%)	3 (2.1%)	0
	3	5 (1.0%)	0	0	0	5 (2.1%)	0	0
胃食道逆流性疾患	- Any Grade -	16 (3.3%)	2 (22.2%)	0	2 (5.6%)	4 (1.7%)	8 (5.5%)	0
	1	11 (2.3%)	2 (22.2%)	0	1 (2.8%)	3 (1.3%)	5 (3.4%)	0
	2	5 (1.0%)	0	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	0
腹部膨満	- Any Grade -	15 (3.1%)	0	0	1 (2.8%)	9 (3.8%)	5 (3.4%)	0
	1	10 (2.1%)	0	0	1 (2.8%)	4 (1.7%)	5 (3.4%)	0
	2	5 (1.0%)	0	0	0	5 (2.1%)	0	0

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Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
消化不良	- Any Grade -	11 (2.3%)	1 (11.1%)	0	2 (5.6%)	5 (2.1%)	3 (2.1%)	0
	1	8 (1.7%)	1 (11.1%)	0	2 (5.6%)	3 (1.3%)	2 (1.4%)	0
	2	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
口内炎	- Any Grade -	10 (2.1%)	1 (11.1%)	0	0	6 (2.5%)	3 (2.1%)	0
	1	6 (1.2%)	1 (11.1%)	0	0	3 (1.3%)	2 (1.4%)	0
	2	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
歯痛	- Any Grade -	9 (1.9%)	0	1 (33.3%)	0	2 (0.8%)	5 (3.4%)	1 (2.0%)
	1	7 (1.5%)	0	0	0	2 (0.8%)	4 (2.7%)	1 (2.0%)
	2	2 (0.4%)	0	1 (33.3%)	0	0	1 (0.7%)	0
腹水	- Any Grade -	8 (1.7%)	0	0	0	3 (1.3%)	4 (2.7%)	1 (2.0%)
	2	6 (1.2%)	0	0	0	2 (0.8%)	3 (2.1%)	1 (2.0%)
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
放屁	- Any Grade -	8 (1.7%)	0	0	1 (2.8%)	3 (1.3%)	4 (2.7%)	0
	1	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
下腹部痛	- Any Grade -	7 (1.5%)	0	0	0	4 (1.7%)	3 (2.1%)	0
	1	5 (1.0%)	0	0	0	2 (0.8%)	3 (2.1%)	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
胃炎	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	2 (0.8%)	3 (2.1%)	0
	1	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
口腔内痛	- Any Grade -	6 (1.2%)	1 (11.1%)	0	0	3 (1.3%)	2 (1.4%)	0
	1	6 (1.2%)	1 (11.1%)	0	0	3 (1.3%)	2 (1.4%)	0
痔核	- Any Grade -	5 (1.0%)	0	0	0	1 (0.4%)	4 (2.7%)	0
	1	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腹部不快感	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
小腸閉塞	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	0	1 (2.0%)
	3	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	0	1 (2.0%)
直腸出血	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
おくび	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
メレナ	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
レッチング	- Any Grade -	3 (0.6%)	1 (11.1%)	0	0	0	2 (1.4%)	0
	1	3 (0.6%)	1 (11.1%)	0	0	0	2 (1.4%)	0
胃腸出血	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
食道炎	- Any Grade -	3 (0.6%)	1 (11.1%)	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
大腸ポリープ	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
吐血	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腹部ヘルニア	- Any Grade -	3 (0.6%)	0	1 (33.3%)	0	0	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	1 (33.3%)	0	0	1 (0.7%)	1 (2.0%)
嚥下痛	- Any Grade -	3 (0.6%)	0	0	0	0	2 (1.4%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	0	2 (1.4%)	1 (2.0%)
齲歯	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
アフタ性口内炎	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
胃出血	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
憩室	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
口の感覚鈍麻	- Any Grade -	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
口腔内出血	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
十二指腸潰瘍	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
消化器痛	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
舌痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0

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軟便	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
腹部圧痛	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
肛門周囲痛	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
イレウス	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
異常便	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胃酸過多	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
血便排泄	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
口の錯感覚	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
口腔内潰瘍形成	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
口腔内被膜	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
口腔粘膜疹	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
歯の障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
歯周病	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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歯肉腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
歯肉出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
歯肉痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
痔出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
消化管運動過剰	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
食道狭窄	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
大腸炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
大腸閉塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
地図状舌	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
弛緩歯	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
腸閉塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
直腸分泌物	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
吐き戻し	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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吐糞症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
粘液便	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腹部癒着	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
変色便	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
便失禁	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
嚥下不能	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
鼠径ヘルニア	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
呼吸器、胸郭および縦隔障害								
- Overall -	- Any Grade -	254 (52.8%)	6 (66.7%)	3 (100.0%)	30 (83.3%)	109 (46.2%)	88 (60.3%)	18 (35.3%)
	1	140 (29.1%)	5 (55.6%)	2 (66.7%)	15 (41.7%)	69 (29.2%)	44 (30.1%)	5 (9.8%)
	2	72 (15.0%)	1 (11.1%)	1 (33.3%)	10 (27.8%)	28 (11.9%)	27 (18.5%)	5 (9.8%)
	3	34 (7.1%)	0	0	5 (13.9%)	10 (4.2%)	15 (10.3%)	4 (7.8%)
	4	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	5	6 (1.2%)	0	0	0	2 (0.8%)	1 (0.7%)	3 (5.9%)
咳嗽	- Any Grade -	103 (21.4%)	3 (33.3%)	3 (100.0%)	10 (27.8%)	51 (21.6%)	31 (21.2%)	5 (9.8%)
	1	78 (16.2%)	3 (33.3%)	2 (66.7%)	6 (16.7%)	41 (17.4%)	23 (15.8%)	3 (5.9%)
	2	24 (5.0%)	0	1 (33.3%)	4 (11.1%)	9 (3.8%)	8 (5.5%)	2 (3.9%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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呼吸困難	- Any Grade -	103 (21.4%)	4 (44.4%)	1 (33.3%)	12 (33.3%)	31 (13.1%)	45 (30.8%)	10 (19.6%)
	1	45 (9.4%)	3 (33.3%)	1 (33.3%)	5 (13.9%)	16 (6.8%)	18 (12.3%)	2 (3.9%)
	2	40 (8.3%)	1 (11.1%)	0	5 (13.9%)	11 (4.7%)	18 (12.3%)	5 (9.8%)
	3	17 (3.5%)	0	0	2 (5.6%)	4 (1.7%)	9 (6.2%)	2 (3.9%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
口腔咽頭痛	- Any Grade -	29 (6.0%)	1 (11.1%)	0	7 (19.4%)	10 (4.2%)	11 (7.5%)	0
	1	28 (5.8%)	1 (11.1%)	0	6 (16.7%)	10 (4.2%)	11 (7.5%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
鼻閉	- Any Grade -	28 (5.8%)	1 (11.1%)	2 (66.7%)	3 (8.3%)	11 (4.7%)	11 (7.5%)	0
	1	26 (5.4%)	1 (11.1%)	2 (66.7%)	2 (5.6%)	11 (4.7%)	10 (6.8%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
湿性咳嗽	- Any Grade -	27 (5.6%)	1 (11.1%)	0	4 (11.1%)	9 (3.8%)	13 (8.9%)	0
	1	20 (4.2%)	1 (11.1%)	0	2 (5.6%)	8 (3.4%)	9 (6.2%)	0
	2	7 (1.5%)	0	0	2 (5.6%)	1 (0.4%)	4 (2.7%)	0
労作性呼吸困難	- Any Grade -	17 (3.5%)	0	1 (33.3%)	4 (11.1%)	6 (2.5%)	3 (2.1%)	3 (5.9%)
	1	16 (3.3%)	0	1 (33.3%)	4 (11.1%)	6 (2.5%)	2 (1.4%)	3 (5.9%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
喀血	- Any Grade -	17 (3.5%)	0	0	1 (2.8%)	9 (3.8%)	7 (4.8%)	0
	1	16 (3.3%)	0	0	0	9 (3.8%)	7 (4.8%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
胸水	- Any Grade -	16 (3.3%)	0	0	3 (8.3%)	4 (1.7%)	6 (4.1%)	3 (5.9%)
	2	11 (2.3%)	0	0	2 (5.6%)	4 (1.7%)	3 (2.1%)	2 (3.9%)
	3	5 (1.0%)	0	0	1 (2.8%)	0	3 (2.1%)	1 (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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
低酸素症	- Any Grade -	16 (3.3%)	0	0	2 (5.6%)	6 (2.5%)	8 (5.5%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	6 (1.2%)	0	0	0	1 (0.4%)	5 (3.4%)	0
	3	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
上気道咳症候群	- Any Grade -	12 (2.5%)	1 (11.1%)	0	4 (11.1%)	4 (1.7%)	3 (2.1%)	0
	1	10 (2.1%)	1 (11.1%)	0	3 (8.3%)	3 (1.3%)	3 (2.1%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
喘鳴	- Any Grade -	11 (2.3%)	0	1 (33.3%)	3 (8.3%)	3 (1.3%)	4 (2.7%)	0
	1	6 (1.2%)	0	1 (33.3%)	1 (2.8%)	2 (0.8%)	2 (1.4%)	0
	2	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	2 (1.4%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
肺臓炎	- Any Grade -	10 (2.1%)	0	0	1 (2.8%)	3 (1.3%)	5 (3.4%)	1 (2.0%)
	1	4 (0.8%)	0	0	1 (2.8%)	0	3 (2.1%)	0
	2	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	0	0	1 (2.0%)
発声障害	- Any Grade -	10 (2.1%)	0	0	1 (2.8%)	4 (1.7%)	3 (2.1%)	2 (3.9%)
	1	8 (1.7%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	1 (2.0%)
	2	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
副鼻腔うっ血	- Any Grade -	8 (1.7%)	0	0	4 (11.1%)	3 (1.3%)	1 (0.7%)	0
	1	8 (1.7%)	0	0	4 (11.1%)	3 (1.3%)	1 (0.7%)	0
鼻出血	- Any Grade -	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	1	6 (1.2%)	0	0	1 (2.8%)	2 (0.8%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
鼻漏	- Any Grade -	7 (1.5%)	0	0	0	3 (1.3%)	4 (2.7%)	0
	1	7 (1.5%)	0	0	0	3 (1.3%)	4 (2.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
アレルギー性鼻炎	- Any Grade -	6 (1.2%)	0	0	3 (8.3%)	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	4 (0.8%)	0	0	2 (5.6%)	1 (0.4%)	1 (0.7%)	0
肺塞栓症	- Any Grade -	6 (1.2%)	0	0	3 (8.3%)	2 (0.8%)	1 (0.7%)	0
	3	6 (1.2%)	0	0	3 (8.3%)	2 (0.8%)	1 (0.7%)	0
気胸	- Any Grade -	5 (1.0%)	0	0	0	1 (0.4%)	3 (2.1%)	1 (2.0%)
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	3	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
しゃっくり	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	0	1 (2.0%)
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
気道うっ血	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
くしゃみ	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
咽頭瘻	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
気管支痙攣	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
急性呼吸不全	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	5	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
胸膜痛	- Any Grade -	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
誤嚥	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
誤嚥性肺炎	- Any Grade -	2 (0.4%)	0	0	0	0	0	2 (3.9%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
口腔咽頭不快感	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
睡眠時無呼吸症候群	- Any Grade -	2 (0.4%)	0	0	2 (5.6%)	0	0	0
	1	2 (0.4%)	0	0	2 (5.6%)	0	0	0
副鼻腔不快感	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
いびき	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
カタル	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
安静時呼吸困難	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
咽喉乾燥	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
横隔膜痛	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
気管支分泌増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
気管支閉塞	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
気管瘻	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
呼吸窮迫	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
呼吸時疼痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
呼吸停止	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
呼吸不全	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
喉頭の炎症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
喉頭痙攣	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
徐呼吸	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
息詰まり	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺硬化	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
肺高血圧症	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
肺障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺浸潤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
副鼻腔障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
副鼻腔分泌過多	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
閉塞性気道障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
変色痰	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
慢性閉塞性肺疾患	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
筋骨格系および結合組織障害								
- Overall -	- Any Grade -	251 (52.2%)	6 (66.7%)	3 (100.0%)	23 (63.9%)	125 (53.0%)	82 (56.2%)	12 (23.5%)
	1	141 (29.3%)	5 (55.6%)	2 (66.7%)	13 (36.1%)	73 (30.9%)	43 (29.5%)	5 (9.8%)
	2	86 (17.9%)	1 (11.1%)	1 (33.3%)	9 (25.0%)	40 (16.9%)	31 (21.2%)	4 (7.8%)
	3	24 (5.0%)	0	0	1 (2.8%)	12 (5.1%)	8 (5.5%)	3 (5.9%)
背部痛	- Any Grade -	80 (16.6%)	1 (11.1%)	1 (33.3%)	7 (19.4%)	41 (17.4%)	29 (19.9%)	1 (2.0%)
	1	40 (8.3%)	1 (11.1%)	1 (33.3%)	4 (11.1%)	18 (7.6%)	16 (11.0%)	0
	2	32 (6.7%)	0	0	3 (8.3%)	16 (6.8%)	12 (8.2%)	1 (2.0%)
	3	8 (1.7%)	0	0	0	7 (3.0%)	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
関節痛	- Any Grade -	71 (14.8%)	3 (33.3%)	1 (33.3%)	9 (25.0%)	30 (12.7%)	26 (17.8%)	2 (3.9%)
	1	51 (10.6%)	2 (22.2%)	0	6 (16.7%)	23 (9.7%)	19 (13.0%)	1 (2.0%)
	2	19 (4.0%)	1 (11.1%)	1 (33.3%)	2 (5.6%)	7 (3.0%)	7 (4.8%)	1 (2.0%)
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
四肢痛	- Any Grade -	36 (7.5%)	2 (22.2%)	0	3 (8.3%)	17 (7.2%)	12 (8.2%)	2 (3.9%)
	1	24 (5.0%)	1 (11.1%)	0	3 (8.3%)	10 (4.2%)	10 (6.8%)	0
	2	9 (1.9%)	1 (11.1%)	0	0	5 (2.1%)	2 (1.4%)	1 (2.0%)
	3	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
筋肉痛	- Any Grade -	35 (7.3%)	2 (22.2%)	0	2 (5.6%)	19 (8.1%)	11 (7.5%)	1 (2.0%)
	1	29 (6.0%)	2 (22.2%)	0	1 (2.8%)	15 (6.4%)	10 (6.8%)	1 (2.0%)
	2	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	1 (0.7%)	0
筋骨格痛	- Any Grade -	30 (6.2%)	0	0	7 (19.4%)	7 (3.0%)	15 (10.3%)	1 (2.0%)
	1	18 (3.7%)	0	0	3 (8.3%)	4 (1.7%)	10 (6.8%)	1 (2.0%)
	2	11 (2.3%)	0	0	4 (11.1%)	2 (0.8%)	5 (3.4%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
頚部痛	- Any Grade -	26 (5.4%)	0	0	3 (8.3%)	14 (5.9%)	6 (4.1%)	3 (5.9%)
	1	16 (3.3%)	0	0	2 (5.6%)	10 (4.2%)	3 (2.1%)	1 (2.0%)
	2	8 (1.7%)	0	0	1 (2.8%)	4 (1.7%)	3 (2.1%)	0
	3	2 (0.4%)	0	0	0	0	0	2 (3.9%)
筋力低下	- Any Grade -	19 (4.0%)	0	0	3 (8.3%)	9 (3.8%)	6 (4.1%)	1 (2.0%)
	1	8 (1.7%)	0	0	2 (5.6%)	5 (2.1%)	1 (0.7%)	0
	2	9 (1.9%)	0	0	1 (2.8%)	4 (1.7%)	3 (2.1%)	1 (2.0%)
	3	2 (0.4%)	0	0	0	0	2 (1.4%)	0
筋痙縮	- Any Grade -	19 (4.0%)	1 (11.1%)	0	2 (5.6%)	8 (3.4%)	7 (4.8%)	1 (2.0%)
	1	17 (3.5%)	1 (11.1%)	0	1 (2.8%)	8 (3.4%)	6 (4.1%)	1 (2.0%)
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
筋骨格系胸痛	- Any Grade -	18 (3.7%)	1 (11.1%)	1 (33.3%)	3 (8.3%)	7 (3.0%)	6 (4.1%)	0
	1	11 (2.3%)	1 (11.1%)	1 (33.3%)	0	6 (2.5%)	3 (2.1%)	0
	2	6 (1.2%)	0	0	3 (8.3%)	0	3 (2.1%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
側腹部痛	- Any Grade -	18 (3.7%)	1 (11.1%)	0	2 (5.6%)	8 (3.4%)	7 (4.8%)	0
	1	12 (2.5%)	1 (11.1%)	0	1 (2.8%)	5 (2.1%)	5 (3.4%)	0
	2	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
骨痛	- Any Grade -	13 (2.7%)	0	0	1 (2.8%)	5 (2.1%)	7 (4.8%)	0
	1	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	1 (0.7%)	0
	2	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	3	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
肛径部痛	- Any Grade -	11 (2.3%)	0	0	0	7 (3.0%)	2 (1.4%)	2 (3.9%)
	1	10 (2.1%)	0	0	0	7 (3.0%)	2 (1.4%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
筋骨格硬直	- Any Grade -	7 (1.5%)	0	0	0	5 (2.1%)	1 (0.7%)	1 (2.0%)
	1	7 (1.5%)	0	0	0	5 (2.1%)	1 (0.7%)	1 (2.0%)
関節炎	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
開口障害	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
顎痛	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
筋骨格不快感	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
病的骨折	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	3	3 (0.6%)	0	0	0	0	3 (2.1%)	0
運動性低下	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
関節腫脹	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
脊椎痛	- Any Grade -	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
下肢腫瘤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
顎関節症候群	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
滑液包炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
関節ロック	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
関節可動域低下	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
関節障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
筋萎縮症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
筋炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
筋攣縮	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肩回旋筋腱板症候群	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
骨溶解	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
四肢不快感	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脊椎炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
軟骨炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
軟骨症	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
変形性関節症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
咀嚼障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
腋窩腫瘤	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腱炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
腱痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
代謝および栄養障害								
- Overall -	- Any Grade -	208 (43.2%)	3 (33.3%)	2 (66.7%)	18 (50.0%)	101 (42.8%)	65 (44.5%)	19 (37.3%)
	1	87 (18.1%)	1 (11.1%)	2 (66.7%)	5 (13.9%)	41 (17.4%)	29 (19.9%)	9 (17.6%)
	2	64 (13.3%)	2 (22.2%)	0	8 (22.2%)	26 (11.0%)	21 (14.4%)	7 (13.7%)
	3	52 (10.8%)	0	0	5 (13.9%)	32 (13.6%)	13 (8.9%)	2 (3.9%)
	4	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
食欲減退	- Any Grade -	125 (26.0%)	3 (33.3%)	1 (33.3%)	9 (25.0%)	57 (24.2%)	43 (29.5%)	12 (23.5%)
	1	72 (15.0%)	2 (22.2%)	1 (33.3%)	5 (13.9%)	33 (14.0%)	25 (17.1%)	6 (11.8%)
	2	49 (10.2%)	1 (11.1%)	0	4 (11.1%)	20 (8.5%)	18 (12.3%)	6 (11.8%)
	3	4 (0.8%)	0	0	0	4 (1.7%)	0	0
脱水	- Any Grade -	37 (7.7%)	0	0	3 (8.3%)	16 (6.8%)	15 (10.3%)	3 (5.9%)
	1	12 (2.5%)	0	0	2 (5.6%)	5 (2.1%)	2 (1.4%)	3 (5.9%)
	2	16 (3.3%)	0	0	1 (2.8%)	7 (3.0%)	8 (5.5%)	0
	3	9 (1.9%)	0	0	0	4 (1.7%)	5 (3.4%)	0
低ナトリウム血症	- Any Grade -	22 (4.6%)	0	0	2 (5.6%)	12 (5.1%)	5 (3.4%)	3 (5.9%)
	1	8 (1.7%)	0	0	2 (5.6%)	3 (1.3%)	1 (0.7%)	2 (3.9%)
	3	13 (2.7%)	0	0	0	9 (3.8%)	4 (2.7%)	0
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
高血糖	- Any Grade -	20 (4.2%)	0	0	6 (16.7%)	8 (3.4%)	6 (4.1%)	0
	1	9 (1.9%)	0	0	2 (5.6%)	3 (1.3%)	4 (2.7%)	0
	2	4 (0.8%)	0	0	3 (8.3%)	1 (0.4%)	0	0
	3	7 (1.5%)	0	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
低マグネシウム血症	- Any Grade -	18 (3.7%)	1 (11.1%)	0	1 (2.8%)	9 (3.8%)	5 (3.4%)	2 (3.9%)
	1	17 (3.5%)	0	0	1 (2.8%)	9 (3.8%)	5 (3.4%)	2 (3.9%)
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
高カリウム血症	- Any Grade -	16 (3.3%)	0	0	2 (5.6%)	11 (4.7%)	1 (0.7%)	2 (3.9%)
	1	4 (0.8%)	0	0	0	3 (1.3%)	0	1 (2.0%)
	2	9 (1.9%)	0	0	2 (5.6%)	5 (2.1%)	1 (0.7%)	1 (2.0%)
	3	3 (0.6%)	0	0	0	3 (1.3%)	0	0
低アルブミン血症	- Any Grade -	15 (3.1%)	0	0	0	9 (3.8%)	4 (2.7%)	2 (3.9%)
	1	4 (0.8%)	0	0	0	1 (0.4%)	2 (1.4%)	1 (2.0%)
	2	9 (1.9%)	0	0	0	6 (2.5%)	2 (1.4%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
低リン酸血症	- Any Grade -	14 (2.9%)	0	0	1 (2.8%)	8 (3.4%)	4 (2.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	0	2 (1.4%)	1 (2.0%)
	2	4 (0.8%)	0	0	0	4 (1.7%)	0	0
	3	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
低カリウム血症	- Any Grade -	13 (2.7%)	0	0	2 (5.6%)	6 (2.5%)	4 (2.7%)	1 (2.0%)
	1	9 (1.9%)	0	0	1 (2.8%)	5 (2.1%)	3 (2.1%)	0
	3	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	1 (2.0%)
高カルシウム血症	- Any Grade -	12 (2.5%)	0	0	0	11 (4.7%)	0	1 (2.0%)
	1	8 (1.7%)	0	0	0	8 (3.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
低カルシウム血症	- Any Grade -	7 (1.5%)	0	0	0	3 (1.3%)	1 (0.7%)	3 (5.9%)
	1	6 (1.2%)	0	0	0	2 (0.8%)	1 (0.7%)	3 (5.9%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
高尿酸血症	- Any Grade -	4 (0.8%)	0	1 (33.3%)	0	0	3 (2.1%)	0
	1	3 (0.6%)	0	1 (33.3%)	0	0	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
成長障害	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
低血糖症	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	2	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
栄養障害	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血液量減少症	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
高ナトリウム血症	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
腫瘍崩壊症候群	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	3	2 (0.4%)	0	0	0	0	2 (1.4%)	0
痛風	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
鉄欠乏	- Any Grade -	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	1	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
糖尿病	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	3	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
２型糖尿病	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ケトアシドーシス	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
高トリグリセリド血症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
細胞死	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脂質異常症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
食物不耐性	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
水分摂取量減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
代謝性アシドーシス	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
鉄過剰	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚および皮下組織障害								
- Overall -	- Any Grade -	201 (41.8%)	7 (77.8%)	3 (100.0%)	21 (58.3%)	92 (39.0%)	68 (46.6%)	10 (19.6%)
	1	164 (34.1%)	5 (55.6%)	2 (66.7%)	14 (38.9%)	78 (33.1%)	56 (38.4%)	9 (17.6%)
	2	29 (6.0%)	2 (22.2%)	0	6 (16.7%)	10 (4.2%)	10 (6.8%)	1 (2.0%)
	3	8 (1.7%)	0	1 (33.3%)	1 (2.8%)	4 (1.7%)	2 (1.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
発疹	- Any Grade -	71 (14.8%)	1 (11.1%)	2 (66.7%)	8 (22.2%)	33 (14.0%)	25 (17.1%)	2 (3.9%)
	1	62 (12.9%)	0	1 (33.3%)	8 (22.2%)	29 (12.3%)	23 (15.8%)	1 (2.0%)
	2	9 (1.9%)	1 (11.1%)	1 (33.3%)	0	4 (1.7%)	2 (1.4%)	1 (2.0%)
そう痒症	- Any Grade -	64 (13.3%)	2 (22.2%)	1 (33.3%)	9 (25.0%)	31 (13.1%)	16 (11.0%)	5 (9.8%)
	1	54 (11.2%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	27 (11.4%)	15 (10.3%)	5 (9.8%)
	2	10 (2.1%)	0	0	5 (13.9%)	4 (1.7%)	1 (0.7%)	0
皮膚乾燥	- Any Grade -	36 (7.5%)	1 (11.1%)	1 (33.3%)	2 (5.6%)	21 (8.9%)	9 (6.2%)	2 (3.9%)
	1	34 (7.1%)	1 (11.1%)	1 (33.3%)	2 (5.6%)	20 (8.5%)	8 (5.5%)	2 (3.9%)
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
寝汗	- Any Grade -	29 (6.0%)	2 (22.2%)	3 (100.0%)	3 (8.3%)	12 (5.1%)	8 (5.5%)	1 (2.0%)
	1	28 (5.8%)	2 (22.2%)	3 (100.0%)	3 (8.3%)	12 (5.1%)	7 (4.8%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
紅斑	- Any Grade -	16 (3.3%)	0	1 (33.3%)	2 (5.6%)	6 (2.5%)	6 (4.1%)	1 (2.0%)
	1	14 (2.9%)	0	1 (33.3%)	2 (5.6%)	6 (2.5%)	4 (2.7%)	1 (2.0%)
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
斑状丘疹状皮疹	- Any Grade -	14 (2.9%)	0	0	4 (11.1%)	7 (3.0%)	3 (2.1%)	0
	1	11 (2.3%)	0	0	4 (11.1%)	5 (2.1%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
多汗症	- Any Grade -	12 (2.5%)	2 (22.2%)	0	1 (2.8%)	3 (1.3%)	4 (2.7%)	2 (3.9%)
	1	9 (1.9%)	1 (11.1%)	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	1 (2.0%)
	2	3 (0.6%)	1 (11.1%)	0	0	0	1 (0.7%)	1 (2.0%)
ざ瘡様皮膚炎	- Any Grade -	11 (2.3%)	0	0	3 (8.3%)	2 (0.8%)	6 (4.1%)	0
	1	9 (1.9%)	0	0	2 (5.6%)	2 (0.8%)	5 (3.4%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
脱毛症	- Any Grade -	8 (1.7%)	0	0	0	6 (2.5%)	2 (1.4%)	0
	1	7 (1.5%)	0	0	0	5 (2.1%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
そう痒性皮疹	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	2 (0.8%)	2 (1.4%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
紅斑性皮疹	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	1 (2.0%)
	1	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	1 (2.0%)
尋常性白斑	- Any Grade -	4 (0.8%)	0	1 (33.3%)	1 (2.8%)	2 (0.8%)	0	0
	1	4 (0.8%)	0	1 (33.3%)	1 (2.8%)	2 (0.8%)	0	0
皮膚色素過剰	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	1 (0.7%)	1 (2.0%)
	1	4 (0.8%)	0	0	0	2 (0.8%)	1 (0.7%)	1 (2.0%)
過角化	- Any Grade -	3 (0.6%)	0	1 (33.3%)	0	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	0	1 (33.3%)	0	1 (0.4%)	1 (0.7%)	0
爪破損	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	1	3 (0.6%)	0	0	0	0	3 (2.1%)	0
扁平苔癬	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
乾癬	- Any Grade -	2 (0.4%)	0	0	2 (5.6%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
顔面腫脹	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
脂漏性皮膚炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
湿疹	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
接触性皮膚炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
全身性そう痒症	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
爪変色	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
日光角化症	- Any Grade -	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
	1	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
斑状皮疹	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
皮膚剥脱	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
皮膚疼痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
蕁麻疹	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
褥瘡性潰瘍	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	1	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
うっ滞性皮膚炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
ざ瘡	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
乾癬様皮膚炎	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
光線過敏性反応	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
紅色症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
脂漏	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
小水疱性皮疹	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
全身紅斑	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
全身性皮疹	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	3	1 (0.2%)	0	1 (33.3%)	0	0	0	0
多形紅斑	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
多毛症	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
胆汁うっ滞性そう痒症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
爪軟化症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
頭部粃糠疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
斑状出血	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮下気腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚腫瘤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚臭異常	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚色素減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚色素脱失	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚潰瘍	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚病変	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
薬疹	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
冷汗	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
睫毛眉毛脱落症	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
感染症および寄生虫症								
- Overall -	- Any Grade -	186 (38.7%)	5 (55.6%)	3 (100.0%)	20 (55.6%)	88 (37.3%)	64 (43.8%)	6 (11.8%)
	1	62 (12.9%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	28 (11.9%)	23 (15.8%)	4 (7.8%)
	2	92 (19.1%)	2 (22.2%)	2 (66.7%)	9 (25.0%)	44 (18.6%)	34 (23.3%)	1 (2.0%)
	3	26 (5.4%)	1 (11.1%)	0	6 (16.7%)	12 (5.1%)	6 (4.1%)	1 (2.0%)
	4	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	5	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
尿路感染	- Any Grade -	54 (11.2%)	1 (11.1%)	0	4 (11.1%)	31 (13.1%)	15 (10.3%)	3 (5.9%)
	1	21 (4.4%)	0	0	2 (5.6%)	13 (5.5%)	3 (2.1%)	3 (5.9%)
	2	27 (5.6%)	0	0	2 (5.6%)	14 (5.9%)	11 (7.5%)	0
	3	6 (1.2%)	1 (11.1%)	0	0	4 (1.7%)	1 (0.7%)	0
上気道感染	- Any Grade -	47 (9.8%)	3 (33.3%)	2 (66.7%)	6 (16.7%)	14 (5.9%)	21 (14.4%)	1 (2.0%)
	1	20 (4.2%)	1 (11.1%)	1 (33.3%)	2 (5.6%)	5 (2.1%)	10 (6.8%)	1 (2.0%)
	2	27 (5.6%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	9 (3.8%)	11 (7.5%)	0
副鼻腔炎	- Any Grade -	18 (3.7%)	0	0	2 (5.6%)	7 (3.0%)	9 (6.2%)	0
	1	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	2	12 (2.5%)	0	0	1 (2.8%)	4 (1.7%)	7 (4.8%)	0
鼻咽頭炎	- Any Grade -	16 (3.3%)	0	0	0	9 (3.8%)	7 (4.8%)	0
	1	12 (2.5%)	0	0	0	8 (3.4%)	4 (2.7%)	0
	2	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
肺炎	- Any Grade -	14 (2.9%)	0	0	2 (5.6%)	6 (2.5%)	6 (4.1%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	5 (1.0%)	0	0	0	2 (0.8%)	3 (2.1%)	0
	3	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	5	1 (0.2%)	0	0	1 (2.8%)	0	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
気管支炎	- Any Grade -	10 (2.1%)	1 (11.1%)	1 (33.3%)	1 (2.8%)	6 (2.5%)	1 (0.7%)	0
	1	8 (1.7%)	1 (11.1%)	1 (33.3%)	1 (2.8%)	5 (2.1%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
口腔ヘルペス	- Any Grade -	7 (1.5%)	0	0	0	3 (1.3%)	4 (2.7%)	0
	1	7 (1.5%)	0	0	0	3 (1.3%)	4 (2.7%)	0
帯状疱疹	- Any Grade -	7 (1.5%)	1 (11.1%)	1 (33.3%)	0	4 (1.7%)	1 (0.7%)	0
	1	4 (0.8%)	1 (11.1%)	1 (33.3%)	0	2 (0.8%)	0	0
	2	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
医療機器関連感染	- Any Grade -	6 (1.2%)	0	0	0	2 (0.8%)	4 (2.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
敗血症	- Any Grade -	6 (1.2%)	1 (11.1%)	0	0	5 (2.1%)	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺感染	- Any Grade -	6 (1.2%)	0	0	3 (8.3%)	1 (0.4%)	2 (1.4%)	0
	2	4 (0.8%)	0	0	2 (5.6%)	0	2 (1.4%)	0
	3	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
口腔カンジダ症	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
鼻炎	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
カンジダ感染	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
咽頭炎	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	1 (2.0%)
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
下気道感染	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
歯感染	- Any Grade -	4 (0.8%)	0	0	2 (5.6%)	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	3 (0.6%)	0	0	2 (5.6%)	0	1 (0.7%)	0
真菌感染	- Any Grade -	4 (0.8%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
蜂巣炎	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	3 (1.3%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	1 (2.8%)	2 (0.8%)	0	0
インフルエンザ	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
気道感染	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
限局性感染	- Any Grade -	3 (0.6%)	0	1 (33.3%)	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	1 (33.3%)	1 (2.8%)	0	0	0
歯膿瘍	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
耳感染	- Any Grade -	3 (0.6%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
膀胱炎	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
せつ	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
外陰腟真菌感染	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
感染	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
感染性関節炎	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	3	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
結膜炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腎盂腎炎	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
創傷感染	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
尿路性敗血症	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
皮膚感染	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
インフルエンザ性肺炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ウイルス性咽頭炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
ウイルス性結膜炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
異型肺炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
胃腸炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝周囲膿瘍	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼感染	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
菌血症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
股部白癬	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
口腔膿瘍	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
根管感染	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
細菌感染	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
歯肉炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
術後創感染	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
髄膜炎	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
丹毒	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
蓄膿	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
中耳炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
爪囲炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
爪真菌症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
粘膜感染	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
膿尿	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
敗血症性ショック	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
皮下組織膿瘍	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
皮膚カンジダ	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
皮膚真菌感染	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腹部膿瘍	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
放線菌症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
癰	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
神経系障害								
- Overall -	- Any Grade -	185 (38.5%)	6 (66.7%)	2 (66.7%)	18 (50.0%)	82 (34.7%)	62 (42.5%)	15 (29.4%)
	1	135 (28.1%)	5 (55.6%)	2 (66.7%)	13 (36.1%)	58 (24.6%)	47 (32.2%)	10 (19.6%)
	2	36 (7.5%)	1 (11.1%)	0	2 (5.6%)	18 (7.6%)	11 (7.5%)	4 (7.8%)
	3	13 (2.7%)	0	0	3 (8.3%)	6 (2.5%)	3 (2.1%)	1 (2.0%)
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
頭痛	- Any Grade -	79 (16.4%)	3 (33.3%)	1 (33.3%)	13 (36.1%)	31 (13.1%)	25 (17.1%)	6 (11.8%)
	1	68 (14.1%)	3 (33.3%)	1 (33.3%)	12 (33.3%)	28 (11.9%)	21 (14.4%)	3 (5.9%)
	2	9 (1.9%)	0	0	0	2 (0.8%)	4 (2.7%)	3 (5.9%)
	3	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
浮動性めまい	- Any Grade -	44 (9.1%)	1 (11.1%)	1 (33.3%)	7 (19.4%)	18 (7.6%)	15 (10.3%)	2 (3.9%)
	1	40 (8.3%)	1 (11.1%)	1 (33.3%)	7 (19.4%)	15 (6.4%)	14 (9.6%)	2 (3.9%)
	2	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
味覚異常	- Any Grade -	19 (4.0%)	2 (22.2%)	0	2 (5.6%)	9 (3.8%)	6 (4.1%)	0
	1	15 (3.1%)	1 (11.1%)	0	1 (2.8%)	7 (3.0%)	6 (4.1%)	0
	2	4 (0.8%)	1 (11.1%)	0	1 (2.8%)	2 (0.8%)	0	0
末梢性ニューロパチー	- Any Grade -	17 (3.5%)	2 (22.2%)	0	0	10 (4.2%)	3 (2.1%)	2 (3.9%)
	1	14 (2.9%)	2 (22.2%)	0	0	7 (3.0%)	3 (2.1%)	2 (3.9%)
	2	3 (0.6%)	0	0	0	3 (1.3%)	0	0
錯感覚	- Any Grade -	13 (2.7%)	0	0	4 (11.1%)	5 (2.1%)	2 (1.4%)	2 (3.9%)
	1	9 (1.9%)	0	0	4 (11.1%)	2 (0.8%)	2 (1.4%)	1 (2.0%)
	2	4 (0.8%)	0	0	0	3 (1.3%)	0	1 (2.0%)
感覚鈍麻	- Any Grade -	9 (1.9%)	1 (11.1%)	0	2 (5.6%)	3 (1.3%)	3 (2.1%)	0
	1	7 (1.5%)	0	0	2 (5.6%)	3 (1.3%)	2 (1.4%)	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
振戦	- Any Grade -	7 (1.5%)	0	0	2 (5.6%)	2 (0.8%)	3 (2.1%)	0
	1	6 (1.2%)	0	0	1 (2.8%)	2 (0.8%)	3 (2.1%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
嗜眠	- Any Grade -	7 (1.5%)	0	0	0	4 (1.7%)	3 (2.1%)	0
	1	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	2	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0

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失神	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
失神寸前の状態	- Any Grade -	5 (1.0%)	0	0	0	1 (0.4%)	3 (2.1%)	1 (2.0%)
	1	5 (1.0%)	0	0	0	1 (0.4%)	3 (2.1%)	1 (2.0%)
神経痛	- Any Grade -	5 (1.0%)	0	0	0	5 (2.1%)	0	0
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
末梢性感覚ニューロパチー	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
	1	4 (0.8%)	0	0	1 (2.8%)	3 (1.3%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
灼熱感	- Any Grade -	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
記憶障害	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
傾眠	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
健忘	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	0	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	1 (2.8%)	0	1 (0.7%)	1 (2.0%)
坐骨神経痛	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
失語症	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
脊髄圧迫	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
副鼻腔炎に伴う頭痛	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
平衡障害	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
運動失調	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
視野欠損	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
認知障害	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脳血管発作	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
片頭痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
末梢性運動ニューロパチー	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腓骨神経麻痺	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
ジスキネジア	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
意識変容状態	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
蟻走感	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
腰髄神経根障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
手根管症候群	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
重症筋無力症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
神経圧迫	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
神経根痛	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
神経毒性	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
第７脳神経麻痺	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
断端痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
知覚過敏	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
注意力障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
認知症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脳症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
部分発作	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
痙攣発作	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
臨床検査								
- Overall -	- Any Grade -	129 (26.8%)	1 (11.1%)	2 (66.7%)	9 (25.0%)	68 (28.8%)	39 (26.7%)	10 (19.6%)
	1	58 (12.1%)	1 (11.1%)	2 (66.7%)	6 (16.7%)	26 (11.0%)	19 (13.0%)	4 (7.8%)
	2	39 (8.1%)	0	0	1 (2.8%)	23 (9.7%)	12 (8.2%)	3 (5.9%)
	3	26 (5.4%)	0	0	1 (2.8%)	16 (6.8%)	6 (4.1%)	3 (5.9%)
	4	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
体重減少	- Any Grade -	32 (6.7%)	0	0	2 (5.6%)	15 (6.4%)	12 (8.2%)	3 (5.9%)
	1	23 (4.8%)	0	0	2 (5.6%)	11 (4.7%)	8 (5.5%)	2 (3.9%)
	2	8 (1.7%)	0	0	0	3 (1.3%)	4 (2.7%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	27 (5.6%)	0	0	0	16 (6.8%)	8 (5.5%)	3 (5.9%)
	1	12 (2.5%)	0	0	0	7 (3.0%)	3 (2.1%)	2 (3.9%)
	2	7 (1.5%)	0	0	0	3 (1.3%)	3 (2.1%)	1 (2.0%)
	3	7 (1.5%)	0	0	0	5 (2.1%)	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
アラニンアミノトランスフェラーゼ増加	- Any Grade -	25 (5.2%)	0	0	1 (2.8%)	13 (5.5%)	9 (6.2%)	2 (3.9%)
	1	14 (2.9%)	0	0	1 (2.8%)	6 (2.5%)	6 (4.1%)	1 (2.0%)
	2	4 (0.8%)	0	0	0	3 (1.3%)	0	1 (2.0%)
	3	5 (1.0%)	0	0	0	2 (0.8%)	3 (2.1%)	0
	4	2 (0.4%)	0	0	0	2 (0.8%)	0	0
血中クレアチニン増加	- Any Grade -	25 (5.2%)	0	0	0	22 (9.3%)	1 (0.7%)	2 (3.9%)
	1	12 (2.5%)	0	0	0	10 (4.2%)	1 (0.7%)	1 (2.0%)
	2	11 (2.3%)	0	0	0	11 (4.7%)	0	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
血中アルカリホスファターゼ増加	- Any Grade -	19 (4.0%)	0	0	0	15 (6.4%)	3 (2.1%)	1 (2.0%)
	1	8 (1.7%)	0	0	0	5 (2.1%)	3 (2.1%)	0
	2	8 (1.7%)	0	0	0	7 (3.0%)	0	1 (2.0%)
	3	3 (0.6%)	0	0	0	3 (1.3%)	0	0
血中ビリルビン増加	- Any Grade -	9 (1.9%)	0	0	1 (2.8%)	6 (2.5%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
リンパ球数減少	- Any Grade -	7 (1.5%)	0	0	2 (5.6%)	3 (1.3%)	1 (0.7%)	1 (2.0%)
	1	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	4	1 (0.2%)	0	0	1 (2.8%)	0	0	0
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	6 (1.2%)	0	0	0	3 (1.3%)	1 (0.7%)	2 (3.9%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	4 (0.8%)	0	0	0	1 (0.4%)	1 (0.7%)	2 (3.9%)
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血小板数減少	- Any Grade -	6 (1.2%)	0	0	2 (5.6%)	3 (1.3%)	1 (0.7%)	0
	1	4 (0.8%)	0	0	1 (2.8%)	3 (1.3%)	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血中リン減少	- Any Grade -	6 (1.2%)	0	0	0	4 (1.7%)	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
白血球数減少	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	0	1 (2.0%)
	1	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
トランスアミナーゼ上昇	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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体重増加	- Any Grade -	5 (1.0%)	0	1 (33.3%)	0	1 (0.4%)	3 (2.1%)	0
	1	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
	2	3 (0.6%)	0	0	0	0	3 (2.1%)	0
国際標準比増加	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
血中甲状腺刺激ホルモン増加	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
リパーゼ増加	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
肝機能検査異常	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血中アルブミン減少	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
血中カルシウム減少	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
血中カルシウム増加	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中クレアチンホスホキナーゼ増加	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中乳酸脱水素酵素増加	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0

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アミラーゼ増加	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
グリコヘモグロビン増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
サイロキシン減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
ハプトグロビン減少	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
ヘマトクリット増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
ヘモグロビン減少	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ヘモグロビン増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胸部コンピュータ断層撮影異常	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中クロール増加	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
血中テストステロン減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血中マグネシウム増加	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中甲状腺刺激ホルモン減少	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中尿酸増加	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0

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Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
血中尿素増加	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
酸素飽和度低下	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
出血時間延長	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
心電図ＰＲ延長	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
体温上昇	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
尿培養陽性	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
白血球数増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
便潜血陽性	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
喀痰異常	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血液およびリンパ系障害 - Overall -	- Any Grade -	123 (25.6%)	1 (11.1%)	1 (33.3%)	9 (25.0%)	64 (27.1%)	39 (26.7%)	9 (17.6%)
	1	48 (10.0%)	0	1 (33.3%)	7 (19.4%)	23 (9.7%)	15 (10.3%)	2 (3.9%)
	2	48 (10.0%)	0	0	1 (2.8%)	29 (12.3%)	14 (9.6%)	4 (7.8%)
	3	26 (5.4%)	1 (11.1%)	0	1 (2.8%)	11 (4.7%)	10 (6.8%)	3 (5.9%)
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
貧血	- Any Grade -	97 (20.2%)	1 (11.1%)	0	7 (19.4%)	53 (22.5%)	28 (19.2%)	8 (15.7%)
	1	33 (6.9%)	0	0	6 (16.7%)	16 (6.8%)	8 (5.5%)	3 (5.9%)
	2	43 (8.9%)	0	0	1 (2.8%)	27 (11.4%)	13 (8.9%)	2 (3.9%)
	3	21 (4.4%)	1 (11.1%)	0	0	10 (4.2%)	7 (4.8%)	3 (5.9%)
リンパ球減少症	- Any Grade -	11 (2.3%)	0	0	1 (2.8%)	4 (1.7%)	3 (2.1%)	3 (5.9%)
	1	5 (1.0%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	2 (3.9%)
	2	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
	3	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
血小板減少症	- Any Grade -	11 (2.3%)	0	0	0	8 (3.4%)	1 (0.7%)	2 (3.9%)
	1	7 (1.5%)	0	0	0	6 (2.5%)	0	1 (2.0%)
	2	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
好中球減少症	- Any Grade -	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	1	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
リンパ節症	- Any Grade -	5 (1.0%)	0	1 (33.3%)	0	1 (0.4%)	3 (2.1%)	0
	1	5 (1.0%)	0	1 (33.3%)	0	1 (0.4%)	3 (2.1%)	0
鉄欠乏性貧血	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
白血球増加症	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0

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リンパ節痛	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
凝血異常	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
赤血球増加症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
内出血発生の増加傾向	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脾静脈血栓症	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
精神障害								
- Overall -	- Any Grade -	118 (24.5%)	3 (33.3%)	2 (66.7%)	16 (44.4%)	51 (21.6%)	40 (27.4%)	6 (11.8%)
	1	71 (14.8%)	2 (22.2%)	2 (66.7%)	6 (16.7%)	30 (12.7%)	26 (17.8%)	5 (9.8%)
	2	39 (8.1%)	1 (11.1%)	0	7 (19.4%)	17 (7.2%)	14 (9.6%)	0
	3	6 (1.2%)	0	0	2 (5.6%)	3 (1.3%)	0	1 (2.0%)
	4	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
不眠症	- Any Grade -	60 (12.5%)	2 (22.2%)	1 (33.3%)	10 (27.8%)	25 (10.6%)	20 (13.7%)	2 (3.9%)
	1	40 (8.3%)	1 (11.1%)	1 (33.3%)	8 (22.2%)	14 (5.9%)	14 (9.6%)	2 (3.9%)
	2	19 (4.0%)	1 (11.1%)	0	2 (5.6%)	10 (4.2%)	6 (4.1%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
不安	- Any Grade -	37 (7.7%)	2 (22.2%)	1 (33.3%)	6 (16.7%)	15 (6.4%)	11 (7.5%)	2 (3.9%)
	1	27 (5.6%)	2 (22.2%)	1 (33.3%)	3 (8.3%)	13 (5.5%)	6 (4.1%)	2 (3.9%)
	2	10 (2.1%)	0	0	3 (8.3%)	2 (0.8%)	5 (3.4%)	0

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うつ病	- Any Grade -	24 (5.0%)	0	0	2 (5.6%)	12 (5.1%)	10 (6.8%)	0
	1	15 (3.1%)	0	0	1 (2.8%)	9 (3.8%)	5 (3.4%)	0
	2	9 (1.9%)	0	0	1 (2.8%)	3 (1.3%)	5 (3.4%)	0
錯乱状態	- Any Grade -	15 (3.1%)	0	0	2 (5.6%)	7 (3.0%)	4 (2.7%)	2 (3.9%)
	1	9 (1.9%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	2 (3.9%)
	2	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
精神状態変化	- Any Grade -	5 (1.0%)	0	0	3 (8.3%)	1 (0.4%)	0	1 (2.0%)
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	2 (5.6%)	0	0	1 (2.0%)
気分変化	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	1	3 (0.6%)	0	0	0	0	3 (2.1%)	0
易刺激性	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
気分動揺	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
幻覚	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
失見当識	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
アルコール乱用	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
チック	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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異常な夢	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
陰気	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
激越	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
幻視	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
自殺企図	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	4	1 (0.2%)	0	0	1 (2.8%)	0	0	0
閉所恐怖症	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
抑うつ気分	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
腎および尿路障害								
- Overall -	- Any Grade -	76 (15.8%)	3 (33.3%)	2 (66.7%)	10 (27.8%)	39 (16.5%)	19 (13.0%)	3 (5.9%)
	1	51 (10.6%)	2 (22.2%)	1 (33.3%)	10 (27.8%)	23 (9.7%)	14 (9.6%)	1 (2.0%)
	2	13 (2.7%)	1 (11.1%)	0	0	11 (4.7%)	0	1 (2.0%)
	3	12 (2.5%)	0	1 (33.3%)	0	5 (2.1%)	5 (3.4%)	1 (2.0%)
血尿	- Any Grade -	15 (3.1%)	0	2 (66.7%)	3 (8.3%)	7 (3.0%)	2 (1.4%)	1 (2.0%)
	1	15 (3.1%)	0	2 (66.7%)	3 (8.3%)	7 (3.0%)	2 (1.4%)	1 (2.0%)
頻尿	- Any Grade -	15 (3.1%)	2 (22.2%)	0	4 (11.1%)	6 (2.5%)	3 (2.1%)	0
	1	14 (2.9%)	2 (22.2%)	0	4 (11.1%)	5 (2.1%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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排尿困難	- Any Grade -	12 (2.5%)	0	0	1 (2.8%)	7 (3.0%)	4 (2.7%)	0
	1	11 (2.3%)	0	0	1 (2.8%)	6 (2.5%)	4 (2.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
夜間頻尿	- Any Grade -	9 (1.9%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	1 (2.0%)
	1	9 (1.9%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	1 (2.0%)
急性腎不全	- Any Grade -	8 (1.7%)	0	0	0	5 (2.1%)	2 (1.4%)	1 (2.0%)
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	4 (0.8%)	0	0	0	4 (1.7%)	0	0
	3	3 (0.6%)	0	0	0	0	2 (1.4%)	1 (2.0%)
蛋白尿	- Any Grade -	7 (1.5%)	0	1 (33.3%)	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
	3	2 (0.4%)	0	1 (33.3%)	0	0	1 (0.7%)	0
腎不全	- Any Grade -	5 (1.0%)	0	0	0	4 (1.7%)	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
水腎症	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
尿閉	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
尿失禁	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0

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尿臭異常	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
排尿躊躇	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
ケトン尿	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
出血性膀胱炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腎機能障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腎仙痛	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腎臓痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
着色尿	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
尿意切迫	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
尿管閉塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
尿道出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
尿道閉塞	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
尿流量減少	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
尿路結石	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
尿路痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
尿路閉塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
膀胱痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血管障害								
- Overall -	- Any Grade -	69 (14.3%)	1 (11.1%)	1 (33.3%)	4 (11.1%)	33 (14.0%)	26 (17.8%)	4 (7.8%)
	1	38 (7.9%)	1 (11.1%)	0	4 (11.1%)	21 (8.9%)	10 (6.8%)	2 (3.9%)
	2	20 (4.2%)	0	0	0	6 (2.5%)	13 (8.9%)	1 (2.0%)
	3	11 (2.3%)	0	1 (33.3%)	0	6 (2.5%)	3 (2.1%)	1 (2.0%)
高血圧	- Any Grade -	14 (2.9%)	0	1 (33.3%)	1 (2.8%)	4 (1.7%)	5 (3.4%)	3 (5.9%)
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	0	1 (2.0%)
	2	7 (1.5%)	0	0	0	3 (1.3%)	3 (2.1%)	1 (2.0%)
	3	4 (0.8%)	0	1 (33.3%)	0	0	2 (1.4%)	1 (2.0%)
低血圧	- Any Grade -	14 (2.9%)	0	0	0	6 (2.5%)	8 (5.5%)	0
	1	9 (1.9%)	0	0	0	4 (1.7%)	5 (3.4%)	0
	2	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ほてり	- Any Grade -	10 (2.1%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	4 (2.7%)	0
	1	8 (1.7%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0

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Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
潮紅	- Any Grade -	7 (1.5%)	0	0	0	6 (2.5%)	1 (0.7%)	0
	1	7 (1.5%)	0	0	0	6 (2.5%)	1 (0.7%)	0
深部静脈血栓症	- Any Grade -	6 (1.2%)	0	0	0	3 (1.3%)	3 (2.1%)	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
リンパ浮腫	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
	1	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
起立性低血圧	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
血腫	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血栓症	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
上大静脈症候群	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
大静脈血栓症	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
リンパ嚢腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
静脈血栓症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
静脈閉塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
静脈瘤	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
大動脈瘤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
動脈硬化症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
表在性血栓性静脈炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
末梢冷感	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腋窩静脈血栓症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼障害								
- Overall -	- Any Grade -	60 (12.5%)	4 (44.4%)	1 (33.3%)	8 (22.2%)	25 (10.6%)	20 (13.7%)	2 (3.9%)
	1	53 (11.0%)	3 (33.3%)	1 (33.3%)	8 (22.2%)	23 (9.7%)	16 (11.0%)	2 (3.9%)
	2	7 (1.5%)	1 (11.1%)	0	0	2 (0.8%)	4 (2.7%)	0
霧視	- Any Grade -	13 (2.7%)	0	0	3 (8.3%)	3 (1.3%)	6 (4.1%)	1 (2.0%)
	1	12 (2.5%)	0	0	3 (8.3%)	2 (0.8%)	6 (4.1%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
視力障害	- Any Grade -	7 (1.5%)	0	0	1 (2.8%)	2 (0.8%)	4 (2.7%)	0
	1	6 (1.2%)	0	0	1 (2.8%)	2 (0.8%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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眼乾燥	- Any Grade -	6 (1.2%)	0	0	0	5 (2.1%)	1 (0.7%)	0
	1	5 (1.0%)	0	0	0	5 (2.1%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼充血	- Any Grade -	5 (1.0%)	0	0	0	4 (1.7%)	0	1 (2.0%)
	1	5 (1.0%)	0	0	0	4 (1.7%)	0	1 (2.0%)
硝子体浮遊物	- Any Grade -	5 (1.0%)	0	0	2 (5.6%)	1 (0.4%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	2 (5.6%)	1 (0.4%)	2 (1.4%)	0
眼そう痒症	- Any Grade -	3 (0.6%)	2 (22.2%)	0	0	1 (0.4%)	0	0
	1	3 (0.6%)	2 (22.2%)	0	0	1 (0.4%)	0	0
眼痛	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼窩周囲浮腫	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
視力低下	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
複視	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
流涙増加	- Any Grade -	3 (0.6%)	2 (22.2%)	1 (33.3%)	0	0	0	0
	1	3 (0.6%)	2 (22.2%)	1 (33.3%)	0	0	0	0
黄疸眼	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
羞明	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0

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黄斑円孔	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
黄斑変性	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
角膜炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼部腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
眼瞼炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
眼瞼嚢胞	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼瞼浮腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
結膜出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
光輪視	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
縮瞳	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
深径覚の変化	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
注視麻痺	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
潰瘍性角膜炎	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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緑内障	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
傷害、中毒および処置合併症								
- Overall -	- Any Grade -	55 (11.4%)	1 (11.1%)	2 (66.7%)	6 (16.7%)	24 (10.2%)	19 (13.0%)	3 (5.9%)
	1	34 (7.1%)	1 (11.1%)	2 (66.7%)	2 (5.6%)	14 (5.9%)	13 (8.9%)	2 (3.9%)
	2	14 (2.9%)	0	0	4 (11.1%)	6 (2.5%)	4 (2.7%)	0
	3	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	5	3 (0.6%)	0	0	0	2 (0.8%)	0	1 (2.0%)
転倒	- Any Grade -	12 (2.5%)	0	0	2 (5.6%)	3 (1.3%)	7 (4.8%)	0
	1	7 (1.5%)	0	0	0	2 (0.8%)	5 (3.4%)	0
	2	3 (0.6%)	0	0	2 (5.6%)	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
処置による疼痛	- Any Grade -	6 (1.2%)	0	0	2 (5.6%)	2 (0.8%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	3 (0.6%)	0	0	2 (5.6%)	0	1 (0.7%)	0
挫傷	- Any Grade -	5 (1.0%)	0	0	0	2 (0.8%)	3 (2.1%)	0
	1	5 (1.0%)	0	0	0	2 (0.8%)	3 (2.1%)	0
肉離れ	- Any Grade -	4 (0.8%)	0	1 (33.3%)	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	1 (33.3%)	0	0	1 (0.7%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
節足動物咬傷	- Any Grade -	2 (0.4%)	0	0	2 (5.6%)	0	0	0
	1	2 (0.4%)	0	0	2 (5.6%)	0	0	0

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注入に伴う反応	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
頭部損傷	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚擦過傷	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
裂傷	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
肋骨骨折	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ウロストミー合併症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
圧迫骨折	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
栄養補給チューブ合併症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
過量投与	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	5	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝血腫	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)

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Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
鎖骨骨折	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
四肢損傷	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
歯牙破折	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
処置後挫傷	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
処置部位反応	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
神経損傷	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
切開部位合併症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
切開部位痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
創合併症	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
創傷	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
創離開	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
足骨折	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
大腿骨頚部骨折	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
大腿骨骨折	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脳振盪	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚損傷	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
表在性異物	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
放射線性肺臓炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
放射線皮膚損傷	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
漿液腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
靱帯断裂	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	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 -	42 (8.7%)	1 (11.1%)	1 (33.3%)	3 (8.3%)	22 (9.3%)	14 (9.6%)	1 (2.0%)
	1	17 (3.5%)	1 (11.1%)	0	1 (2.8%)	9 (3.8%)	5 (3.4%)	1 (2.0%)
	2	19 (4.0%)	0	1 (33.3%)	1 (2.8%)	10 (4.2%)	7 (4.8%)	0
	3	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腫瘍疼痛	- Any Grade -	11 (2.3%)	0	0	0	4 (1.7%)	7 (4.8%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	7 (1.5%)	0	0	0	3 (1.3%)	4 (2.7%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
腫瘍出血	- Any Grade -	6 (1.2%)	0	1 (33.3%)	0	4 (1.7%)	0	1 (2.0%)
	1	4 (0.8%)	0	1 (33.3%)	0	2 (0.8%)	0	1 (2.0%)
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
脂漏性角化症	- Any Grade -	4 (0.8%)	1 (11.1%)	0	0	3 (1.3%)	0	0
	1	4 (0.8%)	1 (11.1%)	0	0	3 (1.3%)	0	0
中枢神経系転移	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
感染性新生物	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
基底細胞癌	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
腫瘍の潰瘍形成	- Any Grade -	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	1 (33.3%)	0	0	0	0
腫瘍浸潤	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
扁平上皮癌	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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アクロコルドン	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
メラノサイト性母斑	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
リンパ管腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
悪性胸水	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
癌疼痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
甲状腺癌	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
子宮頚部新生物	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
子宮平滑筋腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腫瘍フレア	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
腫瘍壊死	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
腫瘍熱	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
新生物	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
新生物腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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転移部痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚乳頭腫	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
皮膚良性新生物	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
生殖系および乳房障害								
- Overall -	- Any Grade -	36 (7.5%)	1 (11.1%)	1 (33.3%)	4 (11.1%)	14 (5.9%)	15 (10.3%)	1 (2.0%)
	1	25 (5.2%)	1 (11.1%)	1 (33.3%)	3 (8.3%)	8 (3.4%)	11 (7.5%)	1 (2.0%)
	2	10 (2.1%)	0	0	1 (2.8%)	5 (2.1%)	4 (2.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
骨盤痛	- Any Grade -	6 (1.2%)	0	0	0	5 (2.1%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	4 (0.8%)	0	0	0	4 (1.7%)	0	0
勃起不全	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	0
	1	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
乳房痛	- Any Grade -	4 (0.8%)	0	1 (33.3%)	0	1 (0.4%)	2 (1.4%)	0
	1	4 (0.8%)	0	1 (33.3%)	0	1 (0.4%)	2 (1.4%)	0
腟分泌物	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
陰茎障害	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
陰茎痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	1	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)

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外陰腟そう痒症	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
外陰腟乾燥	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
外陰腟痛	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
女性生殖器瘻	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
精巣痛	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
腟出血	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
バルトリン嚢腫	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
陰茎出血	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
陰茎分泌物	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
陰嚢痛	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
会陰紅斑	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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外陰腟灼熱感	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
外陰腟不快感	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
亀頭包皮炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
骨盤不快感	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
女性化乳房	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
性器発疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
精巣腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
前立腺炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
乳房圧痛	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
乳房炎症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
乳房腫脹	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
不正子宮出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腟粘膜水疱形成	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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耳および迷路障害								
- Overall -	- Any Grade -	32 (6.7%)	0	2 (66.7%)	5 (13.9%)	18 (7.6%)	7 (4.8%)	0
	1	28 (5.8%)	0	2 (66.7%)	3 (8.3%)	16 (6.8%)	7 (4.8%)	0
	2	4 (0.8%)	0	0	2 (5.6%)	2 (0.8%)	0	0
回転性めまい	- Any Grade -	8 (1.7%)	0	1 (33.3%)	1 (2.8%)	4 (1.7%)	2 (1.4%)	0
	1	7 (1.5%)	0	1 (33.3%)	0	4 (1.7%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
耳不快感	- Any Grade -	6 (1.2%)	0	0	0	5 (2.1%)	1 (0.7%)	0
	1	6 (1.2%)	0	0	0	5 (2.1%)	1 (0.7%)	0
耳痛	- Any Grade -	5 (1.0%)	0	0	2 (5.6%)	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
耳鳴	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
	1	4 (0.8%)	0	0	0	1 (0.4%)	3 (2.1%)	0
聴力低下	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
難聴	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
外耳痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
耳垢栓塞	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
耳出血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
耳閉	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
耳漏	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
聴覚障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
聴覚不全	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
片耳難聴	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
心臓障害								
- Overall -	- Any Grade -	32 (6.7%)	3 (33.3%)	0	4 (11.1%)	10 (4.2%)	14 (9.6%)	1 (2.0%)
	1	17 (3.5%)	2 (22.2%)	0	3 (8.3%)	5 (2.1%)	6 (4.1%)	1 (2.0%)
	2	5 (1.0%)	1 (11.1%)	0	0	1 (0.4%)	3 (2.1%)	0
	3	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	4	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	5	2 (0.4%)	0	0	0	0	2 (1.4%)	0
頻脈	- Any Grade -	9 (1.9%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	1 (2.0%)
	1	8 (1.7%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	1 (0.7%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心房細動	- Any Grade -	7 (1.5%)	1 (11.1%)	0	1 (2.8%)	3 (1.3%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	3 (0.6%)	1 (11.1%)	0	0	1 (0.4%)	1 (0.7%)	0
	3	3 (0.6%)	0	0	0	2 (0.8%)	1 (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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
動悸	- Any Grade -	6 (1.2%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	0
	1	6 (1.2%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	0
洞性頻脈	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
心タンポナーデ	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心嚢液貯留	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
徐脈	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心粗動	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心肺停止	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心房粗動	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
内分泌障害								
- Overall -	- Any Grade -	31 (6.4%)	0	0	4 (11.1%)	15 (6.4%)	11 (7.5%)	1 (2.0%)
	1	9 (1.9%)	0	0	0	6 (2.5%)	2 (1.4%)	1 (2.0%)
	2	19 (4.0%)	0	0	4 (11.1%)	6 (2.5%)	9 (6.2%)	0
	3	3 (0.6%)	0	0	0	3 (1.3%)	0	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
甲状腺機能低下症	- Any Grade -	20 (4.2%)	0	0	4 (11.1%)	9 (3.8%)	7 (4.8%)	0
	1	5 (1.0%)	0	0	0	5 (2.1%)	0	0
	2	15 (3.1%)	0	0	4 (11.1%)	4 (1.7%)	7 (4.8%)	0
甲状腺機能亢進症	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	2 (1.4%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
副腎機能不全	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
悪性腫瘍に伴う高カルシウム血症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
下垂体炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
甲状腺炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
肝胆道系障害								
- Overall -	- Any Grade -	27 (5.6%)	0	0	1 (2.8%)	15 (6.4%)	10 (6.8%)	1 (2.0%)
	1	12 (2.5%)	0	0	1 (2.8%)	6 (2.5%)	5 (3.4%)	0
	2	4 (0.8%)	0	0	0	2 (0.8%)	1 (0.7%)	1 (2.0%)
	3	8 (1.7%)	0	0	0	6 (2.5%)	2 (1.4%)	0
	4	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
黄疸	- Any Grade -	5 (1.0%)	0	0	0	1 (0.4%)	4 (2.7%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
高ビリルビン血症	- Any Grade -	5 (1.0%)	0	0	0	5 (2.1%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	3 (0.6%)	0	0	0	3 (1.3%)	0	0
肝細胞損傷	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝臓痛	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	0	1 (2.0%)
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
自己免疫性肝炎	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝機能異常	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
胆管炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胆管閉塞	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胆石症	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
門脈血栓症	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
後天性肝内胆管拡張症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
脂肪肝	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胆道仙痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胆嚢炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
胆嚢穿孔	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
免疫系障害								
- Overall -	- Any Grade -	10 (2.1%)	0	0	1 (2.8%)	5 (2.1%)	4 (2.7%)	0
	1	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	2	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
季節性アレルギー	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	2 (0.8%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	2 (0.8%)	2 (1.4%)	0
過敏症	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
植物アレルギー	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
造影剤アレルギー	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
外科および内科処置								
- Overall -	- Any Grade -	9 (1.9%)	0	1 (33.3%)	1 (2.8%)	6 (2.5%)	1 (0.7%)	0
	1	5 (1.0%)	0	0	0	4 (1.7%)	1 (0.7%)	0
	2	3 (0.6%)	0	1 (33.3%)	0	2 (0.8%)	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
ステント除去	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
抜歯	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
ヘルニア修復	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
胃瘻造設術	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
開頭	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
開腹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
結腸瘻造設	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
股関節形成	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	2	1 (0.2%)	0	1 (33.3%)	0	0	0	0
腎臓手術	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

表 2.7.6.2.1.1-2　すべての副作用（PCD4989g 試験）

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
- Any adverse events -	- Any Grade -	347 (72.1%)	8 (88.9%)	3 (100.0%)	31 (86.1%)	172 (72.9%)	108 (74.0%)	25 (49.0%)
	1	150 (31.2%)	3 (33.3%)	1 (33.3%)	14 (38.9%)	81 (34.3%)	43 (29.5%)	8 (15.7%)
	2	134 (27.9%)	5 (55.6%)	1 (33.3%)	11 (30.6%)	60 (25.4%)	47 (32.2%)	10 (19.6%)
	3	52 (10.8%)	0	1 (33.3%)	5 (13.9%)	25 (10.6%)	16 (11.0%)	5 (9.8%)
	4	8 (1.7%)	0	0	1 (2.8%)	6 (2.5%)	1 (0.7%)	0
	5	3 (0.6%)	0	0	0	0	1 (0.7%)	2 (3.9%)
一般・全身障害および投与部位の状態								
- Overall -	- Any Grade -	218 (45.3%)	8 (88.9%)	2 (66.7%)	22 (61.1%)	102 (43.2%)	66 (45.2%)	18 (35.3%)
	1	118 (24.5%)	6 (66.7%)	1 (33.3%)	15 (41.7%)	55 (23.3%)	35 (24.0%)	6 (11.8%)
	2	85 (17.7%)	2 (22.2%)	1 (33.3%)	6 (16.7%)	41 (17.4%)	24 (16.4%)	11 (21.6%)
	3	14 (2.9%)	0	0	1 (2.8%)	6 (2.5%)	7 (4.8%)	0
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
疲労	- Any Grade -	111 (23.1%)	6 (66.7%)	2 (66.7%)	13 (36.1%)	51 (21.6%)	33 (22.6%)	6 (11.8%)
	1	61 (12.7%)	4 (44.4%)	1 (33.3%)	8 (22.2%)	28 (11.9%)	18 (12.3%)	2 (3.9%)
	2	44 (9.1%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	22 (9.3%)	11 (7.5%)	4 (7.8%)
	3	6 (1.2%)	0	0	1 (2.8%)	1 (0.4%)	4 (2.7%)	0
発熱	- Any Grade -	58 (12.1%)	1 (11.1%)	0	6 (16.7%)	30 (12.7%)	16 (11.0%)	5 (9.8%)
	1	39 (8.1%)	1 (11.1%)	0	6 (16.7%)	18 (7.6%)	10 (6.8%)	4 (7.8%)
	2	19 (4.0%)	0	0	0	12 (5.1%)	6 (4.1%)	1 (2.0%)
無力症	- Any Grade -	49 (10.2%)	1 (11.1%)	0	1 (2.8%)	25 (10.6%)	16 (11.0%)	6 (11.8%)
	1	19 (4.0%)	1 (11.1%)	0	1 (2.8%)	12 (5.1%)	4 (2.7%)	1 (2.0%)
	2	26 (5.4%)	0	0	0	11 (4.7%)	10 (6.8%)	5 (9.8%)
	3	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
悪寒	- Any Grade -	31 (6.4%)	3 (33.3%)	1 (33.3%)	4 (11.1%)	12 (5.1%)	10 (6.8%)	1 (2.0%)
	1	26 (5.4%)	2 (22.2%)	1 (33.3%)	3 (8.3%)	11 (4.7%)	8 (5.5%)	1 (2.0%)
	2	5 (1.0%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	2 (1.4%)	0
インフルエンザ様疾患	- Any Grade -	29 (6.0%)	0	0	5 (13.9%)	9 (3.8%)	13 (8.9%)	2 (3.9%)
	1	23 (4.8%)	0	0	4 (11.1%)	8 (3.4%)	10 (6.8%)	1 (2.0%)
	2	5 (1.0%)	0	0	1 (2.8%)	0	3 (2.1%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
疼痛	- Any Grade -	23 (4.8%)	3 (33.3%)	0	2 (5.6%)	9 (3.8%)	7 (4.8%)	2 (3.9%)
	1	17 (3.5%)	3 (33.3%)	0	2 (5.6%)	8 (3.4%)	4 (2.7%)	0
	2	5 (1.0%)	0	0	0	1 (0.4%)	2 (1.4%)	2 (3.9%)
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
粘膜の炎症	- Any Grade -	7 (1.5%)	0	0	1 (2.8%)	3 (1.3%)	3 (2.1%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	2 (0.8%)	2 (1.4%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
末梢性浮腫	- Any Grade -	7 (1.5%)	0	0	3 (8.3%)	2 (0.8%)	2 (1.4%)	0
	1	5 (1.0%)	0	0	3 (8.3%)	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
倦怠感	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	4 (1.7%)	0	1 (2.0%)
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
胸痛	- Any Grade -	3 (0.6%)	1 (11.1%)	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	2 (0.4%)	1 (11.1%)	0	1 (2.8%)	0	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
胸部不快感	- Any Grade -	2 (0.4%)	1 (11.1%)	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
高熱	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
不快感	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
カテーテル留置部位紅斑	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
カテーテル留置部位発疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
圧痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
温度変化不耐症	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
乾燥症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
顔面浮腫	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
局所腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
限局性浮腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
死亡	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)

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Extraction date: 15May2015 Datacut date: 02Dec2014

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
治癒不良	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
全身健康状態低下	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
全身性炎症反応症候群	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
早期満腹	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
低体温	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
分泌物分泌	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
腋窩痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚および皮下組織障害								
- Overall -	- Any Grade -	140 (29.1%)	6 (66.7%)	3 (100.0%)	19 (52.8%)	59 (25.0%)	47 (32.2%)	6 (11.8%)
	1	116 (24.1%)	4 (44.4%)	2 (66.7%)	13 (36.1%)	50 (21.2%)	42 (28.8%)	5 (9.8%)
	2	18 (3.7%)	2 (22.2%)	0	5 (13.9%)	6 (2.5%)	4 (2.7%)	1 (2.0%)
	3	6 (1.2%)	0	1 (33.3%)	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
発疹	- Any Grade -	50 (10.4%)	1 (11.1%)	2 (66.7%)	7 (19.4%)	23 (9.7%)	15 (10.3%)	2 (3.9%)
	1	43 (8.9%)	0	1 (33.3%)	7 (19.4%)	20 (8.5%)	14 (9.6%)	1 (2.0%)
	2	7 (1.5%)	1 (11.1%)	1 (33.3%)	0	3 (1.3%)	1 (0.7%)	1 (2.0%)
そう痒症	- Any Grade -	46 (9.6%)	2 (22.2%)	1 (33.3%)	8 (22.2%)	22 (9.3%)	11 (7.5%)	2 (3.9%)
	1	40 (8.3%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	20 (8.5%)	11 (7.5%)	2 (3.9%)
	2	6 (1.2%)	0	0	4 (11.1%)	2 (0.8%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
皮膚乾燥	- Any Grade -	20 (4.2%)	0	1 (33.3%)	2 (5.6%)	11 (4.7%)	6 (4.1%)	0
	1	19 (4.0%)	0	1 (33.3%)	2 (5.6%)	10 (4.2%)	6 (4.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
寝汗	- Any Grade -	15 (3.1%)	1 (11.1%)	1 (33.3%)	3 (8.3%)	4 (1.7%)	5 (3.4%)	1 (2.0%)
	1	15 (3.1%)	1 (11.1%)	1 (33.3%)	3 (8.3%)	4 (1.7%)	5 (3.4%)	1 (2.0%)
斑状丘疹状皮疹	- Any Grade -	11 (2.3%)	0	0	2 (5.6%)	6 (2.5%)	3 (2.1%)	0
	1	8 (1.7%)	0	0	2 (5.6%)	4 (1.7%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
多汗症	- Any Grade -	8 (1.7%)	2 (22.2%)	0	0	1 (0.4%)	4 (2.7%)	1 (2.0%)
	1	6 (1.2%)	1 (11.1%)	0	0	1 (0.4%)	3 (2.1%)	1 (2.0%)
	2	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
ざ瘡様皮膚炎	- Any Grade -	7 (1.5%)	0	0	2 (5.6%)	0	5 (3.4%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	0	4 (2.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
紅斑	- Any Grade -	7 (1.5%)	0	1 (33.3%)	1 (2.8%)	3 (1.3%)	1 (0.7%)	1 (2.0%)
	1	7 (1.5%)	0	1 (33.3%)	1 (2.8%)	3 (1.3%)	1 (0.7%)	1 (2.0%)
そう痒性皮疹	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
	1	4 (0.8%)	0	0	1 (2.8%)	2 (0.8%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
尋常性白斑	- Any Grade -	4 (0.8%)	0	1 (33.3%)	1 (2.8%)	2 (0.8%)	0	0
	1	4 (0.8%)	0	1 (33.3%)	1 (2.8%)	2 (0.8%)	0	0
紅斑性皮疹	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	0	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	1 (2.8%)	0	1 (0.7%)	1 (2.0%)

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
扁平苔癬	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
全身性そう痒症	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
爪変色	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
斑状皮疹	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
皮膚色素過剰	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
皮膚剥脱	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
蕁麻疹	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
ざ瘡	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
過角化	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
乾癬	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
乾癬様皮膚炎	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
顔面腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
脂漏	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
湿疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
全身紅斑	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
全身性皮疹	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	3	1 (0.2%)	0	1 (33.3%)	0	0	0	0
多形紅斑	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脱毛症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
爪破損	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
頭部粃糠疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
斑状出血	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚腫瘤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚色素減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚色素脱失	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
皮膚潰瘍	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
皮膚疼痛	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
薬疹	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
睫毛眉毛脱落症	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
胃腸障害								
- Overall -	- Any Grade -	131 (27.2%)	8 (88.9%)	1 (33.3%)	19 (52.8%)	56 (23.7%)	36 (24.7%)	11 (21.6%)
	1	95 (19.8%)	5 (55.6%)	1 (33.3%)	10 (27.8%)	47 (19.9%)	26 (17.8%)	6 (11.8%)
	2	33 (6.9%)	3 (33.3%)	0	8 (22.2%)	9 (3.8%)	9 (6.2%)	4 (7.8%)
	3	3 (0.6%)	0	0	1 (2.8%)	0	1 (0.7%)	1 (2.0%)
悪心	- Any Grade -	63 (13.1%)	6 (66.7%)	1 (33.3%)	7 (19.4%)	23 (9.7%)	18 (12.3%)	8 (15.7%)
	1	48 (10.0%)	6 (66.7%)	1 (33.3%)	5 (13.9%)	20 (8.5%)	12 (8.2%)	4 (7.8%)
	2	13 (2.7%)	0	0	2 (5.6%)	3 (1.3%)	5 (3.4%)	3 (5.9%)
	3	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
下痢	- Any Grade -	49 (10.2%)	3 (33.3%)	0	10 (27.8%)	21 (8.9%)	11 (7.5%)	4 (7.8%)
	1	35 (7.3%)	1 (11.1%)	0	6 (16.7%)	18 (7.6%)	8 (5.5%)	2 (3.9%)
	2	14 (2.9%)	2 (22.2%)	0	4 (11.1%)	3 (1.3%)	3 (2.1%)	2 (3.9%)
嘔吐	- Any Grade -	26 (5.4%)	0	0	2 (5.6%)	10 (4.2%)	11 (7.5%)	3 (5.9%)
	1	22 (4.6%)	0	0	2 (5.6%)	9 (3.8%)	10 (6.8%)	1 (2.0%)
	2	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	3	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)

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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
口内乾燥	- Any Grade -	12 (2.5%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	5 (3.4%)	1 (2.0%)
	1	12 (2.5%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	5 (3.4%)	1 (2.0%)
腹痛	- Any Grade -	12 (2.5%)	2 (22.2%)	0	1 (2.8%)	5 (2.1%)	3 (2.1%)	1 (2.0%)
	1	8 (1.7%)	2 (22.2%)	0	0	5 (2.1%)	1 (0.7%)	0
	2	4 (0.8%)	0	0	1 (2.8%)	0	2 (1.4%)	1 (2.0%)
口内炎	- Any Grade -	8 (1.7%)	1 (11.1%)	0	0	5 (2.1%)	2 (1.4%)	0
	1	4 (0.8%)	1 (11.1%)	0	0	2 (0.8%)	1 (0.7%)	0
	2	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
便秘	- Any Grade -	7 (1.5%)	0	0	1 (2.8%)	0	6 (4.1%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	0	4 (2.7%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
上腹部痛	- Any Grade -	5 (1.0%)	1 (11.1%)	0	2 (5.6%)	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	1 (11.1%)	0	1 (2.8%)	0	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
消化不良	- Any Grade -	3 (0.6%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	0	0
	1	3 (0.6%)	1 (11.1%)	0	1 (2.8%)	1 (0.4%)	0	0
腹部不快感	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
アフタ性口内炎	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
レッチング	- Any Grade -	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
	1	2 (0.4%)	1 (11.1%)	0	0	0	1 (0.7%)	0
胃食道逆流性疾患	- Any Grade -	2 (0.4%)	1 (11.1%)	0	1 (2.8%)	0	0	0
	1	2 (0.4%)	1 (11.1%)	0	1 (2.8%)	0	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
口腔内痛	- Any Grade -	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
	1	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
軟便	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
腹部膨満	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
放屁	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
胃炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
口の感覚鈍麻	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
口の錯感覚	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
十二指腸潰瘍	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
食道炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
大腸炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
地図状舌	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腹水	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
腹部圧痛	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
嚥下障害	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
嚥下痛	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
代謝および栄養障害								
- Overall -	- Any Grade -	83 (17.3%)	3 (33.3%)	1 (33.3%)	9 (25.0%)	35 (14.8%)	25 (17.1%)	10 (19.6%)
	1	45 (9.4%)	1 (11.1%)	1 (33.3%)	6 (16.7%)	22 (9.3%)	10 (6.8%)	5 (9.8%)
	2	28 (5.8%)	2 (22.2%)	0	3 (8.3%)	9 (3.8%)	10 (6.8%)	4 (7.8%)
	3	10 (2.1%)	0	0	0	4 (1.7%)	5 (3.4%)	1 (2.0%)
食欲減退	- Any Grade -	59 (12.3%)	3 (33.3%)	1 (33.3%)	6 (16.7%)	26 (11.0%)	15 (10.3%)	8 (15.7%)
	1	35 (7.3%)	2 (22.2%)	1 (33.3%)	4 (11.1%)	16 (6.8%)	8 (5.5%)	4 (7.8%)
	2	23 (4.8%)	1 (11.1%)	0	2 (5.6%)	9 (3.8%)	7 (4.8%)	4 (7.8%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
脱水	- Any Grade -	8 (1.7%)	0	0	0	3 (1.3%)	4 (2.7%)	1 (2.0%)
	1	4 (0.8%)	0	0	0	2 (0.8%)	1 (0.7%)	1 (2.0%)
	2	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
低ナトリウム血症	- Any Grade -	6 (1.2%)	0	0	1 (2.8%)	1 (0.4%)	2 (1.4%)	2 (3.9%)
	1	4 (0.8%)	0	0	1 (2.8%)	0	1 (0.7%)	2 (3.9%)
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
低マグネシウム血症	- Any Grade -	6 (1.2%)	1 (11.1%)	0	0	3 (1.3%)	1 (0.7%)	1 (2.0%)
	1	5 (1.0%)	0	0	0	3 (1.3%)	1 (0.7%)	1 (2.0%)
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
低アルブミン血症	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	1 (0.7%)	2 (3.9%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	2	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
低リン酸血症	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
高カリウム血症	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
高血糖	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
腫瘍崩壊症候群	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	3	2 (0.4%)	0	0	0	0	2 (1.4%)	0
低カリウム血症	- Any Grade -	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
低血糖症	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
ケトアシドーシス	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
高尿酸血症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
糖尿病	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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神経系障害								
- Overall -	- Any Grade -	72 (15.0%)	6 (66.7%)	1 (33.3%)	13 (36.1%)	28 (11.9%)	19 (13.0%)	5 (9.8%)
	1	57 (11.9%)	5 (55.6%)	1 (33.3%)	11 (30.6%)	22 (9.3%)	14 (9.6%)	4 (7.8%)
	2	14 (2.9%)	1 (11.1%)	0	1 (2.8%)	6 (2.5%)	5 (3.4%)	1 (2.0%)
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
頭痛	- Any Grade -	31 (6.4%)	3 (33.3%)	1 (33.3%)	7 (19.4%)	5 (2.1%)	11 (7.5%)	4 (7.8%)
	1	26 (5.4%)	3 (33.3%)	1 (33.3%)	6 (16.7%)	5 (2.1%)	8 (5.5%)	3 (5.9%)
	2	4 (0.8%)	0	0	0	0	3 (2.1%)	1 (2.0%)
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
味覚異常	- Any Grade -	12 (2.5%)	2 (22.2%)	0	2 (5.6%)	6 (2.5%)	2 (1.4%)	0
	1	8 (1.7%)	1 (11.1%)	0	1 (2.8%)	4 (1.7%)	2 (1.4%)	0
	2	4 (0.8%)	1 (11.1%)	0	1 (2.8%)	2 (0.8%)	0	0
浮動性めまい	- Any Grade -	11 (2.3%)	1 (11.1%)	0	2 (5.6%)	5 (2.1%)	2 (1.4%)	1 (2.0%)
	1	9 (1.9%)	1 (11.1%)	0	2 (5.6%)	4 (1.7%)	1 (0.7%)	1 (2.0%)
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
感覚鈍麻	- Any Grade -	5 (1.0%)	1 (11.1%)	0	2 (5.6%)	1 (0.4%)	1 (0.7%)	0
	1	4 (0.8%)	0	0	2 (5.6%)	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
錯感覚	- Any Grade -	4 (0.8%)	0	0	2 (5.6%)	2 (0.8%)	0	0
	1	3 (0.6%)	0	0	2 (5.6%)	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
末梢性ニューロパチー	- Any Grade -	4 (0.8%)	2 (22.2%)	0	0	1 (0.4%)	1 (0.7%)	0
	1	4 (0.8%)	2 (22.2%)	0	0	1 (0.4%)	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
嗜眠	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
運動失調	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
失語症	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
失神寸前の状態	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
重症筋無力症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
振戦	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
副鼻腔炎に伴う頭痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
片頭痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
末梢性運動ニューロパチー	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
筋骨格系および結合組織障害 - Overall -	- Any Grade -	69 (14.3%)	3 (33.3%)	1 (33.3%)	12 (33.3%)	33 (14.0%)	20 (13.7%)	0
	1	47 (9.8%)	2 (22.2%)	1 (33.3%)	8 (22.2%)	23 (9.7%)	13 (8.9%)	0
	2	19 (4.0%)	1 (11.1%)	0	4 (11.1%)	9 (3.8%)	5 (3.4%)	0
	3	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
関節痛	- Any Grade -	33 (6.9%)	1 (11.1%)	0	7 (19.4%)	17 (7.2%)	8 (5.5%)	0
	1	24 (5.0%)	0	0	5 (13.9%)	13 (5.5%)	6 (4.1%)	0
	2	9 (1.9%)	1 (11.1%)	0	2 (5.6%)	4 (1.7%)	2 (1.4%)	0
筋肉痛	- Any Grade -	19 (4.0%)	1 (11.1%)	0	2 (5.6%)	9 (3.8%)	7 (4.8%)	0
	1	16 (3.3%)	1 (11.1%)	0	1 (2.8%)	8 (3.4%)	6 (4.1%)	0
	2	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
背部痛	- Any Grade -	9 (1.9%)	0	1 (33.3%)	0	4 (1.7%)	4 (2.7%)	0
	1	6 (1.2%)	0	1 (33.3%)	0	2 (0.8%)	3 (2.1%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
筋力低下	- Any Grade -	6 (1.2%)	0	0	2 (5.6%)	2 (0.8%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
筋痙縮	- Any Grade -	6 (1.2%)	0	0	2 (5.6%)	3 (1.3%)	1 (0.7%)	0
	1	5 (1.0%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
四肢痛	- Any Grade -	6 (1.2%)	1 (11.1%)	0	0	2 (0.8%)	3 (2.1%)	0
	1	5 (1.0%)	1 (11.1%)	0	0	1 (0.4%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
骨痛	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	1 (0.4%)	3 (2.1%)	0
	1	3 (0.6%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	0
	3	2 (0.4%)	0	0	0	0	2 (1.4%)	0
筋骨格系胸痛	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
関節炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
筋骨格痛	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
関節腫脹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
関節障害	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
筋炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
頚部痛	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
側腹部痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
呼吸器、胸郭および縦隔障害								
- Overall -	- Any Grade -	53 (11.0%)	4 (44.4%)	2 (66.7%)	7 (19.4%)	16 (6.8%)	19 (13.0%)	5 (9.8%)
	1	31 (6.4%)	3 (33.3%)	1 (33.3%)	6 (16.7%)	10 (4.2%)	9 (6.2%)	2 (3.9%)
	2	11 (2.3%)	1 (11.1%)	1 (33.3%)	1 (2.8%)	2 (0.8%)	6 (4.1%)	0
	3	9 (1.9%)	0	0	0	4 (1.7%)	4 (2.7%)	1 (2.0%)
	4	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)

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事象名：MedDRA ver. 18.0
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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
呼吸困難	- Any Grade -	16 (3.3%)	2 (22.2%)	1 (33.3%)	2 (5.6%)	3 (1.3%)	6 (4.1%)	2 (3.9%)
	1	7 (1.5%)	1 (11.1%)	1 (33.3%)	1 (2.8%)	2 (0.8%)	1 (0.7%)	1 (2.0%)
	2	5 (1.0%)	1 (11.1%)	0	1 (2.8%)	0	3 (2.1%)	0
	3	4 (0.8%)	0	0	0	1 (0.4%)	2 (1.4%)	1 (2.0%)
咳嗽	- Any Grade -	11 (2.3%)	2 (22.2%)	1 (33.3%)	1 (2.8%)	4 (1.7%)	3 (2.1%)	0
	1	7 (1.5%)	2 (22.2%)	0	0	2 (0.8%)	3 (2.1%)	0
	2	3 (0.6%)	0	1 (33.3%)	1 (2.8%)	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺臓炎	- Any Grade -	8 (1.7%)	0	0	1 (2.8%)	2 (0.8%)	4 (2.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	1 (2.8%)	0	2 (1.4%)	0
	2	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	4	1 (0.2%)	0	0	0	0	0	1 (2.0%)
口腔咽頭痛	- Any Grade -	4 (0.8%)	0	0	2 (5.6%)	0	2 (1.4%)	0
	1	4 (0.8%)	0	0	2 (5.6%)	0	2 (1.4%)	0
湿性咳嗽	- Any Grade -	4 (0.8%)	1 (11.1%)	0	0	1 (0.4%)	2 (1.4%)	0
	1	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
低酸素症	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
発声障害	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
鼻閉	- Any Grade -	3 (0.6%)	1 (11.1%)	0	0	1 (0.4%)	1 (0.7%)	0
	1	3 (0.6%)	1 (11.1%)	0	0	1 (0.4%)	1 (0.7%)	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
喘鳴	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
上気道咳症候群	- Any Grade -	2 (0.4%)	0	0	2 (5.6%)	0	0	0
	1	2 (0.4%)	0	0	2 (5.6%)	0	0	0
鼻出血	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
安静時呼吸困難	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
気管支閉塞	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
喉頭の炎症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺高血圧症	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	5	1 (0.2%)	0	0	0	0	0	1 (2.0%)
肺浸潤	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
鼻漏	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
労作性呼吸困難	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
臨床検査								
- Overall -	- Any Grade -	43 (8.9%)	0	1 (33.3%)	3 (8.3%)	22 (9.3%)	14 (9.6%)	3 (5.9%)
	1	24 (5.0%)	0	1 (33.3%)	1 (2.8%)	10 (4.2%)	11 (7.5%)	1 (2.0%)
	2	6 (1.2%)	0	0	1 (2.8%)	3 (1.3%)	1 (0.7%)	1 (2.0%)
	3	9 (1.9%)	0	0	0	6 (2.5%)	2 (1.4%)	1 (2.0%)
	4	4 (0.8%)	0	0	1 (2.8%)	3 (1.3%)	0	0
アラニンアミノトランスフェラーゼ増加	- Any Grade -	15 (3.1%)	0	0	1 (2.8%)	7 (3.0%)	5 (3.4%)	2 (3.9%)
	1	10 (2.1%)	0	0	1 (2.8%)	4 (1.7%)	4 (2.7%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	3	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	4	2 (0.4%)	0	0	0	2 (0.8%)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	10 (2.1%)	0	0	0	7 (3.0%)	2 (1.4%)	1 (2.0%)
	1	5 (1.0%)	0	0	0	3 (1.3%)	1 (0.7%)	1 (2.0%)
	3	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
体重減少	- Any Grade -	8 (1.7%)	0	0	1 (2.8%)	2 (0.8%)	4 (2.7%)	1 (2.0%)
	1	8 (1.7%)	0	0	1 (2.8%)	2 (0.8%)	4 (2.7%)	1 (2.0%)
血中アルカリホスファターゼ増加	- Any Grade -	5 (1.0%)	0	0	0	4 (1.7%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
リンパ球数減少	- Any Grade -	3 (0.6%)	0	0	2 (5.6%)	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	4	1 (0.2%)	0	0	1 (2.8%)	0	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
血小板数減少	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
血中ビリルビン増加	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	2 (0.8%)	0	0
	2	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中甲状腺刺激ホルモン増加	- Any Grade -	3 (0.6%)	0	0	0	0	3 (2.1%)	0
	1	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
白血球数減少	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
トランスアミナーゼ上昇	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝機能検査異常	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血中クレアチニン増加	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
サイロキシン減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
ハプトグロビン減少	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
リパーゼ増加	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
胸部コンピュータ断層撮影異常	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中クレアチンホスホキナーゼ増加	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
血中テストステロン減少	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血中リン減少	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
国際標準比増加	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
体温上昇	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
白血球数増加	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
血液およびリンパ系障害 - Overall -	- Any Grade -	35 (7.3%)	0	0	2 (5.6%)	16 (6.8%)	12 (8.2%)	5 (9.8%)
	1	17 (3.5%)	0	0	2 (5.6%)	5 (2.1%)	8 (5.5%)	2 (3.9%)
	2	10 (2.1%)	0	0	0	7 (3.0%)	1 (0.7%)	2 (3.9%)
	3	8 (1.7%)	0	0	0	4 (1.7%)	3 (2.1%)	1 (2.0%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
貧血	- Any Grade -	24 (5.0%)	0	0	2 (5.6%)	11 (4.7%)	8 (5.5%)	3 (5.9%)
	1	11 (2.3%)	0	0	2 (5.6%)	3 (1.3%)	5 (3.4%)	1 (2.0%)
	2	8 (1.7%)	0	0	0	6 (2.5%)	1 (0.7%)	1 (2.0%)
	3	5 (1.0%)	0	0	0	2 (0.8%)	2 (1.4%)	1 (2.0%)
血小板減少症	- Any Grade -	7 (1.5%)	0	0	0	4 (1.7%)	1 (0.7%)	2 (3.9%)
	1	4 (0.8%)	0	0	0	3 (1.3%)	0	1 (2.0%)
	2	2 (0.4%)	0	0	0	0	1 (0.7%)	1 (2.0%)
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
リンパ球減少症	- Any Grade -	5 (1.0%)	0	0	1 (2.8%)	1 (0.4%)	1 (0.7%)	2 (3.9%)
	1	4 (0.8%)	0	0	1 (2.8%)	1 (0.4%)	0	2 (3.9%)
	3	1 (0.2%)	0	0	0	0	1 (0.7%)	0
好中球減少症	- Any Grade -	5 (1.0%)	0	0	0	3 (1.3%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
リンパ節症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
リンパ節痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
白血球増加症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
感染症および寄生虫症								
- Overall -	- Any Grade -	27 (5.6%)	2 (22.2%)	1 (33.3%)	3 (8.3%)	12 (5.1%)	8 (5.5%)	1 (2.0%)
	1	9 (1.9%)	0	1 (33.3%)	1 (2.8%)	4 (1.7%)	3 (2.1%)	0
	2	15 (3.1%)	2 (22.2%)	0	2 (5.6%)	6 (2.5%)	5 (3.4%)	0
	3	2 (0.4%)	0	0	0	1 (0.4%)	0	1 (2.0%)
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
上気道感染	- Any Grade -	6 (1.2%)	2 (22.2%)	0	0	1 (0.4%)	3 (2.1%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	4 (0.8%)	2 (22.2%)	0	0	0	2 (1.4%)	0
帯状疱疹	- Any Grade -	4 (0.8%)	0	1 (33.3%)	0	3 (1.3%)	0	0
	1	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
	2	2 (0.4%)	0	0	0	2 (0.8%)	0	0
口腔ヘルペス	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
尿路感染	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
鼻炎	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
インフルエンザ性肺炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
ウイルス性咽頭炎	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
気管支炎	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
気道感染	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
口腔カンジダ症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
口腔膿瘍	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
耳感染	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
髄膜炎	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	3	1 (0.2%)	0	0	0	0	0	1 (2.0%)
敗血症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肺感染	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
皮膚カンジダ	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
皮膚真菌感染	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	2	1 (0.2%)	0	0	1 (2.8%)	0	0	0
鼻咽頭炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
副鼻腔炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
蜂巣炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
内分泌障害								
- Overall -	- Any Grade -	25 (5.2%)	0	0	4 (11.1%)	10 (4.2%)	10 (6.8%)	1 (2.0%)
	1	7 (1.5%)	0	0	0	4 (1.7%)	2 (1.4%)	1 (2.0%)
	2	16 (3.3%)	0	0	4 (11.1%)	4 (1.7%)	8 (5.5%)	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
甲状腺機能低下症	- Any Grade -	16 (3.3%)	0	0	4 (11.1%)	6 (2.5%)	6 (4.1%)	0
	1	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	2	13 (2.7%)	0	0	4 (11.1%)	3 (1.3%)	6 (4.1%)	0
甲状腺機能亢進症	- Any Grade -	4 (0.8%)	0	0	0	1 (0.4%)	2 (1.4%)	1 (2.0%)
	1	3 (0.6%)	0	0	0	1 (0.4%)	1 (0.7%)	1 (2.0%)
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
副腎機能不全	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	2	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
下垂体炎	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
甲状腺炎	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
眼障害								
- Overall -	- Any Grade -	15 (3.1%)	3 (33.3%)	0	2 (5.6%)	8 (3.4%)	2 (1.4%)	0
	1	12 (2.5%)	2 (22.2%)	0	2 (5.6%)	7 (3.0%)	1 (0.7%)	0
	2	3 (0.6%)	1 (11.1%)	0	0	1 (0.4%)	1 (0.7%)	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
霧視	- Any Grade -	3 (0.6%)	0	0	1 (2.8%)	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
眼痛	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
視力低下	- Any Grade -	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	1	2 (0.4%)	0	0	0	2 (0.8%)	0	0
流涙増加	- Any Grade -	2 (0.4%)	2 (22.2%)	0	0	0	0	0
	1	2 (0.4%)	2 (22.2%)	0	0	0	0	0
眼そう痒症	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
眼乾燥	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
眼充血	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
眼瞼浮腫	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
眼窩周囲浮腫	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
硝子体浮遊物	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
深径覚の変化	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	1	1 (0.2%)	1 (11.1%)	0	0	0	0	0
注視麻痺	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
潰瘍性角膜炎	- Any Grade -	1 (0.2%)	1 (11.1%)	0	0	0	0	0
	2	1 (0.2%)	1 (11.1%)	0	0	0	0	0
血管障害								
- Overall -	- Any Grade -	13 (2.7%)	1 (11.1%)	0	0	9 (3.8%)	3 (2.1%)	0
	1	12 (2.5%)	1 (11.1%)	0	0	8 (3.4%)	3 (2.1%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
潮紅	- Any Grade -	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
	1	4 (0.8%)	0	0	0	3 (1.3%)	1 (0.7%)	0
低血圧	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	1	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
ほてり	- Any Grade -	3 (0.6%)	1 (11.1%)	0	0	2 (0.8%)	0	0
	1	3 (0.6%)	1 (11.1%)	0	0	2 (0.8%)	0	0
大静脈血栓症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
末梢冷感	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
精神障害								
- Overall -	- Any Grade -	12 (2.5%)	2 (22.2%)	0	2 (5.6%)	5 (2.1%)	3 (2.1%)	0
	1	9 (1.9%)	1 (11.1%)	0	2 (5.6%)	3 (1.3%)	3 (2.1%)	0
	2	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
不眠症	- Any Grade -	7 (1.5%)	2 (22.2%)	0	2 (5.6%)	2 (0.8%)	1 (0.7%)	0
	1	5 (1.0%)	1 (11.1%)	0	2 (5.6%)	1 (0.4%)	1 (0.7%)	0
	2	2 (0.4%)	1 (11.1%)	0	0	1 (0.4%)	0	0

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
うつ病	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
易刺激性	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
気分変化	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
錯乱状態	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝胆道系障害								
- Overall -	- Any Grade -	8 (1.7%)	0	0	0	6 (2.5%)	2 (1.4%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	3	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
自己免疫性肝炎	- Any Grade -	3 (0.6%)	0	0	0	3 (1.3%)	0	0
	3	2 (0.4%)	0	0	0	2 (0.8%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝細胞損傷	- Any Grade -	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
肝臓痛	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
高ビリルビン血症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	3	1 (0.2%)	0	0	0	1 (0.4%)	0	0

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門脈血栓症	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心臓障害								
- Overall -	- Any Grade -	7 (1.5%)	0	0	2 (5.6%)	2 (0.8%)	3 (2.1%)	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	4	2 (0.4%)	0	0	0	1 (0.4%)	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	0	1 (0.7%)	0
洞性頻脈	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	0	1 (0.7%)	0
	2	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	3	1 (0.2%)	0	0	1 (2.8%)	0	0	0
頻脈	- Any Grade -	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
	1	2 (0.4%)	0	0	1 (2.8%)	1 (0.4%)	0	0
心タンポナーデ	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	4	1 (0.2%)	0	0	0	0	1 (0.7%)	0
心嚢液貯留	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	4	1 (0.2%)	0	0	0	1 (0.4%)	0	0
心肺停止	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	5	1 (0.2%)	0	0	0	0	1 (0.7%)	0
耳および迷路障害								
- Overall -	- Any Grade -	6 (1.2%)	0	2 (66.7%)	1 (2.8%)	1 (0.4%)	2 (1.4%)	0
	1	6 (1.2%)	0	2 (66.7%)	1 (2.8%)	1 (0.4%)	2 (1.4%)	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.
Extraction date: 15May2015 Datacut date: 02Dec2014

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
耳鳴	- Any Grade -	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
	1	3 (0.6%)	0	0	0	1 (0.4%)	2 (1.4%)	0
回転性めまい	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
耳閉	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
難聴	- Any Grade -	1 (0.2%)	0	0	1 (2.8%)	0	0	0
	1	1 (0.2%)	0	0	1 (2.8%)	0	0	0
腎および尿路障害								
- Overall -	- Any Grade -	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
	1	4 (0.8%)	0	0	0	2 (0.8%)	2 (1.4%)	0
血尿	- Any Grade -	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
	1	3 (0.6%)	0	0	0	2 (0.8%)	1 (0.7%)	0
頻尿	- Any Grade -	1 (0.2%)	0	0	0	0	1 (0.7%)	0
	1	1 (0.2%)	0	0	0	0	1 (0.7%)	0
生殖系および乳房障害								
- Overall -	- Any Grade -	3 (0.6%)	0	1 (33.3%)	0	1 (0.4%)	0	1 (2.0%)
	1	3 (0.6%)	0	1 (33.3%)	0	1 (0.4%)	0	1 (2.0%)
陰茎出血	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
陰茎痛	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (2.0%)
陰茎分泌物	- Any Grade -	1 (0.2%)	0	0	0	0	0	1 (2.0%)
	1	1 (0.2%)	0	0	0	0	0	1 (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.
Extraction date: 15May2015 Datacut date: 02Dec2014

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
性器発疹	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
乳房痛	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	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 -	3 (0.6%)	0	1 (33.3%)	0	0	2 (1.4%)	0
	2	3 (0.6%)	0	1 (33.3%)	0	0	2 (1.4%)	0
腫瘍疼痛	- Any Grade -	2 (0.4%)	0	0	0	0	2 (1.4%)	0
	2	2 (0.4%)	0	0	0	0	2 (1.4%)	0
腫瘍の潰瘍形成	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	2	1 (0.2%)	0	1 (33.3%)	0	0	0	0
傷害、中毒および処置合併症								
- Overall -	- Any Grade -	2 (0.4%)	0	1 (33.3%)	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
創合併症	- Any Grade -	1 (0.2%)	0	1 (33.3%)	0	0	0	0
	1	1 (0.2%)	0	1 (33.3%)	0	0	0	0
注入に伴う反応	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
外科および内科処置								
- Overall -	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO27831:PCD4989g)
Protocol: GO27831
Population: Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab Total (N=481)	atezolizumab <=1 mg/kg q3w IV (N=9)	atezolizumab 3 mg/kg q3w IV (N=3)	atezolizumab 10 mg/kg q3w IV (N=36)	atezolizumab 15 mg/kg q3w IV (N=236)	atezolizumab 20 mg/kg q3w IV (N=146)	atezolizumab 1200 mg q3w IV (N=51)
ヘルニア修復	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	2	1 (0.2%)	0	0	0	1 (0.4%)	0	0
免疫系障害								
- Overall -	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	0	0
過敏症	- Any Grade -	1 (0.2%)	0	0	0	1 (0.4%)	0	0
	1	1 (0.2%)	0	0	0	1 (0.4%)	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.
Extraction date: 15May2015 Datacut date: 02Dec2014

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas / Output: /opt/BIOSTAT/prod/cdt7692j/j27831a/reports/aet04r_GO27831_SE.out
09NOV2016 10:26

［5.3.5.3-1 aet04r_GO27831_SE を再掲］

2.7.6.2.1.2　JO28944試験

表 2.7.6.2.1.2-1　すべての有害事象（JO28944試験）

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED　　Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (10mg/kg/3W); N = 3

Body System/ Adverse Event	Total		CTC Grading									
			1		2		3		4		5	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
ALL BODY SYSTEMS												
Total Pts with at Least one AE	3	(100.0)	3	(100.0)	2	(66.7)	-		-		-	
Total Number of AEs	24		18		6		-		-		-	
皮膚および皮下組織障害												
Total Pts With at Least one AE	3	(100.0)	3	(100.0)	-		-		-		-	
発疹	2	(66.7)	2	(66.7)	-		-		-		-	
ざ瘡様皮膚炎	1	(33.3)	1	(33.3)	-		-		-		-	
そう痒症	1	(33.3)	1	(33.3)	-		-		-		-	
紅斑	1	(33.3)	1	(33.3)	-		-		-		-	
多形紅斑	1	(33.3)	1	(33.3)	-		-		-		-	
Total Number of AEs	6		6		-		-		-		-	
胃腸障害												
Total Pts With at Least one AE	3	(100.0)	2	(66.7)	2	(66.7)	-		-		-	
悪心	1	(33.3)	-		1	(33.3)	-		-		-	
下痢	1	(33.3)	1	(33.3)	-		-		-		-	
歯痛	1	(33.3)	1	(33.3)	-		-		-		-	
嘔吐	1	(33.3)	-		1	(33.3)	-		-		-	
齲歯	1	(33.3)	-		1	(33.3)	-		-		-	
Total Number of AEs	5		2		3		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.
AE17 02FEB2015:13:23:14　　(1 of 10)

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): J028944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (10mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading 1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
臨床検査						
Total Pts With at Least one AE	2 (66.7)	2 (66.7)	1 (33.3)	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
アラニンアミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
血中アルカリホスファターゼ増加	1 (33.3)	-	1 (33.3)	-	-	-
心電図ＱＴ延長	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	4	3	1	-	-	-
一般・全身障害および投与部位の状態						
Total Pts With at Least one AE	2 (66.7)	2 (66.7)	1 (33.3)	-	-	-
インフルエンザ様疾患	1 (33.3)	-	1 (33.3)	-	-	-
発熱	1 (33.3)	1 (33.3)	-	-	-	-
疲労	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	3	2	1	-	-	-
神経系障害						
Total Pts With at Least one AE	2 (66.7)	2 (66.7)	-	-	-	-
頭痛	2 (66.7)	2 (66.7)	-	-	-	-
Total Number of AEs	2	2	-	-	-	-
感染症および寄生虫症						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
鼻咽頭炎	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (10mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
筋骨格系および結合組織障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
筋肉痛	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
呼吸器、胸郭および縦隔障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
口腔咽頭不快感	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
免疫系障害						
Total Pts With at Least one AE	1 (33.3)	-	1 (33.3)	-	-	-
造影剤アレルギー	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	1	-	1	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (20mg/kg/3W): N = 3

Body System/ Adverse Event	Total	CTC Grading 1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
ALL BODY SYSTEMS						
Total Pts with at Least one AE	3 (100.0)	3 (100.0)	2 (66.7)	-	-	-
Total Number of AEs	18	13	5	-	-	-
皮膚および皮下組織障害						
Total Pts With at Least one AE	2 (66.7)	1 (33.3)	1 (33.3)	-	-	-
発疹	1 (33.3)	1 (33.3)	-	-	-	-
蕁麻疹	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	2	1	1	-	-	-
臨床検査						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	1 (33.3)	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
アラニンアミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
リンパ球数減少	1 (33.3)	-	1 (33.3)	-	-	-
血中アルカリホスファターゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
好中球数減少	1 (33.3)	1 (33.3)	-	-	-	-
白血球数減少	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	6	4	2	-	-	-
呼吸器、胸郭および縦隔障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
口腔咽頭痛	1 (33.3)	1 (33.3)	-	-	-	-
喉頭痛	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	2	2	-	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (20mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
傷害、中毒および処置合併症						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
挫傷	1 (33.3)	1 (33.3)	-	-	-	-
擦過傷	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	2	2	-	-	-	-
胃腸障害						
Total Pts With at Least one AE	1 (33.3)	-	1 (33.3)	-	-	-
下痢	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	1	-	1	-	-	-
感染症および寄生虫症						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
肺炎	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
筋骨格系および結合組織障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
筋骨格痛	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
血液およびリンパ系障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
貧血	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
神経系障害						
Total Pts With at Least one AE	1 (33.3)	-	1 (33.3)	-	-	-
迷走神経障害	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	1	-	1	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (20mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading									
		1		2		3		4		5	
	No. (%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
精神障害											
Total Pts With at Least one AE	1 (33.3)	1	(33.3)	-		-		-		-	
不眠症	1 (33.3)	1	(33.3)	-		-		-		-	
Total Number of AEs	1	1		-		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): J028944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading 1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
ALL BODY SYSTEMS						
Total Pts with at Least one AE	6 (100.0)	6 (100.0)	4 (66.7)	-	-	-
Total Number of AEs	42	31	11	-	-	-
皮膚および皮下組織障害						
Total Pts With at Least one AE	5 (83.3)	4 (66.7)	1 (16.7)	-	-	-
発疹	3 (50.0)	3 (50.0)	-	-	-	-
ざ瘡様皮膚炎	1 (16.7)	1 (16.7)	-	-	-	-
そう痒症	1 (16.7)	1 (16.7)	-	-	-	-
紅斑	1 (16.7)	1 (16.7)	-	-	-	-
多形紅斑	1 (16.7)	1 (16.7)	-	-	-	-
蕁麻疹	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	8	7	1	-	-	-
胃腸障害						
Total Pts With at Least one AE	4 (66.7)	2 (33.3)	3 (50.0)	-	-	-
下痢	2 (33.3)	1 (16.7)	1 (16.7)	-	-	-
悪心	1 (16.7)	-	1 (16.7)	-	-	-
歯痛	1 (16.7)	1 (16.7)	-	-	-	-
嘔吐	1 (16.7)	-	1 (16.7)	-	-	-
齲歯	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	6	2	4	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): J028944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
臨床検査						
Total Pts With at Least one AE	3 (50.0)	3 (50.0)	2 (33.3)	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	2 (33.3)	2 (33.3)	-	-	-	-
アラニンアミノトランスフェラーゼ増加	2 (33.3)	2 (33.3)	-	-	-	-
血中アルカリホスファターゼ増加	2 (33.3)	1 (16.7)	1 (16.7)	-	-	-
リンパ球数減少	1 (16.7)	-	1 (16.7)	-	-	-
好中球数減少	1 (16.7)	1 (16.7)	-	-	-	-
心電図ＱＴ延長	1 (16.7)	1 (16.7)	-	-	-	-
白血球数減少	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	10	7	3	-	-	-
神経系障害						
Total Pts With at Least one AE	3 (50.0)	2 (33.3)	1 (16.7)	-	-	-
頭痛	2 (33.3)	2 (33.3)	-	-	-	-
迷走神経障害	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	3	2	1	-	-	-
一般・全身障害および投与部位の状態						
Total Pts With at Least one AE	2 (33.3)	2 (33.3)	1 (16.7)	-	-	-
インフルエンザ様疾患	1 (16.7)	-	1 (16.7)	-	-	-
発熱	1 (16.7)	1 (16.7)	-	-	-	-
疲労	1 (16.7)	1 (16.7)	-	-	-	-
Total Number of AEs	3	2	1	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading									
		1		2		3		4		5	
	No. (%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
呼吸器、胸郭および縦隔障害											
Total Pts With at Least one AE	2 (33.3)	2	(33.3)	-		-		-		-	
口腔咽頭痛	1 (16.7)	1	(16.7)	-		-		-		-	
口腔咽頭不快感	1 (16.7)	1	(16.7)	-		-		-		-	
喉頭痛	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	3	3		-		-		-		-	
感染症および寄生虫症											
Total Pts With at Least one AE	2 (33.3)	2	(33.3)	-		-		-		-	
肺炎	1 (16.7)	1	(16.7)	-		-		-		-	
鼻咽頭炎	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	2	2		-		-		-		-	
筋骨格系および結合組織障害											
Total Pts With at Least one AE	2 (33.3)	2	(33.3)	-		-		-		-	
筋骨格痛	1 (16.7)	1	(16.7)	-		-		-		-	
筋肉痛	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	2	2		-		-		-		-	
傷害、中毒および処置合併症											
Total Pts With at Least one AE	1 (16.7)	1	(16.7)	-		-		-		-	
挫傷	1 (16.7)	1	(16.7)	-		-		-		-	
擦過傷	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	2	2		-		-		-		-	
血液およびリンパ系障害											
Total Pts With at Least one AE	1 (16.7)	1	(16.7)	-		-		-		-	
貧血	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	1	1		-		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17_sp Adverse Events by Intensity (CTCAE Grades 1-5)
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading									
		1		2		3		4		5	
	No. (%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
精神障害											
Total Pts With at Least one AE	1 (16.7)	1	(16.7)	-		-		-		-	
不眠症	1 (16.7)	1	(16.7)	-		-		-		-	
Total Number of AEs	1	1		-		-		-		-	
免疫系障害											
Total Pts With at Least one AE	1 (16.7)	-		1	(16.7)	-		-		-	
造影剤アレルギー	1 (16.7)	-		1	(16.7)	-		-		-	
Total Number of AEs	1	-		1		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.
AE17 02FEB2015:13:23:14 (10 of 10)

［5.3.3.2-2 Table 15.3-5を再掲］

表 2.7.6.2.1.2-2　すべての副作用（JO28944試験）

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED　　Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (10mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
ALL BODY SYSTEMS						
Total Pts with at Least one AE	3 (100.0)	3 (100.0)	2 (66.7)	-	-	-
Total Number of AEs	19	15	4	-	-	-
皮膚および皮下組織障害						
Total Pts With at Least one AE	3 (100.0)	3 (100.0)	-	-	-	-
発疹	2 (66.7)	2 (66.7)	-	-	-	-
ざ瘡様皮膚炎	1 (33.3)	1 (33.3)	-	-	-	-
そう痒症	1 (33.3)	1 (33.3)	-	-	-	-
紅斑	1 (33.3)	1 (33.3)	-	-	-	-
多形紅斑	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	6	6	-	-	-	-
臨床検査						
Total Pts With at Least one AE	2 (66.7)	2 (66.7)	1 (33.3)	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
アラニンアミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
血中アルカリホスファターゼ増加	1 (33.3)	-	1 (33.3)	-	-	-
心電図ＱＴ延長	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	4	3	1	-	-	-
胃腸障害						
Total Pts With at Least one AE	2 (66.7)	1 (33.3)	1 (33.3)	-	-	-
悪心	1 (33.3)	-	1 (33.3)	-	-	-
下痢	1 (33.3)	1 (33.3)	-	-	-	-
嘔吐	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	3	1	2	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.
AE17 02FEB2015:13:23:52　　(1 of 7)

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (10mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading					
		1	2	3	4	5	
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	
神経系障害							
Total Pts With at Least one AE	2 (66.7)	2 (66.7)	-	-	-	-	
頭痛	2 (66.7)	2 (66.7)	-	-	-	-	
Total Number of AEs	2	2	-	-	-	-	
一般・全身障害および投与部位の状態							
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	1 (33.3)	-	-	-	
インフルエンザ様疾患	1 (33.3)	-	1 (33.3)	-	-	-	
疲労	1 (33.3)	1 (33.3)	-	-	-	-	
Total Number of AEs	2	1	1	-	-	-	
筋骨格系および結合組織障害							
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-	
筋肉痛	1 (33.3)	1 (33.3)	-	-	-	-	
Total Number of AEs	1	1	-	-	-	-	
呼吸器、胸郭および縦隔障害							
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-	
口腔咽頭不快感	1 (33.3)	1 (33.3)	-	-	-	-	
Total Number of AEs	1	1	-	-	-	-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (20mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading 1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
ALL BODY SYSTEMS						
Total Pts with at Least one AE	3 (100.0)	3 (100.0)	2 (66.7)	-	-	-
Total Number of AEs	11	7	4	-	-	-
皮膚および皮下組織障害						
Total Pts With at Least one AE	2 (66.7)	1 (33.3)	1 (33.3)	-	-	-
発疹	1 (33.3)	1 (33.3)	-	-	-	-
蕁麻疹	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	2	1	1	-	-	-
臨床検査						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	1 (33.3)	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
アラニンアミノトランスフェラーゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
リンパ球数減少	1 (33.3)	-	1 (33.3)	-	-	-
血中アルカリホスファターゼ増加	1 (33.3)	1 (33.3)	-	-	-	-
好中球数減少	1 (33.3)	1 (33.3)	-	-	-	-
白血球数減少	1 (33.3)	-	1 (33.3)	-	-	-
Total Number of AEs	6	4	2	-	-	-
筋骨格系および結合組織障害						
Total Pts With at Least one AE	1 (33.3)	1 (33.3)	-	-	-	-
筋骨格痛	1 (33.3)	1 (33.3)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: MPDL3280A (20mg/kg/3W); N = 3

Body System/ Adverse Event	Total	CTC Grading									
		1		2		3		4		5	
	No. (%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
血液およびリンパ系障害											
Total Pts With at Least one AE	1 (33.3)	1	(33.3)	-		-		-		-	
貧血	1 (33.3)	1	(33.3)	-		-		-		-	
Total Number of AEs	1	1		-		-		-		-	
神経系障害											
Total Pts With at Least one AE	1 (33.3)	-		1	(33.3)	-		-		-	
迷走神経障害	1 (33.3)	-		1	(33.3)	-		-		-	
Total Number of AEs	1	-		1		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total		CTC Grading									
			1		2		3		4		5	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
ALL BODY SYSTEMS												
Total Pts with at Least one AE	6	(100.0)	6	(100.0)	4	(66.7)	-		-		-	
Total Number of AEs	30		22		8		-		-		-	
皮膚および皮下組織障害												
Total Pts With at Least one AE	5	(83.3)	4	(66.7)	1	(16.7)	-		-		-	
発疹	3	(50.0)	3	(50.0)	-		-		-		-	
ざ瘡様皮膚炎	1	(16.7)	1	(16.7)	-		-		-		-	
そう痒症	1	(16.7)	1	(16.7)	-		-		-		-	
紅斑	1	(16.7)	1	(16.7)	-		-		-		-	
多形紅斑	1	(16.7)	1	(16.7)	-		-		-		-	
蕁麻疹	1	(16.7)	-		1	(16.7)	-		-		-	
Total Number of AEs	8		7		1		-		-		-	
臨床検査												
Total Pts With at Least one AE	3	(50.0)	3	(50.0)	2	(33.3)	-		-		-	
アスパラギン酸アミノトランスフェラーゼ増加	2	(33.3)	2	(33.3)	-		-		-		-	
アラニンアミノトランスフェラーゼ増加	2	(33.3)	2	(33.3)	-		-		-		-	
血中アルカリホスファターゼ増加	2	(33.3)	1	(16.7)	1	(16.7)	-		-		-	
リンパ球数減少	1	(16.7)	-		1	(16.7)	-		-		-	
好中球数減少	1	(16.7)	1	(16.7)	-		-		-		-	
心電図ＱＴ延長	1	(16.7)	1	(16.7)	-		-		-		-	
白血球数減少	1	(16.7)	-		1	(16.7)	-		-		-	
Total Number of AEs	10		7		3		-		-		-	

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
神経系障害						
Total Pts With at Least one AE	3 (50.0)	2 (33.3)	1 (16.7)	-	-	-
頭痛	2 (33.3)	2 (33.3)	-	-	-	-
迷走神経障害	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	3	2	1	-	-	-
胃腸障害						
Total Pts With at Least one AE	2 (33.3)	1 (16.7)	1 (16.7)	-	-	-
悪心	1 (16.7)	-	1 (16.7)	-	-	-
下痢	1 (16.7)	1 (16.7)	-	-	-	-
嘔吐	1 (16.7)	-	1 (16.7)	-	-	-
Total Number of AEs	3	1	2	-	-	-
筋骨格系および結合組織障害						
Total Pts With at Least one AE	2 (33.3)	2 (33.3)	-	-	-	-
筋骨格痛	1 (16.7)	1 (16.7)	-	-	-	-
筋肉痛	1 (16.7)	1 (16.7)	-	-	-	-
Total Number of AEs	2	2	-	-	-	-
一般・全身障害および投与部位の状態						
Total Pts With at Least one AE	1 (16.7)	1 (16.7)	1 (16.7)	-	-	-
インフルエンザ様疾患	1 (16.7)	-	1 (16.7)	-	-	-
疲労	1 (16.7)	1 (16.7)	-	-	-	-
Total Number of AEs	2	1	1	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.

ae17r_sp Related Adverse Events by Intensity (CTCAE Grades 1-5)
Related Adverse Events
Protocol(s): JO28944
Analysis: AS SELECTED Center: ALL CENTERS
Safety Population
Treatment: Total; N = 6

Body System/ Adverse Event	Total	CTC Grading				
		1	2	3	4	5
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
血液およびリンパ系障害						
Total Pts With at Least one AE	1 (16.7)	1 (16.7)	-	-	-	-
貧血	1 (16.7)	1 (16.7)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-
呼吸器、胸郭および縦隔障害						
Total Pts With at Least one AE	1 (16.7)	1 (16.7)	-	-	-	-
口腔咽頭不快感	1 (16.7)	1 (16.7)	-	-	-	-
Total Number of AEs	1	1	-	-	-	-

Investigator text for Adverse Events encoded using MedDRA version 16.1.
Percentages are based on N.
Only the most severe intensity is counted for multiple occurrences of the same adverse event in one individual.
Any difference between the total number and sum of AEs is due to missing investigators assessment of intensity.
AE17 02FEB2015:13:23:52 (7 of 7)

［5.3.3.2-2 Table 15.3-6を再掲］

2.7.6.2.1.3 OAK 試験

表 2.7.6.2.1.3-1 すべての有害事象（OAK 試験）

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
- Any adverse events -	- Any Grade -	573 (94.1%)	555 (96.0%)	1128 (95.0%)
	1	93 (15.3%)	51 (8.8%)	144 (12.1%)
	2	243 (39.9%)	180 (31.1%)	423 (35.6%)
	3	195 (32.0%)	195 (33.7%)	390 (32.9%)
	4	32 (5.3%)	115 (19.9%)	147 (12.4%)
	5	10 (1.6%)	14 (2.4%)	24 (2.0%)
一般・全身障害および投与部位の状態				
- Overall -	- Any Grade -	408 (67.0%)	409 (70.8%)	817 (68.8%)
	1	197 (32.3%)	166 (28.7%)	363 (30.6%)
	2	171 (28.1%)	194 (33.6%)	365 (30.7%)
	3	37 (6.1%)	46 (8.0%)	83 (7.0%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
	5	2 (0.3%)	2 (0.3%)	4 (0.3%)
疲労	- Any Grade -	163 (26.8%)	205 (35.5%)	368 (31.0%)
	1	81 (13.3%)	85 (14.7%)	166 (14.0%)
	2	65 (10.7%)	97 (16.8%)	162 (13.6%)
	3	17 (2.8%)	23 (4.0%)	40 (3.4%)
無力症	- Any Grade -	116 (19.0%)	114 (19.7%)	230 (19.4%)
	1	52 (8.5%)	40 (6.9%)	92 (7.8%)
	2	56 (9.2%)	61 (10.6%)	117 (9.9%)
	3	8 (1.3%)	13 (2.2%)	21 (1.8%)
発熱	- Any Grade -	108 (17.7%)	76 (13.1%)	184 (15.5%)
	1	90 (14.8%)	64 (11.1%)	154 (13.0%)
	2	17 (2.8%)	11 (1.9%)	28 (2.4%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
末梢性浮腫	- Any Grade -	54 (8.9%)	82 (14.2%)	136 (11.5%)
	1	40 (6.6%)	59 (10.2%)	99 (8.3%)
	2	13 (2.1%)	20 (3.5%)	33 (2.8%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
胸痛	- Any Grade -	53 (8.7%)	26 (4.5%)	79 (6.7%)
	1	30 (4.9%)	14 (2.4%)	44 (3.7%)
	2	19 (3.1%)	11 (1.9%)	30 (2.5%)
	3	4 (0.7%)	1 (0.2%)	5 (0.4%)
粘膜の炎症	- Any Grade -	9 (1.5%)	41 (7.1%)	50 (4.2%)
	1	6 (1.0%)	23 (4.0%)	29 (2.4%)
	2	3 (0.5%)	15 (2.6%)	18 (1.5%)
	3	0	3 (0.5%)	3 (0.3%)
インフルエンザ様疾患	- Any Grade -	32 (5.3%)	14 (2.4%)	46 (3.9%)
	1	19 (3.1%)	13 (2.2%)	32 (2.7%)
	2	13 (2.1%)	1 (0.2%)	14 (1.2%)
疼痛	- Any Grade -	24 (3.9%)	19 (3.3%)	43 (3.6%)
	1	10 (1.6%)	6 (1.0%)	16 (1.3%)
	2	13 (2.1%)	9 (1.6%)	22 (1.9%)
	3	1 (0.2%)	4 (0.7%)	5 (0.4%)
倦怠感	- Any Grade -	12 (2.0%)	29 (5.0%)	41 (3.5%)
	1	11 (1.8%)	21 (3.6%)	32 (2.7%)
	2	1 (0.2%)	8 (1.4%)	9 (0.8%)

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To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
悪寒	- Any Grade -	22 (3.6%)	9 (1.6%)	31 (2.6%)
	1	18 (3.0%)	8 (1.4%)	26 (2.2%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
浮腫	- Any Grade -	6 (1.0%)	14 (2.4%)	20 (1.7%)
	1	4 (0.7%)	9 (1.6%)	13 (1.1%)
	2	2 (0.3%)	5 (0.9%)	7 (0.6%)
胸部不快感	- Any Grade -	9 (1.5%)	6 (1.0%)	15 (1.3%)
	1	5 (0.8%)	5 (0.9%)	10 (0.8%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	2 (0.3%)	0	2 (0.2%)
顔面浮腫	- Any Grade -	3 (0.5%)	11 (1.9%)	14 (1.2%)
	1	3 (0.5%)	10 (1.7%)	13 (1.1%)
	2	0	1 (0.2%)	1 (<0.1%)
非心臓性胸痛	- Any Grade -	10 (1.6%)	2 (0.3%)	12 (1.0%)
	1	6 (1.0%)	1 (0.2%)	7 (0.6%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
末梢腫脹	- Any Grade -	5 (0.8%)	5 (0.9%)	10 (0.8%)
	1	4 (0.7%)	5 (0.9%)	9 (0.8%)
	2	1 (0.2%)	0	1 (<0.1%)
全身健康状態低下	- Any Grade -	5 (0.8%)	3 (0.5%)	8 (0.7%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	4 (0.7%)	1 (0.2%)	5 (0.4%)
	3	0	1 (0.2%)	1 (<0.1%)
歩行障害	- Any Grade -	7 (1.1%)	1 (0.2%)	8 (0.7%)
	1	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
カテーテル留置部位疼痛	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
注入部位血管外漏出	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	2 (0.3%)	0	2 (0.2%)
	2	0	3 (0.5%)	3 (0.3%)
腋窩痛	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
限局性浮腫	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
全身性浮腫	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
熱感	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
異常高熱	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
腫脹	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
低体温	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
突然死	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	5	1 (0.2%)	2 (0.3%)	3 (0.3%)
医療機器による疼痛	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
溢出	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
局所腫脹	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腫瘤	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
全身性炎症反応症候群	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
注射部位反応	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
カテーテル留置部位紅斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
カテーテル留置部位静脈炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
カテーテル留置部位内出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
カテーテル留置部位発疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
カテーテル留置部位漏出	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
異物感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
医薬品副作用	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
医療機器関連合併症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
温度変化不耐症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
乾燥症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
口渇	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高熱	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
死亡	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	5	1 (0.2%)	0	1 (<0.1%)
穿刺部位紅斑	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
注射部位漏出	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
注入部位血栓	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
注入部位発疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
注入部位反応	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
捻髪音	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
粘膜乾燥	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
嚢胞	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
不明確な障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
閉塞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
冷感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
胃腸障害				
- Overall -	- Any Grade -	300 (49.3%)	324 (56.1%)	624 (52.6%)
	1	176 (28.9%)	167 (28.9%)	343 (28.9%)
	2	99 (16.3%)	116 (20.1%)	215 (18.1%)
	3	25 (4.1%)	39 (6.7%)	64 (5.4%)
	4	0	1 (0.2%)	1 (<0.1%)
	5	0	1 (0.2%)	1 (<0.1%)
悪心	- Any Grade -	108 (17.7%)	131 (22.7%)	239 (20.1%)
	1	74 (12.2%)	81 (14.0%)	155 (13.1%)
	2	30 (4.9%)	48 (8.3%)	78 (6.6%)
	3	4 (0.7%)	2 (0.3%)	6 (0.5%)
下痢	- Any Grade -	94 (15.4%)	141 (24.4%)	235 (19.8%)
	1	70 (11.5%)	95 (16.4%)	165 (13.9%)
	2	20 (3.3%)	35 (6.1%)	55 (4.6%)
	3	4 (0.7%)	11 (1.9%)	15 (1.3%)
便秘	- Any Grade -	107 (17.6%)	82 (14.2%)	189 (15.9%)
	1	70 (11.5%)	60 (10.4%)	130 (11.0%)
	2	35 (5.7%)	21 (3.6%)	56 (4.7%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
嘔吐	- Any Grade -	74 (12.2%)	62 (10.7%)	136 (11.5%)
	1	52 (8.5%)	44 (7.6%)	96 (8.1%)
	2	20 (3.3%)	14 (2.4%)	34 (2.9%)
	3	2 (0.3%)	4 (0.7%)	6 (0.5%)
口内炎	- Any Grade -	19 (3.1%)	63 (10.9%)	82 (6.9%)
	1	14 (2.3%)	34 (5.9%)	48 (4.0%)
	2	4 (0.7%)	18 (3.1%)	22 (1.9%)
	3	1 (0.2%)	11 (1.9%)	12 (1.0%)
腹痛	- Any Grade -	20 (3.3%)	37 (6.4%)	57 (4.8%)
	1	13 (2.1%)	19 (3.3%)	32 (2.7%)
	2	6 (1.0%)	13 (2.2%)	19 (1.6%)
	3	1 (0.2%)	5 (0.9%)	6 (0.5%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
上腹部痛	- Any Grade -	15 (2.5%)	18 (3.1%)	33 (2.8%)
	1	10 (1.6%)	11 (1.9%)	21 (1.8%)
	2	5 (0.8%)	5 (0.9%)	10 (0.8%)
	3	0	2 (0.3%)	2 (0.2%)
消化不良	- Any Grade -	17 (2.8%)	11 (1.9%)	28 (2.4%)
	1	11 (1.8%)	7 (1.2%)	18 (1.5%)
	2	6 (1.0%)	4 (0.7%)	10 (0.8%)
口内乾燥	- Any Grade -	16 (2.6%)	10 (1.7%)	26 (2.2%)
	1	16 (2.6%)	10 (1.7%)	26 (2.2%)
嚥下障害	- Any Grade -	13 (2.1%)	11 (1.9%)	24 (2.0%)
	1	8 (1.3%)	5 (0.9%)	13 (1.1%)
	2	3 (0.5%)	5 (0.9%)	8 (0.7%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
胃食道逆流性疾患	- Any Grade -	8 (1.3%)	11 (1.9%)	19 (1.6%)
	1	6 (1.0%)	6 (1.0%)	12 (1.0%)
	2	1 (0.2%)	5 (0.9%)	6 (0.5%)
	3	1 (0.2%)	0	1 (<0.1%)
腹部膨満	- Any Grade -	5 (0.8%)	7 (1.2%)	12 (1.0%)
	1	5 (0.8%)	5 (0.9%)	10 (0.8%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
口腔内痛	- Any Grade -	2 (0.3%)	9 (1.6%)	11 (0.9%)
	1	1 (0.2%)	8 (1.4%)	9 (0.8%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
歯痛	- Any Grade -	5 (0.8%)	5 (0.9%)	10 (0.8%)
	1	1 (0.2%)	4 (0.7%)	5 (0.4%)
	2	4 (0.7%)	1 (0.2%)	5 (0.4%)
痔核	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
腹部不快感	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	5 (0.8%)	3 (0.5%)	8 (0.7%)
	2	0	1 (0.2%)	1 (<0.1%)
鼓腸	- Any Grade -	5 (0.8%)	2 (0.3%)	7 (0.6%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
	2	1 (0.2%)	0	1 (<0.1%)
口腔内潰瘍形成	- Any Grade -	2 (0.3%)	5 (0.9%)	7 (0.6%)
	1	2 (0.3%)	5 (0.9%)	7 (0.6%)
胃炎	- Any Grade -	2 (0.3%)	4 (0.7%)	6 (0.5%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
下腹部痛	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
	3	2 (0.3%)	0	2 (0.2%)
歯肉痛	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
大腸炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
嚥下痛	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
齲歯	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
イレウス	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
メレナ	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
腹水	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)
肛門の炎症	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
肛門失禁	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
びらん性食道炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
亜イレウス	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
痔出血	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
小腸閉塞	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
食道炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
舌苔	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
直腸出血	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
変色便	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
肛門周囲痛	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
鼠径ヘルニア	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
おくび	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
びらん性胃炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
アフタ性潰瘍	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
胃腸ポリープ出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
下部消化管出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	5	0	1 (0.2%)	1 (<0.1%)
過敏性腸症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
憩室	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血便排泄	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
口の感覚鈍麻	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
口の錯感覚	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇のひび割れ	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇乾燥	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
口唇腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
口唇痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
絞扼性臍径ヘルニア	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
歯周病	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
歯肉出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
十二指腸穿孔	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
出血性十二指腸潰瘍	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
小腸炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
上部消化管出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
食道障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
食道静脈瘤	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
食道静脈瘤出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
食道痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
食道閉塞症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
食道瘻	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
舌炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
舌腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
舌不快感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
舌浮腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
大腸穿孔	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
腸間膜静脈血栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
腸間膜動脈閉塞	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
腸憩室	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腸閉塞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
吐血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
粘液便	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
非感染性唾液腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腹部圧痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
裂孔ヘルニア	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
肛門そう痒症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肛門出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
膵炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
呼吸器、胸郭および縦隔障害				
- Overall -	- Any Grade -	313 (51.4%)	270 (46.7%)	583 (49.1%)
	1	144 (23.6%)	127 (22.0%)	271 (22.8%)
	2	108 (17.7%)	96 (16.6%)	204 (17.2%)
	3	49 (8.0%)	38 (6.6%)	87 (7.3%)
	4	10 (1.6%)	3 (0.5%)	13 (1.1%)
	5	2 (0.3%)	6 (1.0%)	8 (0.7%)
咳嗽	- Any Grade -	141 (23.2%)	105 (18.2%)	246 (20.7%)
	1	96 (15.8%)	63 (10.9%)	159 (13.4%)
	2	43 (7.1%)	41 (7.1%)	84 (7.1%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
呼吸困難	- Any Grade -	118 (19.4%)	112 (19.4%)	230 (19.4%)
	1	53 (8.7%)	53 (9.2%)	106 (8.9%)
	2	49 (8.0%)	44 (7.6%)	93 (7.8%)
	3	14 (2.3%)	12 (2.1%)	26 (2.2%)
	4	1 (0.2%)	2 (0.3%)	3 (0.3%)
	5	1 (0.2%)	1 (0.2%)	2 (0.2%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
喀血	- Any Grade -	41 (6.7%)	32 (5.5%)	73 (6.1%)
	1	29 (4.8%)	23 (4.0%)	52 (4.4%)
	2	9 (1.5%)	6 (1.0%)	15 (1.3%)
	3	3 (0.5%)	2 (0.3%)	5 (0.4%)
	5	0	1 (0.2%)	1 (<0.1%)
胸水	- Any Grade -	27 (4.4%)	21 (3.6%)	48 (4.0%)
	1	8 (1.3%)	9 (1.6%)	17 (1.4%)
	2	10 (1.6%)	6 (1.0%)	16 (1.3%)
	3	8 (1.3%)	5 (0.9%)	13 (1.1%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
湿性咳嗽	- Any Grade -	24 (3.9%)	21 (3.6%)	45 (3.8%)
	1	20 (3.3%)	16 (2.8%)	36 (3.0%)
	2	3 (0.5%)	5 (0.9%)	8 (0.7%)
	3	1 (0.2%)	0	1 (<0.1%)
口腔咽頭痛	- Any Grade -	19 (3.1%)	18 (3.1%)	37 (3.1%)
	1	17 (2.8%)	14 (2.4%)	31 (2.6%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
	3	0	1 (0.2%)	1 (<0.1%)
労作性呼吸困難	- Any Grade -	21 (3.4%)	11 (1.9%)	32 (2.7%)
	1	15 (2.5%)	9 (1.6%)	24 (2.0%)
	2	5 (0.8%)	1 (0.2%)	6 (0.5%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
鼻出血	- Any Grade -	11 (1.8%)	15 (2.6%)	26 (2.2%)
	1	10 (1.6%)	15 (2.6%)	25 (2.1%)
	2	1 (0.2%)	0	1 (<0.1%)
肺塞栓症	- Any Grade -	15 (2.5%)	10 (1.7%)	25 (2.1%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	8 (1.3%)	5 (0.9%)	13 (1.1%)
	4	4 (0.7%)	0	4 (0.3%)
	5	0	1 (0.2%)	1 (<0.1%)
発声障害	- Any Grade -	17 (2.8%)	6 (1.0%)	23 (1.9%)
	1	13 (2.1%)	4 (0.7%)	17 (1.4%)
	2	4 (0.7%)	2 (0.3%)	6 (0.5%)
低酸素症	- Any Grade -	10 (1.6%)	11 (1.9%)	21 (1.8%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	5 (0.8%)	4 (0.7%)	9 (0.8%)
	3	4 (0.7%)	6 (1.0%)	10 (0.8%)
鼻漏	- Any Grade -	8 (1.3%)	11 (1.9%)	19 (1.6%)
	1	7 (1.1%)	11 (1.9%)	18 (1.5%)
	2	1 (0.2%)	0	1 (<0.1%)
しゃっくり	- Any Grade -	2 (0.3%)	15 (2.6%)	17 (1.4%)
	1	1 (0.2%)	11 (1.9%)	12 (1.0%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
鼻閉	- Any Grade -	11 (1.8%)	6 (1.0%)	17 (1.4%)
	1	9 (1.5%)	6 (1.0%)	15 (1.3%)
	2	2 (0.3%)	0	2 (0.2%)
慢性閉塞性肺疾患	- Any Grade -	9 (1.5%)	6 (1.0%)	15 (1.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	6 (1.0%)	3 (0.5%)	9 (0.8%)
	3	2 (0.3%)	2 (0.3%)	4 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
胸膜痛	- Any Grade -	5 (0.8%)	7 (1.2%)	12 (1.0%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	4 (0.7%)	5 (0.4%)
	3	2 (0.3%)	2 (0.3%)	4 (0.3%)
喘鳴	- Any Grade -	6 (1.0%)	5 (0.9%)	11 (0.9%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
気胸	- Any Grade -	6 (1.0%)	3 (0.5%)	9 (0.8%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	3 (0.5%)	1 (0.2%)	4 (0.3%)
肺臓炎	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	3 (0.5%)	2 (0.3%)	5 (0.4%)
呼吸不全	- Any Grade -	4 (0.7%)	3 (0.5%)	7 (0.6%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	2 (0.3%)	2 (0.3%)	4 (0.3%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
アレルギー性鼻炎	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
上気道咳症候群	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
肺出血	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	2	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
	5	1 (0.2%)	1 (0.2%)	2 (0.2%)
気管支痙攣	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
無気肺	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
間質性肺疾患	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
気管支分泌増加	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
気管支閉塞	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
上気道の炎症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
咽喉刺激感	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
咽頭の炎症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
器質化肺炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
呼吸窮迫	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	5	0	1 (0.2%)	1 (<0.1%)
誤嚥性肺炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
肺気腫	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
肺高血圧症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
肺浸潤	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
肺水腫	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
頻呼吸	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
喀痰増加	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
喘息	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
くしゃみ	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
咽喉絞扼感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
下気道うっ血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
気管支出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
気道うっ血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
急性呼吸窮迫症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
急性呼吸不全	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
胸膜線維症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
胸膜摩擦音	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
胸膜瘻	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
呼吸時疼痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
呼吸抑制	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
誤嚥	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
自然気胸	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	5	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
上気道うっ血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
睡眠時無呼吸症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
低音性連続性ラ音	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肺障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肺痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
非感染性気管支炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
鼻の炎症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
鼻乾燥	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
鼻潰瘍	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
副鼻腔うっ血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
変色痰	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
慢性気管支炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋骨格系および結合組織障害				
- Overall -	- Any Grade -	267 (43.8%)	243 (42.0%)	510 (43.0%)
	1	126 (20.7%)	122 (21.1%)	248 (20.9%)
	2	112 (18.4%)	108 (18.7%)	220 (18.5%)
	3	28 (4.6%)	13 (2.2%)	41 (3.5%)
	4	1 (0.2%)	0	1 (<0.1%)
関節痛	- Any Grade -	73 (12.0%)	58 (10.0%)	131 (11.0%)
	1	44 (7.2%)	35 (6.1%)	79 (6.7%)
	2	26 (4.3%)	22 (3.8%)	48 (4.0%)
	3	3 (0.5%)	1 (0.2%)	4 (0.3%)
筋肉痛	- Any Grade -	39 (6.4%)	91 (15.7%)	130 (11.0%)
	1	28 (4.6%)	53 (9.2%)	81 (6.8%)
	2	10 (1.6%)	34 (5.9%)	44 (3.7%)
	3	1 (0.2%)	4 (0.7%)	5 (0.4%)
背部痛	- Any Grade -	67 (11.0%)	42 (7.3%)	109 (9.2%)
	1	30 (4.9%)	20 (3.5%)	50 (4.2%)
	2	30 (4.9%)	18 (3.1%)	48 (4.0%)
	3	7 (1.1%)	4 (0.7%)	11 (0.9%)
四肢痛	- Any Grade -	51 (8.4%)	39 (6.7%)	90 (7.6%)
	1	29 (4.8%)	26 (4.5%)	55 (4.6%)
	2	21 (3.4%)	11 (1.9%)	32 (2.7%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
筋骨格痛	- Any Grade -	64 (10.5%)	25 (4.3%)	89 (7.5%)
	1	30 (4.9%)	11 (1.9%)	41 (3.5%)
	2	30 (4.9%)	13 (2.2%)	43 (3.6%)
	3	4 (0.7%)	1 (0.2%)	5 (0.4%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
骨痛	- Any Grade -	17 (2.8%)	23 (4.0%)	40 (3.4%)
	1	6 (1.0%)	12 (2.1%)	18 (1.5%)
	2	7 (1.1%)	10 (1.7%)	17 (1.4%)
	3	4 (0.7%)	1 (0.2%)	5 (0.4%)
筋骨格系胸痛	- Any Grade -	30 (4.9%)	7 (1.2%)	37 (3.1%)
	1	20 (3.3%)	1 (0.2%)	21 (1.8%)
	2	7 (1.1%)	6 (1.0%)	13 (1.1%)
	3	3 (0.5%)	0	3 (0.3%)
筋力低下	- Any Grade -	16 (2.6%)	18 (3.1%)	34 (2.9%)
	1	7 (1.1%)	10 (1.7%)	17 (1.4%)
	2	8 (1.3%)	7 (1.2%)	15 (1.3%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
筋痙縮	- Any Grade -	16 (2.6%)	9 (1.6%)	25 (2.1%)
	1	13 (2.1%)	8 (1.4%)	21 (1.8%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
頚部痛	- Any Grade -	10 (1.6%)	3 (0.5%)	13 (1.1%)
	1	7 (1.1%)	1 (0.2%)	8 (0.7%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
脊椎痛	- Any Grade -	10 (1.6%)	3 (0.5%)	13 (1.1%)
	1	7 (1.1%)	2 (0.3%)	9 (0.8%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
側腹部痛	- Any Grade -	7 (1.1%)	4 (0.7%)	11 (0.9%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
	2	3 (0.5%)	2 (0.3%)	5 (0.4%)
関節腫脹	- Any Grade -	6 (1.0%)	2 (0.3%)	8 (0.7%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
関節炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
筋骨格硬直	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	4 (0.7%)	0	4 (0.3%)
筋骨格不快感	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
筋攣縮	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
肩回旋筋腱板症候群	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
腱炎	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
顎痛	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
滑液包炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
関節リウマチ	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)
関節周囲炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
筋緊張	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
変形性関節症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
ばち状指	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
顎関節症候群	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
関節可動域低下	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
筋肉疲労	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
脊椎炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
椎間板突出	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
腱鞘炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
鼡径部痛	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
リウマチ性多発筋痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
横紋筋融解症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
外骨腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
関節硬直	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
骨減少症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
骨折痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
骨粗鬆症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
四肢不快感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
姿勢異常	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
側弯症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
足底筋膜炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
恥骨痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
尾骨痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
変形性脊椎症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
肋間筋肉痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腱痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
感染症および寄生虫症				
- Overall -	- Any Grade -	235 (38.6%)	245 (42.4%)	480 (40.4%)
	1	62 (10.2%)	58 (10.0%)	120 (10.1%)
	2	116 (19.0%)	117 (20.2%)	233 (19.6%)
	3	45 (7.4%)	57 (9.9%)	102 (8.6%)
	4	8 (1.3%)	8 (1.4%)	16 (1.3%)
	5	4 (0.7%)	5 (0.9%)	9 (0.8%)
肺炎	- Any Grade -	41 (6.7%)	48 (8.3%)	89 (7.5%)
	1	4 (0.7%)	4 (0.7%)	8 (0.7%)
	2	16 (2.6%)	13 (2.2%)	29 (2.4%)
	3	19 (3.1%)	27 (4.7%)	46 (3.9%)
	4	1 (0.2%)	2 (0.3%)	3 (0.3%)
	5	1 (0.2%)	2 (0.3%)	3 (0.3%)
尿路感染	- Any Grade -	22 (3.6%)	31 (5.4%)	53 (4.5%)
	1	6 (1.0%)	7 (1.2%)	13 (1.1%)
	2	15 (2.5%)	19 (3.3%)	34 (2.9%)
	3	1 (0.2%)	5 (0.9%)	6 (0.5%)
上気道感染	- Any Grade -	36 (5.9%)	15 (2.6%)	51 (4.3%)
	1	12 (2.0%)	3 (0.5%)	15 (1.3%)
	2	24 (3.9%)	11 (1.9%)	35 (2.9%)
	3	0	1 (0.2%)	1 (<0.1%)
鼻咽頭炎	- Any Grade -	31 (5.1%)	20 (3.5%)	51 (4.3%)
	1	26 (4.3%)	16 (2.8%)	42 (3.5%)
	2	5 (0.8%)	4 (0.7%)	9 (0.8%)
気管支炎	- Any Grade -	24 (3.9%)	26 (4.5%)	50 (4.2%)
	1	6 (1.0%)	1 (0.2%)	7 (0.6%)
	2	18 (3.0%)	22 (3.8%)	40 (3.4%)
	3	0	3 (0.5%)	3 (0.3%)
気道感染	- Any Grade -	22 (3.6%)	19 (3.3%)	41 (3.5%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	13 (2.1%)	12 (2.1%)	25 (2.1%)
	3	6 (1.0%)	1 (0.2%)	7 (0.6%)
	5	0	2 (0.3%)	2 (0.2%)
口腔カンジダ症	- Any Grade -	7 (1.1%)	15 (2.6%)	22 (1.9%)
	1	4 (0.7%)	6 (1.0%)	10 (0.8%)
	2	2 (0.3%)	9 (1.6%)	11 (0.9%)
	3	1 (0.2%)	0	1 (<0.1%)
結膜炎	- Any Grade -	7 (1.1%)	13 (2.2%)	20 (1.7%)
	1	6 (1.0%)	6 (1.0%)	12 (1.0%)
	2	1 (0.2%)	6 (1.0%)	7 (0.6%)
	3	0	1 (0.2%)	1 (<0.1%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
下気道感染	- Any Grade -	9 (1.5%)	7 (1.2%)	16 (1.3%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	3 (0.5%)	4 (0.7%)	7 (0.6%)
	3	3 (0.5%)	2 (0.3%)	5 (0.4%)
肺感染	- Any Grade -	7 (1.1%)	9 (1.6%)	16 (1.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	4 (0.7%)	4 (0.7%)	8 (0.7%)
	3	2 (0.3%)	3 (0.5%)	5 (0.4%)
膀胱炎	- Any Grade -	6 (1.0%)	7 (1.2%)	13 (1.1%)
	1	4 (0.7%)	0	4 (0.3%)
	2	2 (0.3%)	7 (1.2%)	9 (0.8%)
咽頭炎	- Any Grade -	6 (1.0%)	6 (1.0%)	12 (1.0%)
	1	0	2 (0.3%)	2 (0.2%)
	2	5 (0.8%)	4 (0.7%)	9 (0.8%)
	3	1 (0.2%)	0	1 (<0.1%)
爪囲炎	- Any Grade -	0	12 (2.1%)	12 (1.0%)
	1	0	6 (1.0%)	6 (0.5%)
	2	0	5 (0.9%)	5 (0.4%)
	3	0	1 (0.2%)	1 (<0.1%)
副鼻腔炎	- Any Grade -	7 (1.1%)	5 (0.9%)	12 (1.0%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	5 (0.8%)	3 (0.5%)	8 (0.7%)
帯状疱疹	- Any Grade -	8 (1.3%)	2 (0.3%)	10 (0.8%)
	1	4 (0.7%)	0	4 (0.3%)
	2	4 (0.7%)	2 (0.3%)	6 (0.5%)
感染	- Any Grade -	2 (0.3%)	7 (1.2%)	9 (0.8%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
	3	0	4 (0.7%)	4 (0.3%)
胃腸炎	- Any Grade -	3 (0.5%)	5 (0.9%)	8 (0.7%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
敗血症	- Any Grade -	5 (0.8%)	3 (0.5%)	8 (0.7%)
	4	3 (0.5%)	2 (0.3%)	5 (0.4%)
	5	2 (0.3%)	1 (0.2%)	3 (0.3%)
鼻炎	- Any Grade -	6 (1.0%)	2 (0.3%)	8 (0.7%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
	2	2 (0.3%)	0	2 (0.2%)
皮膚感染	- Any Grade -	3 (0.5%)	4 (0.7%)	7 (0.6%)
	1	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
蜂巣炎	- Any Grade -	4 (0.7%)	3 (0.5%)	7 (0.6%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
カンジダ感染	- Any Grade -	0	6 (1.0%)	6 (0.5%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	2 (0.3%)	2 (0.2%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
毛包炎	- Any Grade -	3 (0.5%)	3 (0.5%)	6 (0.5%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	1 (0.2%)	0	1 (<0.1%)
インフルエンザ	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
医療機器関連感染	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
口腔ヘルペス	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
歯周炎	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
クロストリジウム・ディフィシレ大腸炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
憩室炎	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
細菌性肺炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
歯膿瘍	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	2	4 (0.7%)	0	4 (0.3%)
耳感染	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
爪感染	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	2	0	4 (0.7%)	4 (0.3%)
爪真菌症	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
膿疱性皮疹	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
扁桃炎	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	0	3 (0.3%)
ウイルス性胃腸炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)
口角口唇炎	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
口腔真菌感染	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
歯感染	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
歯肉炎	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
髄膜炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
敗血症性ショック	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
	5	1 (0.2%)	0	1 (<0.1%)
皮膚真菌感染	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
ウイルス性気道感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
ブドウ球菌感染	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
ヘルペスウイルス感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
胃感染	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
外陰腟真菌感染	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
感染性腸炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
眼感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
胸膜感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
結腸膿瘍	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
口腔感染	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
喉頭炎	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
好中球減少性敗血症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	4	0	2 (0.3%)	2 (0.2%)
真菌性舌感染	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
熱性感染症	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
粘膜感染	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
膿瘍	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
肺敗血症	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	4	2 (0.3%)	0	2 (0.2%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
皮下組織膿瘍	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
ウイルス感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
ウイルス性気管支炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
クロストリジウム・ディフィシレ感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
サイトメガロウイルス感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
シュードモナス性気管支炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
ニューモシスチス・イロベチイ肺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
ヘモフィルス感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
ヘルペス性状湿疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
モラクセラ感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
レンサ球菌性咽頭炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
外陰部腟カンジダ症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
感染による慢性閉塞性気道疾患の増悪	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
感染性胸水	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
感染性舌炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
感染性皮膚潰瘍	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
偽膜性大腸炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
急性腎盂腎炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
結核	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
限局性感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
骨髄炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
細気管支炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
細菌感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
細菌性咽頭炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
細菌性上気道感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
細菌性敗血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
四肢膿瘍	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
歯髄炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
耳下腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
消化管感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
心内膜炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
真菌感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
真菌性消化管感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
真菌性食道炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
腎感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
足部白癬	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
体部白癬	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
単純ヘルペス	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
中耳炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
虫垂炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
軟部組織膿瘍	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
乳腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
乳様突起炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
尿路性敗血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
脳炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
膿痂疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚カンジダ	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
腹部膿瘍	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
腹部敗血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
慢性中耳炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
慢性副鼻腔炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
涙嚢炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
肛門直腸感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
皮膚および皮下組織障害				
- Overall -	- Any Grade -	176 (28.9%)	274 (47.4%)	450 (37.9%)
	1	125 (20.5%)	143 (24.7%)	268 (22.6%)
	2	40 (6.6%)	127 (22.0%)	167 (14.1%)
	3	11 (1.8%)	4 (0.7%)	15 (1.3%)
脱毛症	- Any Grade -	3 (0.5%)	202 (34.9%)	205 (17.3%)
	1	2 (0.3%)	101 (17.5%)	103 (8.7%)
	2	1 (0.2%)	100 (17.3%)	101 (8.5%)
	3	0	1 (0.2%)	1 (<0.1%)
発疹	- Any Grade -	58 (9.5%)	49 (8.5%)	107 (9.0%)
	1	46 (7.6%)	37 (6.4%)	83 (7.0%)
	2	10 (1.6%)	12 (2.1%)	22 (1.9%)
	3	2 (0.3%)	0	2 (0.2%)
そう痒症	- Any Grade -	50 (8.2%)	18 (3.1%)	68 (5.7%)
	1	39 (6.4%)	15 (2.6%)	54 (4.5%)
	2	8 (1.3%)	3 (0.5%)	11 (0.9%)
	3	3 (0.5%)	0	3 (0.3%)
皮膚乾燥	- Any Grade -	27 (4.4%)	34 (5.9%)	61 (5.1%)
	1	25 (4.1%)	32 (5.5%)	57 (4.8%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
爪の障害	- Any Grade -	0	30 (5.2%)	30 (2.5%)
	1	0	25 (4.3%)	25 (2.1%)
	2	0	4 (0.7%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
爪変色	- Any Grade -	1 (0.2%)	26 (4.5%)	27 (2.3%)
	1	1 (0.2%)	25 (4.3%)	26 (2.2%)
	2	0	1 (0.2%)	1 (<0.1%)
紅斑	- Any Grade -	13 (2.1%)	11 (1.9%)	24 (2.0%)
	1	9 (1.5%)	9 (1.6%)	18 (1.5%)
	2	4 (0.7%)	2 (0.3%)	6 (0.5%)
寝汗	- Any Grade -	14 (2.3%)	4 (0.7%)	18 (1.5%)
	1	12 (2.0%)	3 (0.5%)	15 (1.3%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
斑状丘疹状皮疹	- Any Grade -	9 (1.5%)	5 (0.9%)	14 (1.2%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
爪甲脱落症	- Any Grade -	0	13 (2.2%)	13 (1.1%)
	1	0	7 (1.2%)	7 (0.6%)
	2	0	6 (1.0%)	6 (0.5%)
湿疹	- Any Grade -	7 (1.1%)	3 (0.5%)	10 (0.8%)
	1	6 (1.0%)	3 (0.5%)	9 (0.8%)
	2	1 (0.2%)	0	1 (<0.1%)
ざ瘡様皮膚炎	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
手掌・足底発赤知覚不全症候群	- Any Grade -	0	9 (1.6%)	9 (0.8%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	4 (0.7%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
多汗症	- Any Grade -	5 (0.8%)	3 (0.5%)	8 (0.7%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
皮膚色素過剰	- Any Grade -	4 (0.7%)	4 (0.7%)	8 (0.7%)
	1	4 (0.7%)	3 (0.5%)	7 (0.6%)
	2	0	1 (0.2%)	1 (<0.1%)
爪毒性	- Any Grade -	0	7 (1.2%)	7 (0.6%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	3 (0.5%)	3 (0.3%)
皮膚炎	- Any Grade -	4 (0.7%)	3 (0.5%)	7 (0.6%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
蕁麻疹	- Any Grade -	5 (0.8%)	2 (0.3%)	7 (0.6%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
そう痒性皮疹	- Any Grade -	4 (0.7%)	2 (0.3%)	6 (0.5%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
皮膚剥脱	- Any Grade -	2 (0.3%)	4 (0.7%)	6 (0.5%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	0	1 (0.2%)	1 (<0.1%)
乾癬	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
爪線状隆起	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
紅斑性皮疹	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
全身性そう痒症	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
爪甲離床症	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
皮膚腫瘤	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
顔面腫脹	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
水疱性皮膚炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
爪ジストロフィー	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
点状出血	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
皮膚病変	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
皮膚疼痛	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
褥瘡性潰瘍	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
ざ瘡	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
接触性皮膚炎	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
全身性皮疹	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
多形紅斑	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
爪痛	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
爪破損	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
皮膚硬結	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
皮膚潰瘍	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
皮膚毒性	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
皮膚嚢腫	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚反応	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
嵌入爪	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
うっ滞性皮膚炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
アトピー性皮膚炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
過角化	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
乾皮症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
丘疹性皮疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血管浮腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
光線角化症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
紅色症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
黒皮症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
脂漏性皮膚炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
手掌紅斑	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
色素沈着障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
尋常性白斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
水疱	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
爪床出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
爪肥厚	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
頭部粃糠疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
皮脂欠乏性湿疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
皮膚萎縮	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
皮膚亀裂	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚刺激	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
皮膚色素減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
皮膚軟化	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
皮膚粘膜発疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚変色	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
薬疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
立毛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
類天疱瘡	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
冷汗	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
扁平苔癬	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
痒疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
睫毛眉毛脱落症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
代謝および栄養障害				
- Overall -	- Any Grade -	224 (36.8%)	223 (38.6%)	447 (37.7%)
	1	119 (19.5%)	94 (16.3%)	213 (17.9%)
	2	75 (12.3%)	93 (16.1%)	168 (14.2%)
	3	26 (4.3%)	36 (6.2%)	62 (5.2%)
	4	4 (0.7%)	0	4 (0.3%)
食欲減退	- Any Grade -	143 (23.5%)	136 (23.5%)	279 (23.5%)
	1	90 (14.8%)	66 (11.4%)	156 (13.1%)
	2	51 (8.4%)	61 (10.6%)	112 (9.4%)
	3	2 (0.3%)	9 (1.6%)	11 (0.9%)
低カリウム血症	- Any Grade -	25 (4.1%)	24 (4.2%)	49 (4.1%)
	1	20 (3.3%)	13 (2.2%)	33 (2.8%)
	2	1 (0.2%)	5 (0.9%)	6 (0.5%)
	3	4 (0.7%)	6 (1.0%)	10 (0.8%)
脱水	- Any Grade -	17 (2.8%)	29 (5.0%)	46 (3.9%)
	1	5 (0.8%)	2 (0.3%)	7 (0.6%)
	2	9 (1.5%)	20 (3.5%)	29 (2.4%)
	3	3 (0.5%)	7 (1.2%)	10 (0.8%)
高血糖	- Any Grade -	18 (3.0%)	26 (4.5%)	44 (3.7%)
	1	7 (1.1%)	11 (1.9%)	18 (1.5%)
	2	4 (0.7%)	10 (1.7%)	14 (1.2%)
	3	4 (0.7%)	5 (0.9%)	9 (0.8%)
	4	3 (0.5%)	0	3 (0.3%)
低ナトリウム血症	- Any Grade -	26 (4.3%)	18 (3.1%)	44 (3.7%)
	1	14 (2.3%)	12 (2.1%)	26 (2.2%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	10 (1.6%)	4 (0.7%)	14 (1.2%)
	4	1 (0.2%)	0	1 (<0.1%)
低マグネシウム血症	- Any Grade -	21 (3.4%)	18 (3.1%)	39 (3.3%)
	1	18 (3.0%)	16 (2.8%)	34 (2.9%)
	2	3 (0.5%)	2 (0.3%)	5 (0.4%)
低アルブミン血症	- Any Grade -	19 (3.1%)	19 (3.3%)	38 (3.2%)
	1	12 (2.0%)	10 (1.7%)	22 (1.9%)
	2	7 (1.1%)	8 (1.4%)	15 (1.3%)
	3	0	1 (0.2%)	1 (<0.1%)
低リン酸血症	- Any Grade -	13 (2.1%)	12 (2.1%)	25 (2.1%)
	1	7 (1.1%)	6 (1.0%)	13 (1.1%)
	2	6 (1.0%)	4 (0.7%)	10 (0.8%)
	3	0	2 (0.3%)	2 (0.2%)
高カルシウム血症	- Any Grade -	11 (1.8%)	7 (1.2%)	18 (1.5%)
	1	8 (1.3%)	4 (0.7%)	12 (1.0%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
高カリウム血症	- Any Grade -	7 (1.1%)	9 (1.6%)	16 (1.3%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
低カルシウム血症	- Any Grade -	8 (1.3%)	7 (1.2%)	15 (1.3%)
	1	5 (0.8%)	5 (0.9%)	10 (0.8%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
痛風	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	0	3 (0.5%)	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
低血糖	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
過小食	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
高尿酸血症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
成長障害	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
２型糖尿病	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
高トリグリセリド血症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
食欲亢進	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
鉄欠乏	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
糖尿病	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
１型糖尿病	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
アルコール不耐性	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
悪液質	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
栄養障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血液量減少症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高アルブミン血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高コレステロール血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
高ナトリウム血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高マグネシウム血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
細胞死	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
多飲症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
体液貯留	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
耐糖能障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
低クロール血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
神経系障害				
- Overall -	- Any Grade -	200 (32.8%)	243 (42.0%)	443 (37.3%)
	1	129 (21.2%)	138 (23.9%)	267 (22.5%)
	2	50 (8.2%)	80 (13.8%)	130 (11.0%)
	3	21 (3.4%)	23 (4.0%)	44 (3.7%)
	4	0	2 (0.3%)	2 (0.2%)
頭痛	- Any Grade -	57 (9.4%)	46 (8.0%)	103 (8.7%)
	1	49 (8.0%)	38 (6.6%)	87 (7.3%)
	2	6 (1.0%)	7 (1.2%)	13 (1.1%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
末梢性ニューロパチー	- Any Grade -	24 (3.9%)	65 (11.2%)	89 (7.5%)
	1	15 (2.5%)	33 (5.7%)	48 (4.0%)
	2	9 (1.5%)	25 (4.3%)	34 (2.9%)
	3	0	7 (1.2%)	7 (0.6%)
浮動性めまい	- Any Grade -	46 (7.6%)	33 (5.7%)	79 (6.7%)
	1	41 (6.7%)	27 (4.7%)	68 (5.7%)
	2	4 (0.7%)	4 (0.7%)	8 (0.7%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
味覚異常	- Any Grade -	18 (3.0%)	58 (10.0%)	76 (6.4%)
	1	13 (2.1%)	46 (8.0%)	59 (5.0%)
	2	5 (0.8%)	12 (2.1%)	17 (1.4%)
錯感覚	- Any Grade -	20 (3.3%)	45 (7.8%)	65 (5.5%)
	1	19 (3.1%)	29 (5.0%)	48 (4.0%)
	2	1 (0.2%)	14 (2.4%)	15 (1.3%)
	3	0	2 (0.3%)	2 (0.2%)
末梢性感覚ニューロパチー	- Any Grade -	6 (1.0%)	43 (7.4%)	49 (4.1%)
	1	4 (0.7%)	27 (4.7%)	31 (2.6%)
	2	2 (0.3%)	11 (1.9%)	13 (1.1%)
	3	0	5 (0.9%)	5 (0.4%)
感覚鈍麻	- Any Grade -	5 (0.8%)	15 (2.6%)	20 (1.7%)
	1	3 (0.5%)	11 (1.9%)	14 (1.2%)
	2	2 (0.3%)	4 (0.7%)	6 (0.5%)
失神	- Any Grade -	6 (1.0%)	7 (1.2%)	13 (1.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	5 (0.8%)	7 (1.2%)	12 (1.0%)
傾眠	- Any Grade -	8 (1.3%)	3 (0.5%)	11 (0.9%)
	1	5 (0.8%)	3 (0.5%)	8 (0.7%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
記憶障害	- Any Grade -	5 (0.8%)	3 (0.5%)	8 (0.7%)
	1	3 (0.5%)	2 (0.3%)	5 (0.4%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
坐骨神経痛	- Any Grade -	6 (1.0%)	2 (0.3%)	8 (0.7%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	4 (0.7%)	1 (0.2%)	5 (0.4%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
振戦	- Any Grade -	5 (0.8%)	2 (0.3%)	7 (0.6%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
神経痛	- Any Grade -	5 (0.8%)	1 (0.2%)	6 (0.5%)
	1	3 (0.5%)	0	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	2 (0.3%)	0	2 (0.2%)
嗜眠	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	0	3 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
痙攣発作	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
異常感覚	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	1	0	3 (0.5%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
認知障害	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
ギラン・バレー症候群	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	3	3 (0.5%)	0	3 (0.3%)
意識レベルの低下	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	2 (0.3%)	0	2 (0.2%)
運動失調	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
構語障害	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
神経毒性	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	2	0	3 (0.5%)	3 (0.3%)
多発ニューロパチー	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
知覚過敏	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
平衡障害	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
末梢性運動ニューロパチー	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
味覚減退	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	3 (0.5%)	3 (0.3%)
てんかん	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
下肢静止不能症候群	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
筋痙直	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
失語症	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
手根管症候群	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
神経系障害	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
脳血管発作	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
脳浮腫	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
不全単麻痺	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
くも膜下出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
アカシジア	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
ヘルペス後神経痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
ミオクローヌス	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
意識消失	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
温度覚鈍麻	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
過眠症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
顔面麻痺	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
健忘	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
後頭神経痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
視神経炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
失神寸前の状態	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
灼熱感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
書字障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
錐体外路障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
脊髄圧迫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
前兆	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
全身性強直性間代性発作	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
対麻痺	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
大脳動脈塞栓症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
第６脳神経麻痺	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
注意力障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
鎮静	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
脳血栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
脳症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
白質脳症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
不全片麻痺	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
片頭痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
本態性振戦	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
末梢性感覚運動ニューロパチー	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
味覚消失	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
労作性めまい	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腓骨神経麻痺	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血液およびリンパ系障害				
- Overall -	- Any Grade -	95 (15.6%)	247 (42.7%)	342 (28.8%)
	1	30 (4.9%)	28 (4.8%)	58 (4.9%)
	2	43 (7.1%)	60 (10.4%)	103 (8.7%)
	3	21 (3.4%)	95 (16.4%)	116 (9.8%)
	4	1 (0.2%)	64 (11.1%)	65 (5.5%)

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事象名：MedDRA ver. 19.0
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
貧血	- Any Grade -	70 (11.5%)	136 (23.5%)	206 (17.4%)
	1	22 (3.6%)	35 (6.1%)	57 (4.8%)
	2	34 (5.6%)	68 (11.8%)	102 (8.6%)
	3	14 (2.3%)	32 (5.5%)	46 (3.9%)
	4	0	1 (0.2%)	1 (<0.1%)
好中球減少症	- Any Grade -	10 (1.6%)	90 (15.6%)	100 (8.4%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	4 (0.7%)	11 (1.9%)	15 (1.3%)
	3	2 (0.3%)	25 (4.3%)	27 (2.3%)
	4	1 (0.2%)	50 (8.7%)	51 (4.3%)
発熱性好中球減少症	- Any Grade -	1 (0.2%)	62 (10.7%)	63 (5.3%)
	3	1 (0.2%)	50 (8.7%)	51 (4.3%)
	4	0	12 (2.1%)	12 (1.0%)
白血球減少症	- Any Grade -	4 (0.7%)	25 (4.3%)	29 (2.4%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	3 (0.5%)	6 (0.5%)
	3	0	17 (2.9%)	17 (1.4%)
	4	0	5 (0.9%)	5 (0.4%)
血小板減少症	- Any Grade -	8 (1.3%)	8 (1.4%)	16 (1.3%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
リンパ球減少症	- Any Grade -	3 (0.5%)	7 (1.2%)	10 (0.8%)
	1	0	4 (0.7%)	4 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
白血球増加症	- Any Grade -	2 (0.3%)	6 (1.0%)	8 (0.7%)
	1	0	3 (0.5%)	3 (0.3%)
	3	2 (0.3%)	3 (0.5%)	5 (0.4%)
リンパ節痛	- Any Grade -	5 (0.8%)	1 (0.2%)	6 (0.5%)
	1	5 (0.8%)	1 (0.2%)	6 (0.5%)
リンパ節症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
汎血球減少症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)
リンパ節炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
リンパ節出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血小板増加症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
赤血球増加症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
鉄欠乏性貧血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
播種性血管内凝固	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
無顆粒球症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
臨床検査				
- Overall -	- Any Grade -	159 (26.1%)	137 (23.7%)	296 (24.9%)
	1	88 (14.4%)	47 (8.1%)	135 (11.4%)
	2	48 (7.9%)	27 (4.7%)	75 (6.3%)
	3	22 (3.6%)	22 (3.8%)	44 (3.7%)
	4	1 (0.2%)	41 (7.1%)	42 (3.5%)
体重減少	- Any Grade -	55 (9.0%)	30 (5.2%)	85 (7.2%)
	1	38 (6.2%)	25 (4.3%)	63 (5.3%)
	2	17 (2.8%)	5 (0.9%)	22 (1.9%)
好中球数減少	- Any Grade -	2 (0.3%)	55 (9.5%)	57 (4.8%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	1 (0.2%)	12 (2.1%)	13 (1.1%)
	4	0	40 (6.9%)	40 (3.4%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	38 (6.2%)	12 (2.1%)	50 (4.2%)
	1	22 (3.6%)	9 (1.6%)	31 (2.6%)
	2	11 (1.8%)	1 (0.2%)	12 (1.0%)
	3	5 (0.8%)	2 (0.3%)	7 (0.6%)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	35 (5.7%)	14 (2.4%)	49 (4.1%)
	1	22 (3.6%)	12 (2.1%)	34 (2.9%)
	2	7 (1.1%)	0	7 (0.6%)
	3	6 (1.0%)	2 (0.3%)	8 (0.7%)
血中クレアチニン増加	- Any Grade -	23 (3.8%)	11 (1.9%)	34 (2.9%)
	1	17 (2.8%)	8 (1.4%)	25 (2.1%)
	2	5 (0.8%)	3 (0.5%)	8 (0.7%)
	3	1 (0.2%)	0	1 (<0.1%)
白血球数減少	- Any Grade -	5 (0.8%)	29 (5.0%)	34 (2.9%)
	1	4 (0.7%)	2 (0.3%)	6 (0.5%)
	2	1 (0.2%)	6 (1.0%)	7 (0.6%)
	3	0	14 (2.4%)	14 (1.2%)
	4	0	7 (1.2%)	7 (0.6%)
血小板数減少	- Any Grade -	10 (1.6%)	6 (1.0%)	16 (1.3%)
	1	7 (1.1%)	6 (1.0%)	13 (1.1%)
	2	3 (0.5%)	0	3 (0.3%)
血中アルカリホスファターゼ増加	- Any Grade -	12 (2.0%)	4 (0.7%)	16 (1.3%)
	1	7 (1.1%)	0	7 (0.6%)
	2	3 (0.5%)	4 (0.7%)	7 (0.6%)
	3	2 (0.3%)	0	2 (0.2%)
Ｃ－反応性蛋白増加	- Any Grade -	8 (1.3%)	3 (0.5%)	11 (0.9%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	6 (1.0%)	2 (0.3%)	8 (0.7%)
血中乳酸脱水素酵素増加	- Any Grade -	6 (1.0%)	5 (0.9%)	11 (0.9%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
体重増加	- Any Grade -	5 (0.8%)	6 (1.0%)	11 (0.9%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	4 (0.7%)	6 (0.5%)
	3	1 (0.2%)	0	1 (<0.1%)
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	7 (1.1%)	2 (0.3%)	9 (0.8%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	3 (0.5%)	1 (0.2%)	4 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
血中ビリルビン増加	- Any Grade -	7 (1.1%)	2 (0.3%)	9 (0.8%)
	1	2 (0.3%)	0	2 (0.2%)
	2	4 (0.7%)	0	4 (0.3%)
	3	0	2 (0.3%)	2 (0.2%)
	4	1 (0.2%)	0	1 (<0.1%)
リンパ球数減少	- Any Grade -	5 (0.8%)	2 (0.3%)	7 (0.6%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	4 (0.7%)	0	4 (0.3%)
血中甲状腺刺激ホルモン増加	- Any Grade -	6 (1.0%)	1 (0.2%)	7 (0.6%)
	1	5 (0.8%)	1 (0.2%)	6 (0.5%)
	2	1 (0.2%)	0	1 (<0.1%)
総蛋白減少	- Any Grade -	4 (0.7%)	3 (0.5%)	7 (0.6%)
	1	3 (0.5%)	2 (0.3%)	5 (0.4%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
ヘモグロビン減少	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
好中球数増加	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	1	0	4 (0.7%)	4 (0.3%)
ヘマトクリット減少	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
血中鉄減少	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)
血中尿素増加	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
呼吸音異常	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
白血球数増加	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
トランスアミナーゼ上昇	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	3	2 (0.3%)	0	2 (0.2%)
トロポニンＩ増加	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血小板数増加	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
血中アルカリホスファターゼ	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
血中アルブミン減少	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血中カリウム増加	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
血中ブドウ糖増加	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
血中マグネシウム減少	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)

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Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
国際標準比増加	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
心電図ＱＴ延長	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
尿中ブドウ糖	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
Ｃ－反応性蛋白	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
ＥＣＯＧパフォーマンスステータス悪化	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
ＱＲＳ軸異常	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
アラニンアミノトランスフェラーゼ減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝酵素上昇	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
胸部コンピュータ断層撮影異常	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血清フェリチン増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血中カリウム減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中クレアチン増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血中クロール減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中コレステロール増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中ナトリウム減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中リン減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血中リン増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中甲状腺刺激ホルモン減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血中重炭酸塩減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中尿酸増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中尿素減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
甲状腺機能検査異常	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
酸素飽和度低下	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
心電図Ｔ波逆転	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
心拍数増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
腎クレアチニン・クリアランス減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
赤血球数減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
体温上昇	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
単球数増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
尿中ブドウ糖陽性	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
精神障害				
- Overall -	- Any Grade -	111 (18.2%)	74 (12.8%)	185 (15.6%)
	1	66 (10.8%)	41 (7.1%)	107 (9.0%)
	2	42 (6.9%)	27 (4.7%)	69 (5.8%)
	3	3 (0.5%)	6 (1.0%)	9 (0.8%)
不眠症	- Any Grade -	49 (8.0%)	42 (7.3%)	91 (7.7%)
	1	30 (4.9%)	28 (4.8%)	58 (4.9%)
	2	18 (3.0%)	11 (1.9%)	29 (2.4%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
不安	- Any Grade -	26 (4.3%)	14 (2.4%)	40 (3.4%)
	1	17 (2.8%)	7 (1.2%)	24 (2.0%)
	2	8 (1.3%)	7 (1.2%)	15 (1.3%)
	3	1 (0.2%)	0	1 (<0.1%)
うつ病	- Any Grade -	31 (5.1%)	6 (1.0%)	37 (3.1%)
	1	16 (2.6%)	3 (0.5%)	19 (1.6%)
	2	15 (2.5%)	3 (0.5%)	18 (1.5%)
錯乱状態	- Any Grade -	5 (0.8%)	9 (1.6%)	14 (1.2%)
	1	4 (0.7%)	3 (0.5%)	7 (0.6%)
	2	0	3 (0.5%)	3 (0.3%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
睡眠障害	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
譫妄	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
激越	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
易刺激性	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
神経過敏	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
精神状態変化	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
落ち着きのなさ	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
リビドー減退	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
悪夢	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
気分変化	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
緊張	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
幻覚	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
幻視	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
失見当識	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
適応障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血管障害				
- Overall -	- Any Grade -	63 (10.3%)	69 (11.9%)	132 (11.1%)
	1	21 (3.4%)	23 (4.0%)	44 (3.7%)
	2	32 (5.3%)	36 (6.2%)	68 (5.7%)
	3	8 (1.3%)	10 (1.7%)	18 (1.5%)
	4	2 (0.3%)	0	2 (0.2%)
低血圧	- Any Grade -	17 (2.8%)	23 (4.0%)	40 (3.4%)
	1	6 (1.0%)	7 (1.2%)	13 (1.1%)
	2	9 (1.5%)	13 (2.2%)	22 (1.9%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
	4	1 (0.2%)	0	1 (<0.1%)
高血圧	- Any Grade -	15 (2.5%)	13 (2.2%)	28 (2.4%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	7 (1.1%)	10 (1.7%)	17 (1.4%)
	3	5 (0.8%)	2 (0.3%)	7 (0.6%)
潮紅	- Any Grade -	6 (1.0%)	14 (2.4%)	20 (1.7%)
	1	5 (0.8%)	9 (1.6%)	14 (1.2%)
	2	0	5 (0.9%)	5 (0.4%)
	3	1 (0.2%)	0	1 (<0.1%)
ほてり	- Any Grade -	4 (0.7%)	5 (0.9%)	9 (0.8%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
深部静脈血栓症	- Any Grade -	6 (1.0%)	3 (0.5%)	9 (0.8%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	4 (0.7%)	1 (0.2%)	5 (0.4%)
	3	0	2 (0.3%)	2 (0.2%)
	4	1 (0.2%)	0	1 (<0.1%)
血腫	- Any Grade -	4 (0.7%)	2 (0.3%)	6 (0.5%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
	3	0	1 (0.2%)	1 (<0.1%)
上大静脈症候群	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	2	3 (0.5%)	0	3 (0.3%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
静脈炎	- Any Grade -	0	5 (0.9%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	4 (0.7%)	4 (0.3%)

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AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
塞栓症	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
リンパ浮腫	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
起立性低血圧	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
血栓症	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
頚静脈血栓症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
高血圧クリーゼ	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血管痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血行動態不安定	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血栓性静脈炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
四肢静脈血栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
静脈血栓症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
静脈瘤	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
大静脈血栓症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
大動脈硬化症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
本態性高血圧症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
末梢冷感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
毛細血管漏出症候群	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼障害				
- Overall -	- Any Grade -	41 (6.7%)	48 (8.3%)	89 (7.5%)
	1	32 (5.3%)	31 (5.4%)	63 (5.3%)
	2	7 (1.1%)	17 (2.9%)	24 (2.0%)
	3	2 (0.3%)	0	2 (0.2%)
流涙増加	- Any Grade -	6 (1.0%)	33 (5.7%)	39 (3.3%)
	1	5 (0.8%)	22 (3.8%)	27 (2.3%)
	2	1 (0.2%)	11 (1.9%)	12 (1.0%)
霧視	- Any Grade -	10 (1.6%)	5 (0.9%)	15 (1.3%)
	1	9 (1.5%)	3 (0.5%)	12 (1.0%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
眼乾燥	- Any Grade -	6 (1.0%)	1 (0.2%)	7 (0.6%)
	1	6 (1.0%)	1 (0.2%)	7 (0.6%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
眼窩周囲浮腫	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
眼球浮腫	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
視力低下	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
白内障	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	2 (0.3%)	0	2 (0.2%)
眼そう痒症	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
アレルギー性結膜炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
眼刺激	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼痛	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼部腫脹	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
硝子体浮遊物	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
複視	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
ぶどう膜炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
黄斑変性	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼の炎症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
眼の障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼球突出症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
眼充血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
眼瞼下垂	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
眼瞼紅斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
眼瞼浮腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
屈折障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
結膜出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
後天性涙道狭窄	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
光視症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
視神経乳頭浮腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
視力障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
内分泌性眼症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
不等像視	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
片側失明	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
網膜症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
網膜静脈閉塞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
夜盲	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
羞明	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
心臓障害				
- Overall -	- Any Grade -	42 (6.9%)	41 (7.1%)	83 (7.0%)
	1	15 (2.5%)	19 (3.3%)	34 (2.9%)
	2	14 (2.3%)	11 (1.9%)	25 (2.1%)
	3	10 (1.6%)	9 (1.6%)	19 (1.6%)
	4	2 (0.3%)	2 (0.3%)	4 (0.3%)
	5	1 (0.2%)	0	1 (<0.1%)
心房細動	- Any Grade -	10 (1.6%)	9 (1.6%)	19 (1.6%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	7 (1.1%)	5 (0.9%)	12 (1.0%)
	3	2 (0.3%)	4 (0.7%)	6 (0.5%)
頻脈	- Any Grade -	10 (1.6%)	7 (1.2%)	17 (1.4%)
	1	4 (0.7%)	5 (0.9%)	9 (0.8%)
	2	5 (0.8%)	2 (0.3%)	7 (0.6%)
	3	1 (0.2%)	0	1 (<0.1%)
洞性頻脈	- Any Grade -	3 (0.5%)	9 (1.6%)	12 (1.0%)
	1	1 (0.2%)	6 (1.0%)	7 (0.6%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
心嚢液貯留	- Any Grade -	6 (1.0%)	4 (0.7%)	10 (0.8%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	2 (0.3%)	0	2 (0.2%)
動悸	- Any Grade -	4 (0.7%)	4 (0.7%)	8 (0.7%)
	1	4 (0.7%)	4 (0.7%)	8 (0.7%)
不整脈	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
うっ血性心不全	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
徐脈	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
急性心筋梗塞	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
狭心症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
上室性頻脈	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)
心タンポナーデ	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
心筋梗塞	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	3	2 (0.3%)	0	2 (0.2%)
心膜炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
ストレス心筋症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
拡張機能障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
左室機能不全	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
徐脈性不整脈	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
心筋虚血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	5	1 (0.2%)	0	1 (<0.1%)
心室性期外収縮	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
心停止	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
心房粗動	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
第一度房室ブロック	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
発作性頻脈	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腎および尿路障害				
- Overall -	- Any Grade -	45 (7.4%)	34 (5.9%)	79 (6.7%)
	1	30 (4.9%)	20 (3.5%)	50 (4.2%)
	2	11 (1.8%)	9 (1.6%)	20 (1.7%)
	3	3 (0.5%)	4 (0.7%)	7 (0.6%)
	4	0	1 (0.2%)	1 (<0.1%)
	5	1 (0.2%)	0	1 (<0.1%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
排尿困難	- Any Grade -	11 (1.8%)	6 (1.0%)	17 (1.4%)
	1	9 (1.5%)	4 (0.7%)	13 (1.1%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
急性腎障害	- Any Grade -	6 (1.0%)	7 (1.2%)	13 (1.1%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
血尿	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	4 (0.7%)	4 (0.7%)	8 (0.7%)
	3	1 (0.2%)	0	1 (<0.1%)
頻尿	- Any Grade -	6 (1.0%)	3 (0.5%)	9 (0.8%)
	1	6 (1.0%)	3 (0.5%)	9 (0.8%)
尿失禁	- Any Grade -	3 (0.5%)	3 (0.5%)	6 (0.5%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
蛋白尿	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
尿閉	- Any Grade -	0	5 (0.9%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	4 (0.7%)	4 (0.3%)
腎不全	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
	5	1 (0.2%)	0	1 (<0.1%)
尿意切迫	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	4 (0.7%)	0	4 (0.3%)
失禁	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
尿路痛	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
慢性腎臓病	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
ヘノッホ・シェーンライン紫斑病性腎炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
ヘモグロビン尿	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
急性腎前性腎不全	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
高窒素血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
神経因性膀胱	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腎結石症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腎仙痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腎尿細管障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
腎嚢胞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
水腎症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
切迫性尿失禁	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
多尿	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
尿管結石症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
尿道痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
非感染性膀胱炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
傷害、中毒および処置合併症				
- Overall -	- Any Grade -	40 (6.6%)	31 (5.4%)	71 (6.0%)
	1	18 (3.0%)	9 (1.6%)	27 (2.3%)
	2	13 (2.1%)	15 (2.6%)	28 (2.4%)
	3	8 (1.3%)	7 (1.2%)	15 (1.3%)
	4	1 (0.2%)	0	1 (<0.1%)
転倒	- Any Grade -	9 (1.5%)	9 (1.6%)	18 (1.5%)
	1	4 (0.7%)	4 (0.7%)	8 (0.7%)
	2	4 (0.7%)	5 (0.9%)	9 (0.8%)
	3	1 (0.2%)	0	1 (<0.1%)
注入に伴う反応	- Any Grade -	5 (0.8%)	6 (1.0%)	11 (0.9%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	5 (0.9%)	8 (0.7%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
挫傷	- Any Grade -	4 (0.7%)	2 (0.3%)	6 (0.5%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
股関節部骨折	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	3	2 (0.3%)	0	2 (0.2%)
	4	1 (0.2%)	0	1 (<0.1%)
上腕骨骨折	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
脊椎圧迫骨折	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
創傷	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
胸部損傷	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
四肢損傷	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
節足動物咬傷	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
肉離れ	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)

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Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
放射線性肺臓炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
裂傷	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
リコール現象	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
過量投与	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
外傷性血腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
胸椎骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋損傷	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腰椎骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
擦過傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
四肢骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
歯牙破折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
処置による悪心	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
処置による疼痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
処置後血尿	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
上肢骨折	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
静脈損傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
造影剤反応	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
足骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
体内異物	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
第３度熱傷	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
皮膚擦過傷	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
膝蓋骨骨折	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
放射線皮膚損傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
肋骨骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
橈骨骨折	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
靱帯断裂	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
靱帯捻挫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
耳および迷路障害				
- Overall -	- Any Grade -	22 (3.6%)	20 (3.5%)	42 (3.5%)
	1	17 (2.8%)	11 (1.9%)	28 (2.4%)
	2	5 (0.8%)	9 (1.6%)	14 (1.2%)
回転性めまい	- Any Grade -	7 (1.1%)	7 (1.2%)	14 (1.2%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
耳痛	- Any Grade -	4 (0.7%)	5 (0.9%)	9 (0.8%)
	1	3 (0.5%)	3 (0.5%)	6 (0.5%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
難聴	- Any Grade -	4 (0.7%)	2 (0.3%)	6 (0.5%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
耳鳴	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
耳不快感	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
聴力低下	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
頭位性回転性めまい	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
外耳痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
耳垢栓塞	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
耳閉	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
乗物酔い	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
内分泌障害				
- Overall -	- Any Grade -	28 (4.6%)	1 (0.2%)	29 (2.4%)
	1	8 (1.3%)	0	8 (0.7%)
	2	20 (3.3%)	1 (0.2%)	21 (1.8%)
甲状腺機能低下症	- Any Grade -	18 (3.0%)	1 (0.2%)	19 (1.6%)
	1	4 (0.7%)	0	4 (0.3%)
	2	14 (2.3%)	1 (0.2%)	15 (1.3%)
甲状腺機能亢進症	- Any Grade -	7 (1.1%)	0	7 (0.6%)
	1	3 (0.5%)	0	3 (0.3%)
	2	4 (0.7%)	0	4 (0.3%)
副腎機能不全	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
下垂体炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
原発性副腎機能不全	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
甲状腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
内分泌障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
生殖系および乳房障害				
- Overall -	- Any Grade -	20 (3.3%)	8 (1.4%)	28 (2.4%)
	1	14 (2.3%)	4 (0.7%)	18 (1.5%)
	2	6 (1.0%)	4 (0.7%)	10 (0.8%)
骨盤痛	- Any Grade -	5 (0.8%)	1 (0.2%)	6 (0.5%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
女性化乳房	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
勃起不全	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
乳房潰瘍形成	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
良性前立腺肥大症	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
腟出血	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
会陰痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
外陰腟灼熱感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
外陰腟痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
外陰腟不快感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
精巣痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
前立腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
前立腺腫大	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
乳頭痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
乳房痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
乳房浮腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
不正子宮出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
閉経後出血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
免疫系障害				
- Overall -	- Any Grade -	10 (1.6%)	16 (2.8%)	26 (2.2%)
	1	5 (0.8%)	2 (0.3%)	7 (0.6%)
	2	4 (0.7%)	11 (1.9%)	15 (1.3%)
	3	0	3 (0.5%)	3 (0.3%)
	4	1 (0.2%)	0	1 (<0.1%)
過敏症	- Any Grade -	6 (1.0%)	11 (1.9%)	17 (1.4%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	3 (0.5%)	9 (1.6%)	12 (1.0%)
	4	1 (0.2%)	0	1 (<0.1%)
薬物過敏症	- Any Grade -	3 (0.5%)	3 (0.5%)	6 (0.5%)
	1	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)
アナフィラキシー反応	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
ヨウ素アレルギー	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
植物アレルギー	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝胆道系障害				
- Overall -	- Any Grade -	18 (3.0%)	7 (1.2%)	25 (2.1%)
	1	11 (1.8%)	2 (0.3%)	13 (1.1%)
	2	0	2 (0.3%)	2 (0.2%)
	3	4 (0.7%)	2 (0.3%)	6 (0.5%)
	4	3 (0.5%)	1 (0.2%)	4 (0.3%)
肝機能異常	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
肝炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	4	2 (0.3%)	0	2 (0.2%)
肝臓痛	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
急性胆嚢炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
胆石症	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
肝細胞損傷	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝嚢胞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝病変	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
急性肝炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

Percentages are based on N in the column headings.
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To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
07DEC2016 18:26

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
急性肝不全	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
高ビリルビン血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
脂肪肝	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
胆汁うっ滞	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
胆汁うっ滞性黄疸	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
胆嚢炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
胆嚢浮腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
慢性胆嚢炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
薬物性肝障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
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 -	19 (3.1%)	4 (0.7%)	23 (1.9%)
	1	8 (1.3%)	2 (0.3%)	10 (0.8%)
	2	10 (1.6%)	0	10 (0.8%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
腫瘍疼痛	- Any Grade -	6 (1.0%)	1 (0.2%)	7 (0.6%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	5 (0.8%)	0	5 (0.4%)
癌疼痛	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
基底細胞癌	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
結腸癌	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
脂肪腫	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
悪性新生物	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
骨転移	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
脂漏性角化症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腫瘍随伴症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
前立腺癌	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
外科および内科処置				
- Overall -	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
ギプス包帯使用	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
中心静脈カテーテル留置	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
抜歯	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
副鼻腔手術	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
縫合	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
製品の問題				
- Overall -	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
医療機器内血栓	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
先天性、家族性および遺伝性障害				
- Overall -	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
表皮融解	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04_GO28915_SE.out
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［5.3.5.1-3 aet04_GO28915_SE を再掲］

表 2.7.6.2.1.3-2 すべての副作用（OAK 試験）

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
- Any adverse events -	- Any Grade -	390 (64.0%)	496 (85.8%)	886 (74.6%)
	1	144 (23.6%)	73 (12.6%)	217 (18.3%)
	2	156 (25.6%)	175 (30.3%)	331 (27.9%)
	3	77 (12.6%)	141 (24.4%)	218 (18.4%)
	4	13 (2.1%)	106 (18.3%)	119 (10.0%)
	5	0	1 (0.2%)	1 (<0.1%)
一般・全身障害および投与部位の状態				
- Overall -	- Any Grade -	202 (33.2%)	331 (57.3%)	533 (44.9%)
	1	117 (19.2%)	128 (22.1%)	245 (20.6%)
	2	70 (11.5%)	166 (28.7%)	236 (19.9%)
	3	14 (2.3%)	36 (6.2%)	50 (4.2%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
疲労	- Any Grade -	87 (14.3%)	177 (30.6%)	264 (22.2%)
	1	49 (8.0%)	72 (12.5%)	121 (10.2%)
	2	30 (4.9%)	85 (14.7%)	115 (9.7%)
	3	8 (1.3%)	20 (3.5%)	28 (2.4%)
無力症	- Any Grade -	51 (8.4%)	96 (16.6%)	147 (12.4%)
	1	24 (3.9%)	31 (5.4%)	55 (4.6%)
	2	25 (4.1%)	55 (9.5%)	80 (6.7%)
	3	2 (0.3%)	10 (1.7%)	12 (1.0%)
発熱	- Any Grade -	49 (8.0%)	40 (6.9%)	89 (7.5%)
	1	39 (6.4%)	32 (5.5%)	71 (6.0%)
	2	10 (1.6%)	7 (1.2%)	17 (1.4%)
	4	0	1 (0.2%)	1 (<0.1%)
末梢性浮腫	- Any Grade -	15 (2.5%)	57 (9.9%)	72 (6.1%)
	1	11 (1.8%)	38 (6.6%)	49 (4.1%)
	2	4 (0.7%)	16 (2.8%)	20 (1.7%)
	3	0	3 (0.5%)	3 (0.3%)
粘膜の炎症	- Any Grade -	7 (1.1%)	39 (6.7%)	46 (3.9%)
	1	6 (1.0%)	21 (3.6%)	27 (2.3%)
	2	1 (0.2%)	15 (2.6%)	16 (1.3%)
	3	0	3 (0.5%)	3 (0.3%)
倦怠感	- Any Grade -	12 (2.0%)	27 (4.7%)	39 (3.3%)
	1	11 (1.8%)	21 (3.6%)	32 (2.7%)
	2	1 (0.2%)	6 (1.0%)	7 (0.6%)
インフルエンザ様疾患	- Any Grade -	16 (2.6%)	7 (1.2%)	23 (1.9%)
	1	8 (1.3%)	6 (1.0%)	14 (1.2%)
	2	8 (1.3%)	1 (0.2%)	9 (0.8%)
悪寒	- Any Grade -	13 (2.1%)	5 (0.9%)	18 (1.5%)
	1	10 (1.6%)	5 (0.9%)	15 (1.3%)
	2	3 (0.5%)	0	3 (0.3%)
浮腫	- Any Grade -	3 (0.5%)	11 (1.9%)	14 (1.2%)
	1	3 (0.5%)	6 (1.0%)	9 (0.8%)
	2	0	5 (0.9%)	5 (0.4%)
顔面浮腫	- Any Grade -	1 (0.2%)	9 (1.6%)	10 (0.8%)
	1	1 (0.2%)	8 (1.4%)	9 (0.8%)
	2	0	1 (0.2%)	1 (<0.1%)
疼痛	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
07DEC2016 18:29

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
胸部不快感	- Any Grade -	1 (0.2%)	5 (0.9%)	6 (0.5%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
胸痛	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
熱感	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
全身健康状態低下	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
全身性浮腫	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	2	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
限局性浮腫	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
腫瘤	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
注入部位血管外漏出	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
末梢腫脹	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
異常高熱	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
異物感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
医薬品副作用	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
乾燥症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
局所腫脹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
腫脹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
全身性炎症反応症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
注射部位反応	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
注入部位血栓	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
注入部位発疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
低体温	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
非心臓性胸痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
胃腸障害				
- Overall -	- Any Grade -	136 (22.3%)	254 (43.9%)	390 (32.9%)
	1	100 (16.4%)	137 (23.7%)	237 (20.0%)
	2	30 (4.9%)	90 (15.6%)	120 (10.1%)
	3	6 (1.0%)	26 (4.5%)	32 (2.7%)
	4	0	1 (0.2%)	1 (<0.1%)
悪心	- Any Grade -	53 (8.7%)	112 (19.4%)	165 (13.9%)
	1	41 (6.7%)	74 (12.8%)	115 (9.7%)
	2	10 (1.6%)	36 (6.2%)	46 (3.9%)
	3	2 (0.3%)	2 (0.3%)	4 (0.3%)
下痢	- Any Grade -	47 (7.7%)	109 (18.9%)	156 (13.1%)
	1	35 (5.7%)	69 (11.9%)	104 (8.8%)
	2	9 (1.5%)	31 (5.4%)	40 (3.4%)
	3	3 (0.5%)	9 (1.6%)	12 (1.0%)
便秘	- Any Grade -	28 (4.6%)	46 (8.0%)	74 (6.2%)
	1	23 (3.8%)	36 (6.2%)	59 (5.0%)
	2	5 (0.8%)	10 (1.7%)	15 (1.3%)
嘔吐	- Any Grade -	23 (3.8%)	50 (8.7%)	73 (6.1%)
	1	17 (2.8%)	36 (6.2%)	53 (4.5%)
	2	6 (1.0%)	11 (1.9%)	17 (1.4%)
	3	0	3 (0.5%)	3 (0.3%)
口内炎	- Any Grade -	13 (2.1%)	59 (10.2%)	72 (6.1%)
	1	9 (1.5%)	32 (5.5%)	41 (3.5%)
	2	4 (0.7%)	17 (2.9%)	21 (1.8%)
	3	0	10 (1.7%)	10 (0.8%)
腹痛	- Any Grade -	7 (1.1%)	12 (2.1%)	19 (1.6%)
	1	3 (0.5%)	7 (1.2%)	10 (0.8%)
	2	4 (0.7%)	5 (0.9%)	9 (0.8%)
口内乾燥	- Any Grade -	8 (1.3%)	6 (1.0%)	14 (1.2%)
	1	8 (1.3%)	6 (1.0%)	14 (1.2%)
上腹部痛	- Any Grade -	4 (0.7%)	8 (1.4%)	12 (1.0%)
	1	2 (0.3%)	5 (0.9%)	7 (0.6%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
口腔内痛	- Any Grade -	0	8 (1.4%)	8 (0.7%)
	1	0	7 (1.2%)	7 (0.6%)
	2	0	1 (0.2%)	1 (<0.1%)
消化不良	- Any Grade -	3 (0.5%)	5 (0.9%)	8 (0.7%)
	1	2 (0.3%)	4 (0.7%)	6 (0.5%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
胃食道逆流性疾患	- Any Grade -	0	6 (1.0%)	6 (0.5%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	2 (0.3%)	2 (0.2%)
口腔内潰瘍形成	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	4 (0.7%)	5 (0.4%)
腹部膨満	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
嚥下障害	- Any Grade -	0	5 (0.9%)	5 (0.4%)
	1	0	2 (0.3%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
大腸炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)
胃炎	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
痔核	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
腹部不快感	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
イレウス	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
アフタ性潰瘍	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
メレナ	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
過敏性腸症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
鼓腸	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
口の錯感覚	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇のひび割れ	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
口唇乾燥	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
口唇腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
歯肉痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
十二指腸穿孔	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
小腸炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
上部消化管出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
食道炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
食道静脈瘤出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
舌腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
舌苔	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
舌浮腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
腸閉塞	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
直腸出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
粘液便	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
非感染性唾液腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
嚥下痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
肛門の炎症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚および皮下組織障害				
- Overall -	- Any Grade -	119 (19.5%)	249 (43.1%)	368 (31.0%)
	1	84 (13.8%)	122 (21.1%)	206 (17.4%)
	2	27 (4.4%)	123 (21.3%)	150 (12.6%)
	3	8 (1.3%)	4 (0.7%)	12 (1.0%)
脱毛症	- Any Grade -	3 (0.5%)	198 (34.3%)	201 (16.9%)
	1	2 (0.3%)	97 (16.8%)	99 (8.3%)
	2	1 (0.2%)	100 (17.3%)	101 (8.5%)
	3	0	1 (0.2%)	1 (<0.1%)
発疹	- Any Grade -	42 (6.9%)	37 (6.4%)	79 (6.7%)
	1	33 (5.4%)	28 (4.8%)	61 (5.1%)
	2	7 (1.1%)	9 (1.6%)	16 (1.3%)
	3	2 (0.3%)	0	2 (0.2%)
そう痒症	- Any Grade -	38 (6.2%)	14 (2.4%)	52 (4.4%)
	1	28 (4.6%)	11 (1.9%)	39 (3.3%)
	2	8 (1.3%)	3 (0.5%)	11 (0.9%)
	3	2 (0.3%)	0	2 (0.2%)
皮膚乾燥	- Any Grade -	18 (3.0%)	25 (4.3%)	43 (3.6%)
	1	17 (2.8%)	23 (4.0%)	40 (3.4%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
爪の障害	- Any Grade -	0	27 (4.7%)	27 (2.3%)
	1	0	22 (3.8%)	22 (1.9%)
	2	0	4 (0.7%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
爪変色	- Any Grade -	0	26 (4.5%)	26 (2.2%)
	1	0	25 (4.3%)	25 (2.1%)
	2	0	1 (0.2%)	1 (<0.1%)
爪甲脱落症	- Any Grade -	0	13 (2.2%)	13 (1.1%)
	1	0	7 (1.2%)	7 (0.6%)
	2	0	6 (1.0%)	6 (0.5%)
斑状丘疹状皮疹	- Any Grade -	9 (1.5%)	3 (0.5%)	12 (1.0%)
	1	5 (0.8%)	2 (0.3%)	7 (0.6%)
	2	3 (0.5%)	1 (0.2%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
紅斑	- Any Grade -	4 (0.7%)	7 (1.2%)	11 (0.9%)
	1	2 (0.3%)	5 (0.9%)	7 (0.6%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
ざ瘡様皮膚炎	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
手掌・足底発赤知覚不全症候群	- Any Grade -	0	8 (1.4%)	8 (0.7%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	3 (0.5%)	3 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
爪毒性	- Any Grade -	0	7 (1.2%)	7 (0.6%)
	1	0	4 (0.7%)	4 (0.3%)
	2	0	3 (0.5%)	3 (0.3%)
蕁麻疹	- Any Grade -	4 (0.7%)	2 (0.3%)	6 (0.5%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
そう痒性皮疹	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
乾癬	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)
湿疹	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
皮膚炎	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
皮膚色素過剰	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
寝汗	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
多汗症	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚剥脱	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
紅斑性皮疹	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
全身性そう痒症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
爪ジストロフィー	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
爪甲離床症	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	3 (0.5%)	3 (0.3%)
爪線状隆起	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	3 (0.5%)	3 (0.3%)
ざ瘡	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
水疱性皮膚炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
全身性皮疹	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
多形紅斑	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)

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事象名：MedDRA ver. 19.0
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
爪痛	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
爪破損	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
皮膚硬結	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
皮膚毒性	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
皮膚反応	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
過角化	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
顔面腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
丘疹性皮疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血管浮腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
光線角化症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
紅色症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
手掌紅斑	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
色素沈着障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
尋常性白斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
接触性皮膚炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
爪床出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
爪肥厚	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
点状出血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
斑	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
皮脂欠乏性湿疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
皮膚萎縮	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
皮膚亀裂	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚刺激	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚粘膜発疹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
皮膚嚢腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
皮膚変色	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
薬疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
類天疱瘡	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
嵌入爪	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
扁平苔癬	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
痒疹	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
睫毛眉毛脱落症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血液およびリンパ系障害				
- Overall -	- Any Grade -	42 (6.9%)	221 (38.2%)	263 (22.2%)
	1	14 (2.3%)	24 (4.2%)	38 (3.2%)
	2	19 (3.1%)	52 (9.0%)	71 (6.0%)
	3	8 (1.3%)	84 (14.5%)	92 (7.8%)
	4	1 (0.2%)	61 (10.6%)	62 (5.2%)
貧血	- Any Grade -	24 (3.9%)	114 (19.7%)	138 (11.6%)
	1	10 (1.6%)	31 (5.4%)	41 (3.5%)
	2	11 (1.8%)	58 (10.0%)	69 (5.8%)
	3	3 (0.5%)	25 (4.3%)	28 (2.4%)
好中球減少症	- Any Grade -	7 (1.1%)	85 (14.7%)	92 (7.8%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	2 (0.3%)	10 (1.7%)	12 (1.0%)
	3	2 (0.3%)	24 (4.2%)	26 (2.2%)
	4	1 (0.2%)	48 (8.3%)	49 (4.1%)
発熱性好中球減少症	- Any Grade -	0	61 (10.6%)	61 (5.1%)
	3	0	49 (8.5%)	49 (4.1%)
	4	0	12 (2.1%)	12 (1.0%)
白血球減少症	- Any Grade -	4 (0.7%)	23 (4.0%)	27 (2.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	3 (0.5%)	6 (0.5%)
	3	0	15 (2.6%)	15 (1.3%)
	4	0	5 (0.9%)	5 (0.4%)
血小板減少症	- Any Grade -	7 (1.1%)	8 (1.4%)	15 (1.3%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
リンパ球減少症	- Any Grade -	3 (0.5%)	4 (0.7%)	7 (0.6%)
	1	0	2 (0.3%)	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
リンパ節症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	2 (0.3%)	0	2 (0.2%)

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Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
白血球増加症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
汎血球減少症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	3	0	2 (0.3%)	2 (0.2%)
リンパ節炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血小板増加症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
鉄欠乏性貧血	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
播種性血管内凝固	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
無顆粒球症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
神経系障害				
- Overall -	- Any Grade -	63 (10.3%)	192 (33.2%)	255 (21.5%)
	1	46 (7.6%)	113 (19.6%)	159 (13.4%)
	2	8 (1.3%)	64 (11.1%)	72 (6.1%)
	3	9 (1.5%)	15 (2.6%)	24 (2.0%)
味覚異常	- Any Grade -	11 (1.8%)	56 (9.7%)	67 (5.6%)
	1	7 (1.1%)	46 (8.0%)	53 (4.5%)
	2	4 (0.7%)	10 (1.7%)	14 (1.2%)
末梢性ニューロパチー	- Any Grade -	6 (1.0%)	58 (10.0%)	64 (5.4%)
	1	3 (0.5%)	29 (5.0%)	32 (2.7%)
	2	3 (0.5%)	23 (4.0%)	26 (2.2%)
	3	0	6 (1.0%)	6 (0.5%)
錯感覚	- Any Grade -	6 (1.0%)	41 (7.1%)	47 (4.0%)
	1	6 (1.0%)	26 (4.5%)	32 (2.7%)
	2	0	13 (2.2%)	13 (1.1%)
	3	0	2 (0.3%)	2 (0.2%)
末梢性感覚ニューロパチー	- Any Grade -	1 (0.2%)	41 (7.1%)	42 (3.5%)
	1	1 (0.2%)	26 (4.5%)	27 (2.3%)
	2	0	10 (1.7%)	10 (0.8%)
	3	0	5 (0.9%)	5 (0.4%)
頭痛	- Any Grade -	18 (3.0%)	21 (3.6%)	39 (3.3%)
	1	15 (2.5%)	17 (2.9%)	32 (2.7%)
	2	1 (0.2%)	4 (0.7%)	5 (0.4%)
	3	2 (0.3%)	0	2 (0.2%)
浮動性めまい	- Any Grade -	10 (1.6%)	14 (2.4%)	24 (2.0%)
	1	9 (1.5%)	14 (2.4%)	23 (1.9%)
	3	1 (0.2%)	0	1 (<0.1%)
感覚鈍麻	- Any Grade -	3 (0.5%)	13 (2.2%)	16 (1.3%)
	1	3 (0.5%)	10 (1.7%)	13 (1.1%)
	2	0	3 (0.5%)	3 (0.3%)
ギラン・バレー症候群	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	3	3 (0.5%)	0	3 (0.3%)
異常感覚	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
失神	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	3	0	3 (0.5%)	3 (0.3%)
神経毒性	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	2	0	3 (0.5%)	3 (0.3%)
傾眠	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
多発ニューロパチー	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
認知障害	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
末梢性運動ニューロパチー	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
味覚減退	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
ヘルペス後神経痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
意識レベルの低下	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
温度覚鈍麻	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
過眠症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
記憶障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
筋痙直	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
視神経炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
灼熱感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
振戦	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
知覚過敏	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
不全単麻痺	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
平衡障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
末梢性感覚運動ニューロパチー	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
嗜眠	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
代謝および栄養障害				
- Overall -	- Any Grade -	86 (14.1%)	152 (26.3%)	238 (20.1%)
	1	52 (8.5%)	68 (11.8%)	120 (10.1%)
	2	25 (4.1%)	64 (11.1%)	89 (7.5%)
	3	7 (1.1%)	20 (3.5%)	27 (2.3%)
	4	2 (0.3%)	0	2 (0.2%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
食欲減退	- Any Grade -	52 (8.5%)	116 (20.1%)	168 (14.2%)
	1	35 (5.7%)	57 (9.9%)	92 (7.8%)
	2	17 (2.8%)	50 (8.7%)	67 (5.6%)
	3	0	9 (1.6%)	9 (0.8%)
低アルブミン血症	- Any Grade -	8 (1.3%)	14 (2.4%)	22 (1.9%)
	1	5 (0.8%)	6 (1.0%)	11 (0.9%)
	2	3 (0.5%)	7 (1.2%)	10 (0.8%)
	3	0	1 (0.2%)	1 (<0.1%)
脱水	- Any Grade -	5 (0.8%)	15 (2.6%)	20 (1.7%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	3 (0.5%)	8 (1.4%)	11 (0.9%)
	3	0	6 (1.0%)	6 (0.5%)
低ナトリウム血症	- Any Grade -	13 (2.1%)	6 (1.0%)	19 (1.6%)
	1	8 (1.3%)	3 (0.5%)	11 (0.9%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	5 (0.8%)	2 (0.3%)	7 (0.6%)
低カリウム血症	- Any Grade -	7 (1.1%)	9 (1.6%)	16 (1.3%)
	1	5 (0.8%)	5 (0.9%)	10 (0.8%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
低マグネシウム血症	- Any Grade -	7 (1.1%)	9 (1.6%)	16 (1.3%)
	1	6 (1.0%)	9 (1.6%)	15 (1.3%)
	2	1 (0.2%)	0	1 (<0.1%)
高血糖	- Any Grade -	7 (1.1%)	6 (1.0%)	13 (1.1%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
	4	2 (0.3%)	0	2 (0.2%)
低リン酸血症	- Any Grade -	5 (0.8%)	7 (1.2%)	12 (1.0%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	0	1 (0.2%)	1 (<0.1%)
高カリウム血症	- Any Grade -	4 (0.7%)	4 (0.7%)	8 (0.7%)
	1	3 (0.5%)	3 (0.5%)	6 (0.5%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
低カルシウム血症	- Any Grade -	4 (0.7%)	4 (0.7%)	8 (0.7%)
	1	4 (0.7%)	3 (0.5%)	7 (0.6%)
	2	0	1 (0.2%)	1 (<0.1%)
鉄欠乏	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
１型糖尿病	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
２型糖尿病	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
アルコール不耐性	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
過小食	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
高カルシウム血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
高コレステロール血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
高トリグリセリド血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高ナトリウム血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高マグネシウム血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
高尿酸血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
細胞死	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
体液貯留	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
耐糖能障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
低クロール血症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋骨格系および結合組織障害				
- Overall -	- Any Grade -	73 (12.0%)	150 (26.0%)	223 (18.8%)
	1	40 (6.6%)	85 (14.7%)	125 (10.5%)
	2	27 (4.4%)	60 (10.4%)	87 (7.3%)
	3	5 (0.8%)	5 (0.9%)	10 (0.8%)
	4	1 (0.2%)	0	1 (<0.1%)
筋肉痛	- Any Grade -	21 (3.4%)	81 (14.0%)	102 (8.6%)
	1	15 (2.5%)	44 (7.6%)	59 (5.0%)
	2	5 (0.8%)	34 (5.9%)	39 (3.3%)
	3	1 (0.2%)	3 (0.5%)	4 (0.3%)
関節痛	- Any Grade -	28 (4.6%)	41 (7.1%)	69 (5.8%)
	1	17 (2.8%)	24 (4.2%)	41 (3.5%)
	2	10 (1.6%)	17 (2.9%)	27 (2.3%)
	3	1 (0.2%)	0	1 (<0.1%)
筋骨格痛	- Any Grade -	10 (1.6%)	10 (1.7%)	20 (1.7%)
	1	5 (0.8%)	2 (0.3%)	7 (0.6%)
	2	4 (0.7%)	7 (1.2%)	11 (0.9%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
四肢痛	- Any Grade -	5 (0.8%)	13 (2.2%)	18 (1.5%)
	1	1 (0.2%)	11 (1.9%)	12 (1.0%)
	2	4 (0.7%)	2 (0.3%)	6 (0.5%)
背部痛	- Any Grade -	9 (1.5%)	7 (1.2%)	16 (1.3%)
	1	3 (0.5%)	6 (1.0%)	9 (0.8%)
	2	4 (0.7%)	1 (0.2%)	5 (0.4%)
	3	2 (0.3%)	0	2 (0.2%)
筋力低下	- Any Grade -	3 (0.5%)	11 (1.9%)	14 (1.2%)
	1	1 (0.2%)	5 (0.9%)	6 (0.5%)
	2	2 (0.3%)	6 (1.0%)	8 (0.7%)
筋痙縮	- Any Grade -	4 (0.7%)	7 (1.2%)	11 (0.9%)
	1	3 (0.5%)	7 (1.2%)	10 (0.8%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
骨痛	- Any Grade -	0	7 (1.2%)	7 (0.6%)
	1	0	5 (0.9%)	5 (0.4%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
関節炎	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
筋骨格系胸痛	- Any Grade -	4 (0.7%)	0	4 (0.3%)
	1	4 (0.7%)	0	4 (0.3%)
関節リウマチ	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)
頚部痛	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
関節腫脹	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
筋攣縮	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
ばち状指	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
リウマチ性多発筋痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
横紋筋融解症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
関節可動域低下	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
筋緊張	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋骨格不快感	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
筋肉疲労	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
肩回旋筋腱板症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
姿勢異常	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
脊椎炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
側腹部痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
臨床検査				
- Overall -	- Any Grade -	78 (12.8%)	97 (16.8%)	175 (14.7%)
	1	43 (7.1%)	29 (5.0%)	72 (6.1%)
	2	23 (3.8%)	12 (2.1%)	35 (2.9%)
	3	12 (2.0%)	16 (2.8%)	28 (2.4%)
	4	0	40 (6.9%)	40 (3.4%)
好中球数減少	- Any Grade -	1 (0.2%)	55 (9.5%)	56 (4.7%)
	2	1 (0.2%)	3 (0.5%)	4 (0.3%)
	3	0	12 (2.1%)	12 (1.0%)
	4	0	40 (6.9%)	40 (3.4%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
体重減少	- Any Grade -	26 (4.3%)	20 (3.5%)	46 (3.9%)
	1	17 (2.8%)	18 (3.1%)	35 (2.9%)
	2	9 (1.5%)	2 (0.3%)	11 (0.9%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	24 (3.9%)	6 (1.0%)	30 (2.5%)
	1	15 (2.5%)	6 (1.0%)	21 (1.8%)
	2	6 (1.0%)	0	6 (0.5%)
	3	3 (0.5%)	0	3 (0.3%)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	23 (3.8%)	7 (1.2%)	30 (2.5%)
	1	14 (2.3%)	7 (1.2%)	21 (1.8%)
	2	7 (1.1%)	0	7 (0.6%)
	3	2 (0.3%)	0	2 (0.2%)
白血球数減少	- Any Grade -	4 (0.7%)	26 (4.5%)	30 (2.5%)
	1	3 (0.5%)	2 (0.3%)	5 (0.4%)
	2	1 (0.2%)	4 (0.7%)	5 (0.4%)
	3	0	14 (2.4%)	14 (1.2%)
	4	0	6 (1.0%)	6 (0.5%)
血小板数減少	- Any Grade -	9 (1.5%)	6 (1.0%)	15 (1.3%)
	1	6 (1.0%)	6 (1.0%)	12 (1.0%)
	2	3 (0.5%)	0	3 (0.3%)
血中アルカリホスファターゼ増加	- Any Grade -	8 (1.3%)	1 (0.2%)	9 (0.8%)
	1	6 (1.0%)	0	6 (0.5%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
血中クレアチニン増加	- Any Grade -	4 (0.7%)	5 (0.9%)	9 (0.8%)
	1	4 (0.7%)	3 (0.5%)	7 (0.6%)
	2	0	2 (0.3%)	2 (0.2%)
リンパ球数減少	- Any Grade -	5 (0.8%)	1 (0.2%)	6 (0.5%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	4 (0.7%)	0	4 (0.3%)
血中甲状腺刺激ホルモン増加	- Any Grade -	5 (0.8%)	1 (0.2%)	6 (0.5%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
	2	1 (0.2%)	0	1 (<0.1%)
体重増加	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	2 (0.3%)	3 (0.5%)	5 (0.4%)
総蛋白減少	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
γ－グルタミルトランスフェラーゼ増加	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	3	2 (0.3%)	0	2 (0.2%)
血中ビリルビン増加	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	3 (0.5%)	0	3 (0.3%)
血中乳酸脱水素酵素増加	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
トランスアミナーゼ上昇	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	3	2 (0.3%)	0	2 (0.2%)
ヘモグロビン減少	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血中尿素増加	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
好中球数増加	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)

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AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
国際標準比増加	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
Ｃ－反応性蛋白	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
Ｃ－反応性蛋白増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
トロポニンＩ増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
ヘマトクリット減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
肝酵素上昇	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
胸部コンピュータ断層撮影異常	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中アルカリホスファターゼ	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中アルブミン減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血中カリウム減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中カリウム増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中クロール減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中ナトリウム減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中マグネシウム減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血中リン減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
血中リン増加	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中甲状腺刺激ホルモン減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
血中重炭酸塩減少	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血中尿素減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
甲状腺機能検査異常	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
心拍数増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
赤血球数減少	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
白血球数増加	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
感染症および寄生虫症				
- Overall -	- Any Grade -	43 (7.1%)	98 (17.0%)	141 (11.9%)
	1	12 (2.0%)	30 (5.2%)	42 (3.5%)
	2	20 (3.3%)	41 (7.1%)	61 (5.1%)
	3	9 (1.5%)	21 (3.6%)	30 (2.5%)
	4	2 (0.3%)	5 (0.9%)	7 (0.6%)
	5	0	1 (0.2%)	1 (<0.1%)
肺炎	- Any Grade -	6 (1.0%)	13 (2.2%)	19 (1.6%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	3 (0.5%)	6 (0.5%)
	3	2 (0.3%)	10 (1.7%)	12 (1.0%)
爪囲炎	- Any Grade -	0	11 (1.9%)	11 (0.9%)
	1	0	5 (0.9%)	5 (0.4%)
	2	0	5 (0.9%)	5 (0.4%)
	3	0	1 (0.2%)	1 (<0.1%)
口腔カンジダ症	- Any Grade -	1 (0.2%)	9 (1.6%)	10 (0.8%)
	1	1 (0.2%)	3 (0.5%)	4 (0.3%)
	2	0	6 (1.0%)	6 (0.5%)
鼻咽頭炎	- Any Grade -	6 (1.0%)	4 (0.7%)	10 (0.8%)
	1	4 (0.7%)	4 (0.7%)	8 (0.7%)
	2	2 (0.3%)	0	2 (0.2%)
結膜炎	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	2 (0.3%)	5 (0.9%)	7 (0.6%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
尿路感染	- Any Grade -	2 (0.3%)	6 (1.0%)	8 (0.7%)
	1	0	2 (0.3%)	2 (0.2%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	0	2 (0.3%)	2 (0.2%)
気管支炎	- Any Grade -	2 (0.3%)	5 (0.9%)	7 (0.6%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	4 (0.7%)	6 (0.5%)
肺感染	- Any Grade -	1 (0.2%)	6 (1.0%)	7 (0.6%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
	3	0	3 (0.5%)	3 (0.3%)
気道感染	- Any Grade -	2 (0.3%)	4 (0.7%)	6 (0.5%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
	3	1 (0.2%)	0	1 (<0.1%)
	5	0	1 (0.2%)	1 (<0.1%)
上気道感染	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	2 (0.3%)	4 (0.3%)
カンジダ感染	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	1	0	3 (0.5%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
爪感染	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	2	0	4 (0.7%)	4 (0.3%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
下気道感染	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
口腔真菌感染	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
髄膜炎	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
帯状疱疹	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	2	3 (0.5%)	0	3 (0.3%)
膿疱性皮疹	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
膀胱炎	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)
感染性腸炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
眼感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
口角口唇炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
口腔ヘルペス	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
好中球減少性敗血症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	4	0	2 (0.3%)	2 (0.2%)
細菌性肺炎	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
歯肉炎	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
爪真菌症	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
敗血症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
皮膚感染	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
鼻炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	2 (0.3%)	0	2 (0.2%)
蜂巣炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
毛包炎	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
ニューモシスチス・イロベチイ肺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
咽頭炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
外陰腟真菌感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
感染性舌炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
憩室炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
口腔感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
口唇感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
細菌性上気道感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
細菌性敗血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
歯周炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
耳下腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
消化管感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
真菌感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
真菌性消化管感染	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
真菌性食道炎	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
真菌性舌感染	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
足部白癬	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
脳炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
敗血症性ショック	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
腹部敗血症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
扁桃炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
呼吸器、胸郭および縦隔障害				
- Overall -	- Any Grade -	70 (11.5%)	68 (11.8%)	138 (11.6%)
	1	33 (5.4%)	44 (7.6%)	77 (6.5%)
	2	23 (3.8%)	15 (2.6%)	38 (3.2%)
	3	13 (2.1%)	7 (1.2%)	20 (1.7%)
	4	1 (0.2%)	2 (0.3%)	3 (0.3%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
咳嗽	- Any Grade -	23 (3.8%)	13 (2.2%)	36 (3.0%)
	1	16 (2.6%)	8 (1.4%)	24 (2.0%)
	2	6 (1.0%)	5 (0.9%)	11 (0.9%)
	3	1 (0.2%)	0	1 (<0.1%)
呼吸困難	- Any Grade -	19 (3.1%)	15 (2.6%)	34 (2.9%)
	1	11 (1.8%)	11 (1.9%)	22 (1.9%)
	2	6 (1.0%)	3 (0.5%)	9 (0.8%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
胸水	- Any Grade -	7 (1.1%)	8 (1.4%)	15 (1.3%)
	1	2 (0.3%)	3 (0.5%)	5 (0.4%)
	2	4 (0.7%)	2 (0.3%)	6 (0.5%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
	4	0	1 (0.2%)	1 (<0.1%)
しゃっくり	- Any Grade -	0	9 (1.6%)	9 (0.8%)
	1	0	6 (1.0%)	6 (0.5%)
	2	0	3 (0.5%)	3 (0.3%)
口腔咽頭痛	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	3 (0.5%)	5 (0.9%)	8 (0.7%)
	2	0	1 (0.2%)	1 (<0.1%)
肺臓炎	- Any Grade -	5 (0.8%)	4 (0.7%)	9 (0.8%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)
	3	3 (0.5%)	2 (0.3%)	5 (0.4%)
鼻出血	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	2 (0.3%)	6 (1.0%)	8 (0.7%)
	2	1 (0.2%)	0	1 (<0.1%)
発声障害	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
喀血	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
	2	1 (0.2%)	0	1 (<0.1%)
湿性咳嗽	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
低酸素症	- Any Grade -	3 (0.5%)	0	3 (0.3%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
鼻閉	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
鼻漏	- Any Grade -	1 (0.2%)	2 (0.3%)	3 (0.3%)
	1	1 (0.2%)	2 (0.3%)	3 (0.3%)
咽頭の炎症	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
間質性肺疾患	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	0	2 (0.2%)
気管支痙攣	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
呼吸不全	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
咽喉絞扼感	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
器質化肺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
気胸	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
急性呼吸窮迫症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
胸膜痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
胸膜瘻	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
呼吸窮迫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
誤嚥	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
上気道咳症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肺気腫	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
肺塞栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
肺障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肺浸潤	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
肺水腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
頻呼吸	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
慢性閉塞性肺疾患	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
労作性呼吸困難	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
眼障害				
- Overall -	- Any Grade -	15 (2.5%)	35 (6.1%)	50 (4.2%)
	1	11 (1.8%)	22 (3.8%)	33 (2.8%)
	2	3 (0.5%)	13 (2.2%)	16 (1.3%)
	3	1 (0.2%)	0	1 (<0.1%)
流涙増加	- Any Grade -	2 (0.3%)	24 (4.2%)	26 (2.2%)
	1	1 (0.2%)	15 (2.6%)	16 (1.3%)
	2	1 (0.2%)	9 (1.6%)	10 (0.8%)
眼乾燥	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	4 (0.7%)	1 (0.2%)	5 (0.4%)
霧視	- Any Grade -	2 (0.3%)	3 (0.5%)	5 (0.4%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
眼窩周囲浮腫	- Any Grade -	3 (0.5%)	1 (0.2%)	4 (0.3%)
	1	3 (0.5%)	1 (0.2%)	4 (0.3%)
眼球浮腫	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
眼刺激	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼痛	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼の障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
眼充血	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
眼部腫脹	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
屈折障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
後天性涙道狭窄	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
光視症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
視力低下	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
内分泌性眼症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
複視	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
網膜症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
羞明	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
血管障害				
- Overall -	- Any Grade -	10 (1.6%)	26 (4.5%)	36 (3.0%)
	1	6 (1.0%)	8 (1.4%)	14 (1.2%)
	2	2 (0.3%)	17 (2.9%)	19 (1.6%)
	3	2 (0.3%)	1 (0.2%)	3 (0.3%)
潮紅	- Any Grade -	4 (0.7%)	8 (1.4%)	12 (1.0%)
	1	3 (0.5%)	4 (0.7%)	7 (0.6%)
	2	0	4 (0.7%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
ほてり	- Any Grade -	1 (0.2%)	5 (0.9%)	6 (0.5%)
	1	0	4 (0.7%)	4 (0.3%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
高血圧	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	0	4 (0.7%)	4 (0.3%)
低血圧	- Any Grade -	1 (0.2%)	4 (0.7%)	5 (0.4%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	2 (0.3%)	2 (0.2%)
	3	0	1 (0.2%)	1 (<0.1%)

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事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
静脈炎	- Any Grade -	0	4 (0.7%)	4 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	3 (0.5%)	3 (0.3%)
高血圧クリーゼ	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
起立性低血圧	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
頚静脈血栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
血管痛	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
塞栓症	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
上大静脈症候群	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
深部静脈血栓症	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
毛細血管漏出症候群	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
精神障害				
- Overall -	- Any Grade -	15 (2.5%)	11 (1.9%)	26 (2.2%)
	1	6 (1.0%)	5 (0.9%)	11 (0.9%)
	2	8 (1.3%)	5 (0.9%)	13 (1.1%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
不眠症	- Any Grade -	12 (2.0%)	8 (1.4%)	20 (1.7%)
	1	5 (0.8%)	4 (0.7%)	9 (0.8%)
	2	7 (1.1%)	3 (0.5%)	10 (0.8%)
	3	0	1 (0.2%)	1 (<0.1%)
不安	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
易刺激性	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
錯乱状態	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
睡眠障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
落ち着きのなさ	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
内分泌障害				
- Overall -	- Any Grade -	22 (3.6%)	0	22 (1.9%)
	1	5 (0.8%)	0	5 (0.4%)
	2	17 (2.8%)	0	17 (1.4%)
甲状腺機能低下症	- Any Grade -	15 (2.5%)	0	15 (1.3%)
	1	2 (0.3%)	0	2 (0.2%)
	2	13 (2.1%)	0	13 (1.1%)
甲状腺機能亢進症	- Any Grade -	5 (0.8%)	0	5 (0.4%)
	1	3 (0.5%)	0	3 (0.3%)
	2	2 (0.3%)	0	2 (0.2%)

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事象名：MedDRA ver. 19.0
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
下垂体炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
甲状腺炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
内分泌障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
副腎機能不全	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
傷害、中毒および処置合併症				
- Overall -	- Any Grade -	7 (1.1%)	13 (2.2%)	20 (1.7%)
	1	3 (0.5%)	6 (1.0%)	9 (0.8%)
	2	3 (0.5%)	6 (1.0%)	9 (0.8%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
注入に伴う反応	- Any Grade -	5 (0.8%)	6 (1.0%)	11 (0.9%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	5 (0.9%)	8 (0.7%)
	3	1 (0.2%)	1 (0.2%)	2 (0.2%)
転倒	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
リコール現象	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
外傷性血腫	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
挫傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
擦過傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
処置による悪心	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
静脈損傷	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
放射線性肺臓炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
心臓障害				
- Overall -	- Any Grade -	7 (1.1%)	11 (1.9%)	18 (1.5%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	2	2 (0.3%)	5 (0.9%)	7 (0.6%)
	3	2 (0.3%)	3 (0.5%)	5 (0.4%)
	4	1 (0.2%)	1 (0.2%)	2 (0.2%)
心房細動	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	2 (0.3%)	2 (0.2%)
動悸	- Any Grade -	2 (0.3%)	1 (0.2%)	3 (0.3%)
	1	2 (0.3%)	1 (0.2%)	3 (0.3%)
洞性頻脈	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	0	2 (0.3%)	2 (0.2%)

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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
うっ血性心不全	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
心嚢液貯留	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	0	1 (0.2%)	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
急性心筋梗塞	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
上室性頻脈	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
心タンポナーデ	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
心停止	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
第一度房室ブロック	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
発作性頻脈	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
頻脈	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
免疫系障害				
- Overall -	- Any Grade -	5 (0.8%)	13 (2.2%)	18 (1.5%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	3 (0.5%)	10 (1.7%)	13 (1.1%)
	3	0	3 (0.5%)	3 (0.3%)
	4	1 (0.2%)	0	1 (<0.1%)
過敏症	- Any Grade -	4 (0.7%)	9 (1.6%)	13 (1.1%)
	2	3 (0.5%)	9 (1.6%)	12 (1.0%)
	4	1 (0.2%)	0	1 (<0.1%)
薬物過敏症	- Any Grade -	0	3 (0.5%)	3 (0.3%)
	2	0	1 (0.2%)	1 (<0.1%)
	3	0	2 (0.3%)	2 (0.2%)
アナフィラキシー反応	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
ヨウ素アレルギー	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
腎および尿路障害				
- Overall -	- Any Grade -	4 (0.7%)	8 (1.4%)	12 (1.0%)
	1	2 (0.3%)	4 (0.7%)	6 (0.5%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
	3	1 (0.2%)	2 (0.3%)	3 (0.3%)
	4	0	1 (0.2%)	1 (<0.1%)
急性腎障害	- Any Grade -	2 (0.3%)	2 (0.3%)	4 (0.3%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	0	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
頻尿	- Any Grade -	0	2 (0.3%)	2 (0.2%)
	1	0	2 (0.3%)	2 (0.2%)
ヘノッホ・シェーンライン紫斑病性腎炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)

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To the SOC Overall row counts, a patient contributes only with the AE occurring with the highest grade within the SOC.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
腎尿細管障害	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	4	0	1 (0.2%)	1 (<0.1%)
腎不全	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	3	0	1 (0.2%)	1 (<0.1%)
蛋白尿	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
尿道痛	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
排尿困難	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
慢性腎臓病	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
肝胆道系障害				
- Overall -	- Any Grade -	8 (1.3%)	2 (0.3%)	10 (0.8%)
	1	3 (0.5%)	2 (0.3%)	5 (0.4%)
	3	2 (0.3%)	0	2 (0.2%)
	4	3 (0.5%)	0	3 (0.3%)
肝機能異常	- Any Grade -	3 (0.5%)	2 (0.3%)	5 (0.4%)
	1	2 (0.3%)	2 (0.3%)	4 (0.3%)
	3	1 (0.2%)	0	1 (<0.1%)
肝炎	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	4	2 (0.3%)	0	2 (0.2%)
肝細胞損傷	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
急性肝炎	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	3	1 (0.2%)	0	1 (<0.1%)
薬物性肝障害	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	4	1 (0.2%)	0	1 (<0.1%)
耳および迷路障害				
- Overall -	- Any Grade -	3 (0.5%)	6 (1.0%)	9 (0.8%)
	1	2 (0.3%)	4 (0.7%)	6 (0.5%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
回転性めまい	- Any Grade -	1 (0.2%)	3 (0.5%)	4 (0.3%)
	1	0	1 (0.2%)	1 (<0.1%)
	2	1 (0.2%)	2 (0.3%)	3 (0.3%)
難聴	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	1	1 (0.2%)	1 (0.2%)	2 (0.2%)
耳閉	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
耳鳴	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
頭位性回転性めまい	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
生殖系および乳房障害				
- Overall -	- Any Grade -	4 (0.7%)	1 (0.2%)	5 (0.4%)
	1	2 (0.3%)	0	2 (0.2%)
	2	2 (0.3%)	1 (0.2%)	3 (0.3%)

Percentages are based on N in the column headings.
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.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28915:OAK)
Protocol: GO28915
Population: All Safety Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	Atezolizumab (Actual) (N=609)	Docetaxel (Actual) (N=578)	All Patients (N=1187)
女性化乳房	- Any Grade -	2 (0.3%)	0	2 (0.2%)
	1	1 (0.2%)	0	1 (<0.1%)
	2	1 (0.2%)	0	1 (<0.1%)
勃起不全	- Any Grade -	1 (0.2%)	1 (0.2%)	2 (0.2%)
	2	1 (0.2%)	1 (0.2%)	2 (0.2%)
乳房潰瘍形成	- Any Grade -	1 (0.2%)	0	1 (<0.1%)
	1	1 (0.2%)	0	1 (<0.1%)
外科および内科処置				
- Overall -	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
縫合	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	1	0	1 (0.2%)	1 (<0.1%)
先天性、家族性および遺伝性障害				
- Overall -	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)
表皮融解	- Any Grade -	0	1 (0.2%)	1 (<0.1%)
	2	0	1 (0.2%)	1 (<0.1%)

Percentages are based on N in the column headings.
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.
AEs collected after first treatment dose and within 30 days from last treatment dose are included unless the AE occurred after the start of a non-protocol cancer therapy within the 30 day post-treatment period.
事象名：MedDRA ver. 19.0
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas
Output: /opt/BIOSTAT/prod/cdt7692j/j28915a/reports/aet04r_GO28915_SE.out
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［5.3.5.1-3 aet04r_GO28915_SE を再掲］

2.7.6.2.1.4　POPLAR 試験

表 2.7.6.2.1.4-1　すべての有害事象（POPLAR 試験）

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
- Any adverse events -	- Any Grade -	136 (95.8%)	130 (96.3%)
	1	19 (13.4%)	16 (11.9%)
	2	54 (38.0%)	38 (28.1%)
	3	50 (35.2%)	51 (37.8%)
	4	7 (4.9%)	20 (14.8%)
	5	6 (4.2%)	5 (3.7%)
一般・全身障害および投与部位の状態			
- Overall -	- Any Grade -	92 (64.8%)	90 (66.7%)
	1	41 (28.9%)	27 (20.0%)
	2	44 (31.0%)	47 (34.8%)
	3	6 (4.2%)	14 (10.4%)
	5	1 (0.7%)	2 (1.5%)
疲労	- Any Grade -	55 (38.7%)	54 (40.0%)
	1	26 (18.3%)	16 (11.9%)
	2	26 (18.3%)	28 (20.7%)
	3	3 (2.1%)	10 (7.4%)
発熱	- Any Grade -	24 (16.9%)	16 (11.9%)
	1	15 (10.6%)	12 (8.9%)
	2	9 (6.3%)	4 (3.0%)
無力症	- Any Grade -	14 (9.9%)	22 (16.3%)
	1	9 (6.3%)	11 (8.1%)
	2	4 (2.8%)	8 (5.9%)
	3	1 (0.7%)	3 (2.2%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
末梢性浮腫	- Any Grade -	10 (7.0%)	13 (9.6%)
	1	6 (4.2%)	8 (5.9%)
	2	4 (2.8%)	5 (3.7%)
胸痛	- Any Grade -	10 (7.0%)	6 (4.4%)
	1	5 (3.5%)	4 (3.0%)
	2	4 (2.8%)	1 (0.7%)
	3	1 (0.7%)	1 (0.7%)
疼痛	- Any Grade -	6 (4.2%)	10 (7.4%)
	1	4 (2.8%)	1 (0.7%)
	2	1 (0.7%)	8 (5.9%)
	3	1 (0.7%)	1 (0.7%)
悪寒	- Any Grade -	7 (4.9%)	4 (3.0%)
	1	5 (3.5%)	4 (3.0%)
	2	2 (1.4%)	0
インフルエンザ様疾患	- Any Grade -	7 (4.9%)	2 (1.5%)
	1	4 (2.8%)	0
	2	3 (2.1%)	2 (1.5%)
粘膜の炎症	- Any Grade -	1 (0.7%)	6 (4.4%)
	1	1 (0.7%)	1 (0.7%)
	2	0	5 (3.7%)
末梢腫脹	- Any Grade -	3 (2.1%)	3 (2.2%)
	1	1 (0.7%)	2 (1.5%)
	2	2 (1.4%)	1 (0.7%)
胸部不快感	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	3 (2.2%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
倦怠感	- Any Grade -	2 (1.4%)	2 (1.5%)
	1	2 (1.4%)	0
	2	0	2 (1.5%)
浮腫	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	0	1 (0.7%)
	2	1 (0.7%)	2 (1.5%)
限局性浮腫	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	2 (1.4%)	1 (0.7%)
カテーテル留置部位紅斑	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
死亡	- Any Grade -	0	2 (1.5%)
	5	0	2 (1.5%)
注射部位疼痛	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
非心臓性胸痛	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
異物感	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
医療機器位置異常	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
医療機器関連の血栓症	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
壊死	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
腫脹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
全身性浮腫	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
潰瘍性出血	- Any Grade -	1 (0.7%)	0
	5	1 (0.7%)	0
低体温	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
冷感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
胃腸障害			
- Overall -	- Any Grade -	86 (60.6%)	92 (68.1%)
	1	49 (34.5%)	46 (34.1%)
	2	27 (19.0%)	40 (29.6%)
	3	8 (5.6%)	5 (3.7%)
	4	2 (1.4%)	1 (0.7%)
悪心	- Any Grade -	31 (21.8%)	45 (33.3%)
	1	20 (14.1%)	24 (17.8%)
	2	10 (7.0%)	21 (15.6%)
	3	1 (0.7%)	0
下痢	- Any Grade -	24 (16.9%)	38 (28.1%)
	1	22 (15.5%)	28 (20.7%)
	2	1 (0.7%)	6 (4.4%)
	3	1 (0.7%)	3 (2.2%)
	4	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
便秘	- Any Grade -	29 (20.4%)	32 (23.7%)
	1	19 (13.4%)	22 (16.3%)
	2	10 (7.0%)	9 (6.7%)
	3	0	1 (0.7%)
嘔吐	- Any Grade -	18 (12.7%)	18 (13.3%)
	1	13 (9.2%)	12 (8.9%)
	2	5 (3.5%)	6 (4.4%)
胃食道逆流性疾患	- Any Grade -	7 (4.9%)	7 (5.2%)
	1	1 (0.7%)	5 (3.7%)
	2	5 (3.5%)	2 (1.5%)
	3	1 (0.7%)	0
腹痛	- Any Grade -	7 (4.9%)	7 (5.2%)
	1	5 (3.5%)	3 (2.2%)
	2	2 (1.4%)	3 (2.2%)
	3	0	1 (0.7%)
口内炎	- Any Grade -	3 (2.1%)	9 (6.7%)
	1	2 (1.4%)	9 (6.7%)
	2	1 (0.7%)	0
嚥下障害	- Any Grade -	8 (5.6%)	3 (2.2%)
	1	4 (2.8%)	1 (0.7%)
	2	1 (0.7%)	2 (1.5%)
	3	2 (1.4%)	0
	4	1 (0.7%)	0
消化不良	- Any Grade -	3 (2.1%)	7 (5.2%)
	1	3 (2.1%)	3 (2.2%)
	2	0	4 (3.0%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
上腹部痛	- Any Grade -	4 (2.8%)	5 (3.7%)
	1	4 (2.8%)	4 (3.0%)
	2	0	1 (0.7%)
腹部膨満	- Any Grade -	5 (3.5%)	0
	1	5 (3.5%)	0
口内乾燥	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	2 (1.4%)	1 (0.7%)
	2	1 (0.7%)	0
胃炎	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
口腔内痛	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)
大腸炎	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
	3	1 (0.7%)	0
直腸出血	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
アフタ性口内炎	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
口腔内潰瘍形成	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
痔出血	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
腹部不快感	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)
おくび	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
レッチング	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
下腹部痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
血栓性痔核	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
口腔知覚不全	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
口腔内不快感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
口唇痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
口内丘疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
硬便	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
歯の発育障害	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
歯痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
小腸閉塞	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
上部消化管出血	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
食道痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
食道痙攣	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
大腸穿孔	- Any Grade -	1 (0.7%)	0
	4	1 (0.7%)	0
腹水	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
放屁	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
呼吸器、胸郭および縦隔障害			
- Overall -	- Any Grade -	85 (59.9%)	70 (51.9%)
	1	24 (16.9%)	29 (21.5%)
	2	37 (26.1%)	28 (20.7%)
	3	21 (14.8%)	10 (7.4%)
	4	1 (0.7%)	2 (1.5%)
	5	2 (1.4%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
咳嗽	- Any Grade -	38 (26.8%)	33 (24.4%)
	1	20 (14.1%)	13 (9.6%)
	2	18 (12.7%)	20 (14.8%)
呼吸困難	- Any Grade -	38 (26.8%)	27 (20.0%)
	1	12 (8.5%)	11 (8.1%)
	2	16 (11.3%)	14 (10.4%)
	3	10 (7.0%)	2 (1.5%)
喀血	- Any Grade -	13 (9.2%)	8 (5.9%)
	1	9 (6.3%)	4 (3.0%)
	2	3 (2.1%)	2 (1.5%)
	3	1 (0.7%)	2 (1.5%)
胸水	- Any Grade -	9 (6.3%)	4 (3.0%)
	1	2 (1.4%)	0
	2	5 (3.5%)	4 (3.0%)
	3	2 (1.4%)	0
労作性呼吸困難	- Any Grade -	9 (6.3%)	3 (2.2%)
	1	4 (2.8%)	1 (0.7%)
	2	5 (3.5%)	2 (1.5%)
湿性咳嗽	- Any Grade -	8 (5.6%)	2 (1.5%)
	1	5 (3.5%)	2 (1.5%)
	2	2 (1.4%)	0
	3	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
肺塞栓症	- Any Grade -	4 (2.8%)	6 (4.4%)
	1	1 (0.7%)	0
	3	2 (1.4%)	4 (3.0%)
	4	0	2 (1.5%)
	5	1 (0.7%)	0
口腔咽頭痛	- Any Grade -	5 (3.5%)	4 (3.0%)
	1	5 (3.5%)	3 (2.2%)
	2	0	1 (0.7%)
鼻出血	- Any Grade -	3 (2.1%)	6 (4.4%)
	1	3 (2.1%)	6 (4.4%)
低酸素症	- Any Grade -	6 (4.2%)	1 (0.7%)
	2	0	1 (0.7%)
	3	5 (3.5%)	0
	4	1 (0.7%)	0
肺臓炎	- Any Grade -	4 (2.8%)	1 (0.7%)
	1	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	1 (0.7%)
発声障害	- Any Grade -	5 (3.5%)	0
	1	4 (2.8%)	0
	2	1 (0.7%)	0
鼻閉	- Any Grade -	4 (2.8%)	1 (0.7%)
	1	4 (2.8%)	0
	2	0	1 (0.7%)
副鼻腔うっ血	- Any Grade -	3 (2.1%)	2 (1.5%)
	1	3 (2.1%)	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
しゃっくり	- Any Grade -	0	4 (3.0%)
	1	0	4 (3.0%)
鼻漏	- Any Grade -	2 (1.4%)	2 (1.5%)
	1	2 (1.4%)	2 (1.5%)
慢性閉塞性肺疾患	- Any Grade -	1 (0.7%)	3 (2.2%)
	2	0	1 (0.7%)
	3	1 (0.7%)	2 (1.5%)
アレルギー性鼻炎	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
胸膜痛	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	0	1 (0.7%)
	2	2 (1.4%)	0
咽喉刺激感	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
気胸	- Any Grade -	2 (1.4%)	0
	3	1 (0.7%)	0
	5	1 (0.7%)	0
呼吸不全	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	0
上気道咳症候群	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
喘鳴	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
咽喉乾燥	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
気道うっ血	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
急性呼吸窮迫症候群	- Any Grade -	0	1 (0.7%)
	5	0	1 (0.7%)
胸膜炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
誤嚥性肺炎	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
喉頭出血	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
高粘稠性鼻汁	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
上気道分泌増加	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
睡眠時無呼吸症候群	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
肺硬化	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
肺出血	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
肺障害	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
肺浸潤	- Any Grade -	1 (0.7%)	0
	1	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
頻呼吸	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
副鼻腔不快感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
慢性気管支炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
筋骨格系および結合組織障害			
- Overall -	- Any Grade -	67 (47.2%)	65 (48.1%)
	1	34 (23.9%)	30 (22.2%)
	2	24 (16.9%)	26 (19.3%)
	3	9 (6.3%)	8 (5.9%)
	4	0	1 (0.7%)
関節痛	- Any Grade -	22 (15.5%)	12 (8.9%)
	1	11 (7.7%)	7 (5.2%)
	2	8 (5.6%)	3 (2.2%)
	3	3 (2.1%)	2 (1.5%)
背部痛	- Any Grade -	16 (11.3%)	11 (8.1%)
	1	6 (4.2%)	5 (3.7%)
	2	9 (6.3%)	5 (3.7%)
	3	1 (0.7%)	1 (0.7%)
筋骨格痛	- Any Grade -	19 (13.4%)	7 (5.2%)
	1	11 (7.7%)	1 (0.7%)
	2	6 (4.2%)	4 (3.0%)
	3	2 (1.4%)	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
筋肉痛	- Any Grade -	8 (5.6%)	18 (13.3%)
	1	7 (4.9%)	10 (7.4%)
	2	0	5 (3.7%)
	3	1 (0.7%)	3 (2.2%)
四肢痛	- Any Grade -	8 (5.6%)	13 (9.6%)
	1	3 (2.1%)	9 (6.7%)
	2	4 (2.8%)	4 (3.0%)
	3	1 (0.7%)	0
筋骨格系胸痛	- Any Grade -	9 (6.3%)	4 (3.0%)
	1	5 (3.5%)	1 (0.7%)
	2	3 (2.1%)	2 (1.5%)
	3	1 (0.7%)	0
	4	0	1 (0.7%)
骨痛	- Any Grade -	4 (2.8%)	6 (4.4%)
	1	1 (0.7%)	4 (3.0%)
	2	2 (1.4%)	2 (1.5%)
	3	1 (0.7%)	0
筋痙縮	- Any Grade -	5 (3.5%)	2 (1.5%)
	1	3 (2.1%)	2 (1.5%)
	2	2 (1.4%)	0
頚部痛	- Any Grade -	4 (2.8%)	2 (1.5%)
	1	2 (1.4%)	2 (1.5%)
	2	1 (0.7%)	0
	3	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
顎痛	- Any Grade -	3 (2.1%)	0
	1	1 (0.7%)	0
	2	2 (1.4%)	0
筋力低下	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
脊椎痛	- Any Grade -	2 (1.4%)	1 (0.7%)
	2	2 (1.4%)	1 (0.7%)
側腹部痛	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)
肛径部痛	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
骨粗鬆症	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
デュプイトラン拘縮	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
顎骨壊死	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
滑液嚢腫	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
関節腫脹	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
関節滲出液	- Any Grade -	1 (0.7%)	0
	1	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
筋緊張	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
骨壊死	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
四肢不快感	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
自己免疫性関節炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
脊柱管狭窄症	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
変形性脊椎症	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
皮膚および皮下組織障害			
- Overall -	- Any Grade -	46 (32.4%)	71 (52.6%)
	1	34 (23.9%)	37 (27.4%)
	2	10 (7.0%)	32 (23.7%)
	3	2 (1.4%)	2 (1.5%)
脱毛症	- Any Grade -	3 (2.1%)	52 (38.5%)
	1	2 (1.4%)	27 (20.0%)
	2	1 (0.7%)	24 (17.8%)
	3	0	1 (0.7%)
発疹	- Any Grade -	15 (10.6%)	16 (11.9%)
	1	10 (7.0%)	13 (9.6%)
	2	3 (2.1%)	2 (1.5%)
	3	2 (1.4%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
そう痒症	- Any Grade -	12 (8.5%)	5 (3.7%)
	1	9 (6.3%)	4 (3.0%)
	2	3 (2.1%)	1 (0.7%)
皮膚乾燥	- Any Grade -	3 (2.1%)	10 (7.4%)
	1	2 (1.4%)	9 (6.7%)
	2	1 (0.7%)	1 (0.7%)
寝汗	- Any Grade -	6 (4.2%)	4 (3.0%)
	1	6 (4.2%)	3 (2.2%)
	2	0	1 (0.7%)
爪の障害	- Any Grade -	1 (0.7%)	9 (6.7%)
	1	1 (0.7%)	9 (6.7%)
紅斑	- Any Grade -	4 (2.8%)	4 (3.0%)
	1	2 (1.4%)	4 (3.0%)
	2	2 (1.4%)	0
斑状丘疹状皮疹	- Any Grade -	4 (2.8%)	2 (1.5%)
	1	4 (2.8%)	2 (1.5%)
手掌・足底発赤知覚不全症候群	- Any Grade -	0	4 (3.0%)
	1	0	1 (0.7%)
	2	0	3 (2.2%)
皮膚色素過剰	- Any Grade -	0	4 (3.0%)
	1	0	3 (2.2%)
	2	0	1 (0.7%)
そう痒性皮疹	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
爪痛	- Any Grade -	0	3 (2.2%)
	1	0	3 (2.2%)
爪変色	- Any Grade -	0	3 (2.2%)
	1	0	2 (1.5%)
	2	0	1 (0.7%)
光線過敏性反応	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
湿疹	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)
爪甲脱落症	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
爪甲離床症	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
爪線状隆起	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)
爪毒性	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
斑状皮疹	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
皮膚潰瘍	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
皮膚剥脱	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
ざ瘡	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
過角化	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
丘疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
丘疹落屑性皮疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
紅斑性皮疹	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
脂漏性皮膚炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
色素沈着障害	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
多汗症	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
多毛症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
爪肥厚	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
剥脱性皮膚炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
斑状出血	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
皮膚炎	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
皮膚疼痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
代謝および栄養障害			
- Overall -	- Any Grade -	69 (48.6%)	46 (34.1%)
	1	30 (21.1%)	18 (13.3%)
	2	30 (21.1%)	19 (14.1%)
	3	9 (6.3%)	8 (5.9%)
	4	0	1 (0.7%)
食欲減退	- Any Grade -	49 (34.5%)	28 (20.7%)
	1	25 (17.6%)	12 (8.9%)
	2	22 (15.5%)	16 (11.9%)
	3	2 (1.4%)	0
脱水	- Any Grade -	5 (3.5%)	11 (8.1%)
	1	0	1 (0.7%)
	2	5 (3.5%)	7 (5.2%)
	3	0	3 (2.2%)
低カリウム血症	- Any Grade -	9 (6.3%)	4 (3.0%)
	1	7 (4.9%)	2 (1.5%)
	2	2 (1.4%)	1 (0.7%)
	3	0	1 (0.7%)
低マグネシウム血症	- Any Grade -	7 (4.9%)	5 (3.7%)
	1	6 (4.2%)	4 (3.0%)
	2	1 (0.7%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
低ナトリウム血症	- Any Grade -	8 (5.6%)	3 (2.2%)
	1	3 (2.1%)	1 (0.7%)
	3	5 (3.5%)	2 (1.5%)
高血糖	- Any Grade -	3 (2.1%)	6 (4.4%)
	1	0	2 (1.5%)
	2	1 (0.7%)	1 (0.7%)
	3	2 (1.4%)	2 (1.5%)
	4	0	1 (0.7%)
低アルブミン血症	- Any Grade -	4 (2.8%)	4 (3.0%)
	1	1 (0.7%)	3 (2.2%)
	2	1 (0.7%)	1 (0.7%)
	3	2 (1.4%)	0
低カルシウム血症	- Any Grade -	2 (1.4%)	2 (1.5%)
	1	0	1 (0.7%)
	2	2 (1.4%)	1 (0.7%)
低リン酸血症	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	0
	3	0	2 (1.5%)
高カルシウム血症	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
２型糖尿病	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
アシドーシス	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
アルコール不耐性	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
悪液質	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
血液量減少症	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
高カリウム血症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
高ナトリウム血症	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
食欲障害	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
水分過負荷	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
痛風	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
感染症および寄生虫症			
- Overall -	- Any Grade -	60 (42.3%)	44 (32.6%)
	1	15 (10.6%)	9 (6.7%)
	2	31 (21.8%)	30 (22.2%)
	3	13 (9.2%)	2 (1.5%)
	4	0	1 (0.7%)
	5	1 (0.7%)	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
肺炎	- Any Grade -	15 (10.6%)	4 (3.0%)
	1	2 (1.4%)	0
	2	4 (2.8%)	2 (1.5%)
	3	8 (5.6%)	2 (1.5%)
	5	1 (0.7%)	0
上気道感染	- Any Grade -	9 (6.3%)	3 (2.2%)
	1	1 (0.7%)	0
	2	8 (5.6%)	3 (2.2%)
口腔カンジダ症	- Any Grade -	5 (3.5%)	4 (3.0%)
	1	2 (1.4%)	3 (2.2%)
	2	3 (2.1%)	1 (0.7%)
気管支炎	- Any Grade -	4 (2.8%)	4 (3.0%)
	1	0	2 (1.5%)
	2	3 (2.1%)	2 (1.5%)
	3	1 (0.7%)	0
気道感染	- Any Grade -	7 (4.9%)	1 (0.7%)
	1	2 (1.4%)	0
	2	4 (2.8%)	1 (0.7%)
	3	1 (0.7%)	0
帯状疱疹	- Any Grade -	4 (2.8%)	4 (3.0%)
	1	1 (0.7%)	1 (0.7%)
	2	3 (2.1%)	3 (2.2%)
鼻咽頭炎	- Any Grade -	6 (4.2%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	5 (3.5%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
尿路感染	- Any Grade -	4 (2.8%)	3 (2.2%)
	1	1 (0.7%)	0
	2	3 (2.1%)	3 (2.2%)
副鼻腔炎	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	0	1 (0.7%)
	2	2 (1.4%)	2 (1.5%)
咽頭炎	- Any Grade -	4 (2.8%)	0
	1	3 (2.1%)	0
	2	1 (0.7%)	0
下気道感染	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	1 (0.7%)	0
	2	1 (0.7%)	1 (0.7%)
	3	1 (0.7%)	0
結膜炎	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	2 (1.4%)	0
	2	0	1 (0.7%)
敗血症	- Any Grade -	0	3 (2.2%)
	4	0	1 (0.7%)
	5	0	2 (1.5%)
肺感染	- Any Grade -	3 (2.1%)	0
	2	3 (2.1%)	0
カンジダ感染	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
気管炎	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
口腔真菌感染	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
細気管支炎	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
爪囲炎	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
爪感染	- Any Grade -	0	2 (1.5%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)
膿尿	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
皮膚感染	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
鼻炎	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
蜂巣炎	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
	3	1 (0.7%)	0
膀胱炎	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
腟感染	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
Ｈ１Ｎ１インフルエンザ	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
せつ	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
インフルエンザ	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
ウイルス性気管支炎	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
サルモネラ症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
ヘルペスウイルス感染	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
外耳炎	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
顎膿瘍	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
感染性胸水	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
感染性皮膚嚢腫	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
喉頭炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
骨髄炎	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
細菌性気管支炎	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
細菌性気道感染	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
歯膿瘍	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
真菌性食道炎	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
足部白癬	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
大腸菌感染	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
大葉性肺炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
丹毒	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
軟部組織感染	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
乳房蜂巣炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
粘膜感染	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
白癬感染	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
皮下組織膿瘍	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
慢性副鼻腔炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
毛包炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
瘢風	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
神経系障害			
- Overall -	- Any Grade -	28 (19.7%)	54 (40.0%)
	1	17 (12.0%)	28 (20.7%)
	2	7 (4.9%)	16 (11.9%)
	3	4 (2.8%)	10 (7.4%)
頭痛	- Any Grade -	10 (7.0%)	10 (7.4%)
	1	9 (6.3%)	7 (5.2%)
	2	1 (0.7%)	2 (1.5%)
	3	0	1 (0.7%)
浮動性めまい	- Any Grade -	9 (6.3%)	11 (8.1%)
	1	7 (4.9%)	9 (6.7%)
	2	2 (1.4%)	1 (0.7%)
	3	0	1 (0.7%)
末梢性ニューロパチー	- Any Grade -	2 (1.4%)	16 (11.9%)
	1	1 (0.7%)	5 (3.7%)
	2	1 (0.7%)	10 (7.4%)
	3	0	1 (0.7%)
末梢性感覚ニューロパチー	- Any Grade -	2 (1.4%)	12 (8.9%)
	1	0	5 (3.7%)
	2	1 (0.7%)	3 (2.2%)
	3	1 (0.7%)	4 (3.0%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
錯感覚	- Any Grade -	4 (2.8%)	4 (3.0%)
	1	4 (2.8%)	3 (2.2%)
	3	0	1 (0.7%)
味覚異常	- Any Grade -	1 (0.7%)	7 (5.2%)
	1	1 (0.7%)	2 (1.5%)
	2	0	5 (3.7%)
感覚鈍麻	- Any Grade -	2 (1.4%)	4 (3.0%)
	1	2 (1.4%)	2 (1.5%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)
失神	- Any Grade -	2 (1.4%)	1 (0.7%)
	3	2 (1.4%)	1 (0.7%)
多発ニューロパチー	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
	3	0	1 (0.7%)
過眠症	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
神経痛	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
片頭痛	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
末梢性運動ニューロパチー	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
嗜眠	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
ホルネル症候群	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
緊張性頭痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
失神寸前の状態	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
灼熱感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
体位性めまい	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
平衡障害	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
血液およびリンパ系障害			
- Overall -	- Any Grade -	32 (22.5%)	49 (36.3%)
	1	10 (7.0%)	8 (5.9%)
	2	14 (9.9%)	14 (10.4%)
	3	6 (4.2%)	13 (9.6%)
	4	2 (1.4%)	14 (10.4%)
貧血	- Any Grade -	23 (16.2%)	26 (19.3%)
	1	7 (4.9%)	8 (5.9%)
	2	12 (8.5%)	13 (9.6%)
	3	4 (2.8%)	5 (3.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
好中球減少症	- Any Grade -	2 (1.4%)	17 (12.6%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
	3	0	3 (2.2%)
	4	0	12 (8.9%)
発熱性好中球減少症	- Any Grade -	0	11 (8.1%)
	3	0	8 (5.9%)
	4	0	3 (2.2%)
血小板減少症	- Any Grade -	6 (4.2%)	1 (0.7%)
	1	3 (2.1%)	0
	2	1 (0.7%)	1 (0.7%)
	4	2 (1.4%)	0
リンパ球減少症	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)
白血球減少症	- Any Grade -	0	4 (3.0%)
	2	0	1 (0.7%)
	3	0	3 (2.2%)
小球性貧血	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
鉄欠乏性貧血	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
リンパ節症	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
悪性疾患下の貧血	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
凝血異常	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
溶血	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
臨床検査			
- Overall -	- Any Grade -	37 (26.1%)	29 (21.5%)
	1	21 (14.8%)	15 (11.1%)
	2	11 (7.7%)	7 (5.2%)
	3	5 (3.5%)	6 (4.4%)
	4	0	1 (0.7%)
体重減少	- Any Grade -	14 (9.9%)	9 (6.7%)
	1	9 (6.3%)	8 (5.9%)
	2	5 (3.5%)	1 (0.7%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	6 (4.2%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	2	2 (1.4%)	0
	3	3 (2.1%)	0
アラニンアミノトランスフェラーゼ増加	- Any Grade -	6 (4.2%)	0
	2	3 (2.1%)	0
	3	3 (2.1%)	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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
好中球数減少	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	0
	3	0	3 (2.2%)
	4	0	1 (0.7%)
血中アルカリホスファターゼ増加	- Any Grade -	4 (2.8%)	0
	1	1 (0.7%)	0
	2	2 (1.4%)	0
	3	1 (0.7%)	0
Ｃ－反応性蛋白増加	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	0
	2	1 (0.7%)	1 (0.7%)
ヘモグロビン減少	- Any Grade -	1 (0.7%)	2 (1.5%)
	2	0	2 (1.5%)
	3	1 (0.7%)	0
血中クレアチニン増加	- Any Grade -	3 (2.1%)	0
	1	2 (1.4%)	0
	2	1 (0.7%)	0
国際標準比増加	- Any Grade -	0	3 (2.2%)
	2	0	2 (1.5%)
	3	0	1 (0.7%)
体重増加	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	2 (1.4%)	1 (0.7%)
白血球数減少	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	0
	3	0	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
リンパ球数減少	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	0
血中ビリルビン増加	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
ステノトロフォモナス検査陽性	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
フィブリンDダイマー増加	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
プロカルシトニン増加	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
リンパ球数増加	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
活性化部分トロンボプラスチン時間延長	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
肝機能検査異常	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
血中アルブミン減少	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
血中クロール減少	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
血中クロール増加	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
呼吸音異常	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
好酸球数増加	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
好中球数増加	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
酸素飽和度低下	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
糸球体濾過率減少	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
心雑音	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
心電図ＱＴ延長	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
体温上昇	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
尿量減少	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
精神障害			
- Overall -	- Any Grade -	30 (21.1%)	18 (13.3%)
	1	12 (8.5%)	6 (4.4%)
	2	17 (12.0%)	9 (6.7%)
	3	1 (0.7%)	3 (2.2%)
不眠症	- Any Grade -	19 (13.4%)	11 (8.1%)
	1	7 (4.9%)	4 (3.0%)
	2	12 (8.5%)	5 (3.7%)
	3	0	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
うつ病	- Any Grade -	6 (4.2%)	5 (3.7%)
	1	3 (2.1%)	2 (1.5%)
	2	3 (2.1%)	3 (2.2%)
不安	- Any Grade -	5 (3.5%)	2 (1.5%)
	1	2 (1.4%)	0
	2	3 (2.1%)	2 (1.5%)
錯乱状態	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	3	1 (0.7%)	0
ストレス	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
リビドー減退	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
激越	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
幻覚	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
睡眠障害	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
譫妄	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
血管障害			
- Overall -	- Any Grade -	22 (15.5%)	19 (14.1%)
	1	8 (5.6%)	9 (6.7%)
	2	10 (7.0%)	6 (4.4%)
	3	3 (2.1%)	3 (2.2%)
	4	0	1 (0.7%)
	5	1 (0.7%)	0
低血圧	- Any Grade -	9 (6.3%)	4 (3.0%)
	1	4 (2.8%)	3 (2.2%)
	2	5 (3.5%)	0
	3	0	1 (0.7%)
高血圧	- Any Grade -	3 (2.1%)	3 (2.2%)
	2	2 (1.4%)	1 (0.7%)
	3	1 (0.7%)	2 (1.5%)
深部静脈血栓症	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	0	1 (0.7%)
	2	1 (0.7%)	3 (2.2%)
潮紅	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	2 (1.4%)	3 (2.2%)
ほてり	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
頚静脈血栓症	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
上大静脈症候群	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	0
起立性低血圧	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
血管痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
塞栓症	- Any Grade -	1 (0.7%)	0
	5	1 (0.7%)	0
静脈炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
静脈狭窄	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
静脈塞栓症	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
末梢血管塞栓症	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
末梢性虚血	- Any Grade -	0	1 (0.7%)
	4	0	1 (0.7%)
眼障害			
- Overall -	- Any Grade -	9 (6.3%)	16 (11.9%)
	1	6 (4.2%)	11 (8.1%)
	2	3 (2.1%)	4 (3.0%)
	3	0	1 (0.7%)

Percentages are based on N in the column headings.
事象名 : MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
流涙増加	- Any Grade -	1 (0.7%)	7 (5.2%)
	1	1 (0.7%)	4 (3.0%)
	2	0	3 (2.2%)
眼乾燥	- Any Grade -	2 (1.4%)	4 (3.0%)
	1	2 (1.4%)	3 (2.2%)
	2	0	1 (0.7%)
硝子体浮遊物	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
白内障	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
	3	0	1 (0.7%)
霧視	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
アレルギー性結膜炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
眼そう痒症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
眼痛	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
眼瞼下垂	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
眼瞼痙攣	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
視力障害	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)

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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
複視	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
心臓障害			
- Overall -	- Any Grade -	12 (8.5%)	10 (7.4%)
	1	5 (3.5%)	2 (1.5%)
	2	3 (2.1%)	6 (4.4%)
	3	1 (0.7%)	1 (0.7%)
	4	2 (1.4%)	1 (0.7%)
	5	1 (0.7%)	0
頻脈	- Any Grade -	6 (4.2%)	4 (3.0%)
	1	4 (2.8%)	2 (1.5%)
	2	1 (0.7%)	2 (1.5%)
	3	1 (0.7%)	0
心嚢液貯留	- Any Grade -	2 (1.4%)	2 (1.5%)
	2	2 (1.4%)	2 (1.5%)
心房細動	- Any Grade -	2 (1.4%)	1 (0.7%)
	2	2 (1.4%)	0
	3	0	1 (0.7%)
心タンポナーデ	- Any Grade -	2 (1.4%)	0
	4	2 (1.4%)	0
洞性頻脈	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
期外収縮	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
急性心筋梗塞	- Any Grade -	0	1 (0.7%)
	4	0	1 (0.7%)
心筋症	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
心不全	- Any Grade -	1 (0.7%)	0
	5	1 (0.7%)	0
心房粗動	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
心房頻脈	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
動悸	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
傷害、中毒および処置合併症			
- Overall -	- Any Grade -	11 (7.7%)	9 (6.7%)
	1	4 (2.8%)	2 (1.5%)
	2	5 (3.5%)	5 (3.7%)
	3	1 (0.7%)	2 (1.5%)
	4	1 (0.7%)	0
転倒	- Any Grade -	2 (1.4%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)
	2	1 (0.7%)	0
挫傷	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
注入に伴う反応	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
	3	1 (0.7%)	0
陰茎損傷	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
気管閉塞	- Any Grade -	1 (0.7%)	0
	4	1 (0.7%)	0
胸椎骨折	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
骨盤骨折	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
歯牙破折	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
処置による疼痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
処置後腫脹	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
上腕骨骨折	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
創合併症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
創傷出血	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
創部分泌	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
足骨折	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
動物咬傷	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
放射線性肺臓炎	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
放射線皮膚損傷	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
裂傷	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
肋骨骨折	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
腎および尿路障害			
- Overall -	- Any Grade -	8 (5.6%)	10 (7.4%)
	1	5 (3.5%)	5 (3.7%)
	2	2 (1.4%)	3 (2.2%)
	3	1 (0.7%)	2 (1.5%)
急性腎不全	- Any Grade -	3 (2.1%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
	3	1 (0.7%)	1 (0.7%)
蛋白尿	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	2 (1.4%)	0
	2	1 (0.7%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
血尿	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)
出血性膀胱炎	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
神経因性膀胱	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
腎出血	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
腎不全	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
着色尿	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
尿失禁	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
排尿困難	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
非感染性膀胱炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
頻尿	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
夜間頻尿	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0

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事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
内分泌障害			
- Overall -	- Any Grade -	9 (6.3%)	0
	2	8 (5.6%)	0
	3	1 (0.7%)	0
甲状腺機能低下症	- Any Grade -	8 (5.6%)	0
	2	7 (4.9%)	0
	3	1 (0.7%)	0
甲状腺機能亢進症	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
耳および迷路障害			
- Overall -	- Any Grade -	2 (1.4%)	5 (3.7%)
	1	1 (0.7%)	3 (2.2%)
	2	1 (0.7%)	1 (0.7%)
	3	0	1 (0.7%)
耳痛	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	0	2 (1.5%)
	2	1 (0.7%)	1 (0.7%)
耳そう痒症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
耳の障害	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
耳出血	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
耳閉	- Any Grade -	1 (0.7%)	0
	1	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
耳鳴	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
聴覚障害	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
聴力低下	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
難聴	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
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 -	4 (2.8%)	3 (2.2%)
	1	0	2 (1.5%)
	2	2 (1.4%)	0
	3	2 (1.4%)	1 (0.7%)
腫瘍疼痛	- Any Grade -	2 (1.4%)	0
	3	2 (1.4%)	0
転移部痛	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	3	0	1 (0.7%)
移行上皮癌	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
口腔乳頭腫	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
腫瘍熱	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
新生物	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
免疫系障害			
- Overall -	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	3 (2.2%)
	2	0	1 (0.7%)
過敏症	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	1 (0.7%)	2 (1.5%)
	2	0	1 (0.7%)
季節性アレルギー	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
生殖系および乳房障害			
- Overall -	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	1 (0.7%)	0
	2	2 (1.4%)	1 (0.7%)
前立腺症	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
乳房痛	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
勃起不全	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
膣出血	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
外科および内科処置			
- Overall -	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	0
	2	0	2 (1.5%)
脱毛術	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
副鼻腔手術	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
肝胆道系障害			
- Overall -	- Any Grade -	3 (2.1%)	0
	1	2 (1.4%)	0
	2	1 (0.7%)	0
肝炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
肝臓痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
胆管炎	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04.sas / Output: /opt/BIOSTAT/prod/cdt7692j/j28753a/reports/aet04_GO28753_SE.out
17NOV2016 13:36

［5.3.5.3-1 aet04_GO28753_SE を再掲］

表 2.7.6.2.1.4-2　すべての副作用（POPLAR 試験）

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
- Any adverse events -	- Any Grade -	95 (66.9%)	119 (88.1%)
	1	35 (24.6%)	26 (19.3%)
	2	43 (30.3%)	38 (28.1%)
	3	16 (11.3%)	37 (27.4%)
	4	0	15 (11.1%)
	5	1 (0.7%)	3 (2.2%)
一般・全身障害および投与部位の状態			
- Overall -	- Any Grade -	48 (33.8%)	75 (55.6%)
	1	24 (16.9%)	23 (17.0%)
	2	22 (15.5%)	39 (28.9%)
	3	2 (1.4%)	12 (8.9%)
	5	0	1 (0.7%)
疲労	- Any Grade -	29 (20.4%)	47 (34.8%)
	1	14 (9.9%)	13 (9.6%)
	2	14 (9.9%)	25 (18.5%)
	3	1 (0.7%)	9 (6.7%)
無力症	- Any Grade -	9 (6.3%)	18 (13.3%)
	1	6 (4.2%)	10 (7.4%)
	2	2 (1.4%)	6 (4.4%)
	3	1 (0.7%)	2 (1.5%)
発熱	- Any Grade -	10 (7.0%)	8 (5.9%)
	1	4 (2.8%)	5 (3.7%)
	2	6 (4.2%)	3 (2.2%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
末梢性浮腫	- Any Grade -	5 (3.5%)	6 (4.4%)
	1	4 (2.8%)	5 (3.7%)
	2	1 (0.7%)	1 (0.7%)
インフルエンザ様疾患	- Any Grade -	4 (2.8%)	2 (1.5%)
	1	2 (1.4%)	0
	2	2 (1.4%)	2 (1.5%)
粘膜の炎症	- Any Grade -	0	5 (3.7%)
	1	0	1 (0.7%)
	2	0	4 (3.0%)
疼痛	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	0
	2	0	3 (2.2%)
	3	0	1 (0.7%)
悪寒	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	2 (1.4%)	1 (0.7%)
	2	1 (0.7%)	0
倦怠感	- Any Grade -	2 (1.4%)	2 (1.5%)
	1	2 (1.4%)	0
	2	0	2 (1.5%)
浮腫	- Any Grade -	0	3 (2.2%)
	1	0	1 (0.7%)
	2	0	2 (1.5%)
末梢腫脹	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
胸部不快感	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
胸痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
限局性浮腫	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
死亡	- Any Grade -	0	1 (0.7%)
	5	0	1 (0.7%)
全身性浮腫	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
非心臓性胸痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
冷感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
胃腸障害			
- Overall -	- Any Grade -	39 (27.5%)	71 (52.6%)
	1	24 (16.9%)	35 (25.9%)
	2	12 (8.5%)	32 (23.7%)
	3	3 (2.1%)	3 (2.2%)
	4	0	1 (0.7%)
悪心	- Any Grade -	17 (12.0%)	37 (27.4%)
	1	13 (9.2%)	18 (13.3%)
	2	3 (2.1%)	19 (14.1%)
	3	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
下痢	- Any Grade -	10 (7.0%)	30 (22.2%)
	1	9 (6.3%)	22 (16.3%)
	2	0	5 (3.7%)
	3	1 (0.7%)	2 (1.5%)
	4	0	1 (0.7%)
嘔吐	- Any Grade -	8 (5.6%)	16 (11.9%)
	1	5 (3.5%)	11 (8.1%)
	2	3 (2.1%)	5 (3.7%)
便秘	- Any Grade -	7 (4.9%)	16 (11.9%)
	1	5 (3.5%)	10 (7.4%)
	2	2 (1.4%)	5 (3.7%)
	3	0	1 (0.7%)
口内炎	- Any Grade -	2 (1.4%)	9 (6.7%)
	1	2 (1.4%)	9 (6.7%)
胃食道逆流性疾患	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	0	3 (2.2%)
	2	1 (0.7%)	1 (0.7%)
消化不良	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	2 (1.4%)	2 (1.5%)
	2	0	1 (0.7%)
腹痛	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	2 (1.4%)	0
	2	1 (0.7%)	1 (0.7%)
上腹部痛	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
嚥下障害	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
胃炎	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
口腔内痛	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
口腔内潰瘍形成	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
口内乾燥	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	2	1 (0.7%)	0
大腸炎	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	0
アフタ性口内炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
口腔知覚不全	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
硬便	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
腹水	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
腹部不快感	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
腹部膨満	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
皮膚および皮下組織障害			
- Overall -	- Any Grade -	34 (23.9%)	67 (49.6%)
	1	25 (17.6%)	34 (25.2%)
	2	7 (4.9%)	31 (23.0%)
	3	2 (1.4%)	2 (1.5%)
脱毛症	- Any Grade -	2 (1.4%)	51 (37.8%)
	1	2 (1.4%)	26 (19.3%)
	2	0	24 (17.8%)
	3	0	1 (0.7%)
発疹	- Any Grade -	10 (7.0%)	13 (9.6%)
	1	5 (3.5%)	10 (7.4%)
	2	3 (2.1%)	2 (1.5%)
	3	2 (1.4%)	1 (0.7%)
そう痒症	- Any Grade -	10 (7.0%)	3 (2.2%)
	1	7 (4.9%)	3 (2.2%)
	2	3 (2.1%)	0
皮膚乾燥	- Any Grade -	3 (2.1%)	7 (5.2%)
	1	2 (1.4%)	6 (4.4%)
	2	1 (0.7%)	1 (0.7%)
爪の障害	- Any Grade -	0	9 (6.7%)
	1	0	9 (6.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
寝汗	- Any Grade -	4 (2.8%)	2 (1.5%)
	1	4 (2.8%)	1 (0.7%)
	2	0	1 (0.7%)
斑状丘疹状皮疹	- Any Grade -	4 (2.8%)	1 (0.7%)
	1	4 (2.8%)	1 (0.7%)
手掌・足底発赤知覚不全症候群	- Any Grade -	0	4 (3.0%)
	1	0	1 (0.7%)
	2	0	3 (2.2%)
そう痒性皮疹	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
紅斑	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	2 (1.5%)
爪変色	- Any Grade -	0	3 (2.2%)
	1	0	2 (1.5%)
	2	0	1 (0.7%)
光線過敏性反応	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
爪甲脱落症	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
爪甲離床症	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
爪線状隆起	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
爪毒性	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)
皮膚色素過剰	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
皮膚剥脱	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)
ざ瘡	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
過角化	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
丘疹落屑性皮疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
紅斑性皮疹	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
湿疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
色素沈着障害	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
多汗症	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
爪痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
爪肥厚	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
剥脱性皮膚炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
斑状皮疹	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
皮膚炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
皮膚疼痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
代謝および栄養障害			
- Overall -	- Any Grade -	29 (20.4%)	33 (24.4%)
	1	14 (9.9%)	14 (10.4%)
	2	13 (9.2%)	15 (11.1%)
	3	2 (1.4%)	4 (3.0%)
食欲減退	- Any Grade -	25 (17.6%)	21 (15.6%)
	1	14 (9.9%)	10 (7.4%)
	2	11 (7.7%)	11 (8.1%)
脱水	- Any Grade -	0	8 (5.9%)
	2	0	5 (3.7%)
	3	0	3 (2.2%)
低カリウム血症	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	2 (1.4%)	1 (0.7%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
低ナトリウム血症	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	1 (0.7%)	1 (0.7%)
	3	1 (0.7%)	2 (1.5%)
低マグネシウム血症	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	1 (0.7%)	3 (2.2%)
低アルブミン血症	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	0	2 (1.5%)
	2	1 (0.7%)	0
高血糖	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	0	1 (0.7%)
	3	1 (0.7%)	0
低カルシウム血症	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
アシドーシス	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
食欲障害	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
神経系障害			
- Overall -	- Any Grade -	12 (8.5%)	42 (31.1%)
	1	10 (7.0%)	19 (14.1%)
	2	2 (1.4%)	16 (11.9%)
	3	0	7 (5.2%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
末梢性ニューロパチー	- Any Grade -	1 (0.7%)	15 (11.1%)
	1	0	5 (3.7%)
	2	1 (0.7%)	9 (6.7%)
	3	0	1 (0.7%)
末梢性感覚ニューロパチー	- Any Grade -	1 (0.7%)	11 (8.1%)
	1	1 (0.7%)	4 (3.0%)
	2	0	4 (3.0%)
	3	0	3 (2.2%)
頭痛	- Any Grade -	6 (4.2%)	3 (2.2%)
	1	5 (3.5%)	2 (1.5%)
	2	1 (0.7%)	1 (0.7%)
浮動性めまい	- Any Grade -	2 (1.4%)	5 (3.7%)
	1	2 (1.4%)	4 (3.0%)
	3	0	1 (0.7%)
味覚異常	- Any Grade -	0	7 (5.2%)
	1	0	2 (1.5%)
	2	0	5 (3.7%)
錯感覚	- Any Grade -	2 (1.4%)	4 (3.0%)
	1	2 (1.4%)	3 (2.2%)
	3	0	1 (0.7%)
感覚鈍麻	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
神経痛	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
多発ニューロパチー	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	3	0	1 (0.7%)
失神	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
末梢性運動ニューロパチー	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
嗜眠	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
血液およびリンパ系障害			
- Overall -	- Any Grade -	9 (6.3%)	44 (32.6%)
	1	4 (2.8%)	6 (4.4%)
	2	4 (2.8%)	12 (8.9%)
	3	1 (0.7%)	12 (8.9%)
	4	0	14 (10.4%)
貧血	- Any Grade -	8 (5.6%)	22 (16.3%)
	1	4 (2.8%)	7 (5.2%)
	2	3 (2.1%)	11 (8.1%)
	3	1 (0.7%)	4 (3.0%)
好中球減少症	- Any Grade -	1 (0.7%)	15 (11.1%)
	2	1 (0.7%)	1 (0.7%)
	3	0	3 (2.2%)
	4	0	11 (8.1%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
発熱性好中球減少症	- Any Grade -	0	11 (8.1%)
	3	0	8 (5.9%)
	4	0	3 (2.2%)
白血球減少症	- Any Grade -	0	4 (3.0%)
	2	0	1 (0.7%)
	3	0	3 (2.2%)
血小板減少症	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	1 (0.7%)	0
	2	1 (0.7%)	1 (0.7%)
リンパ球減少症	- Any Grade -	0	2 (1.5%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)
小球性貧血	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
溶血	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
筋骨格系および結合組織障害			
- Overall -	- Any Grade -	14 (9.9%)	26 (19.3%)
	1	10 (7.0%)	11 (8.1%)
	2	3 (2.1%)	12 (8.9%)
	3	1 (0.7%)	3 (2.2%)
筋肉痛	- Any Grade -	4 (2.8%)	13 (9.6%)
	1	4 (2.8%)	6 (4.4%)
	2	0	5 (3.7%)
	3	0	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
関節痛	- Any Grade -	6 (4.2%)	7 (5.2%)
	1	4 (2.8%)	4 (3.0%)
	2	1 (0.7%)	1 (0.7%)
	3	1 (0.7%)	2 (1.5%)
四肢痛	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	0	2 (1.5%)
	2	1 (0.7%)	2 (1.5%)
背部痛	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	1 (0.7%)	0
	2	0	3 (2.2%)
筋骨格痛	- Any Grade -	2 (1.4%)	1 (0.7%)
	1	2 (1.4%)	0
	2	0	1 (0.7%)
骨痛	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
筋緊張	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
筋骨格系胸痛	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
筋痙縮	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
自己免疫性関節炎	- Any Grade -	1 (0.7%)	0
	2	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
呼吸器、胸郭および縦隔障害			
- Overall -	- Any Grade -	16 (11.3%)	18 (13.3%)
	1	7 (4.9%)	9 (6.7%)
	2	5 (3.5%)	7 (5.2%)
	3	4 (2.8%)	1 (0.7%)
	5	0	1 (0.7%)
呼吸困難	- Any Grade -	7 (4.9%)	4 (3.0%)
	1	2 (1.4%)	1 (0.7%)
	2	3 (2.1%)	3 (2.2%)
	3	2 (1.4%)	0
咳嗽	- Any Grade -	1 (0.7%)	5 (3.7%)
	1	0	3 (2.2%)
	2	1 (0.7%)	2 (1.5%)
胸水	- Any Grade -	1 (0.7%)	3 (2.2%)
	1	1 (0.7%)	0
	2	0	3 (2.2%)
肺臓炎	- Any Grade -	3 (2.1%)	1 (0.7%)
	1	2 (1.4%)	0
	3	1 (0.7%)	1 (0.7%)
口腔咽頭痛	- Any Grade -	0	3 (2.2%)
	1	0	2 (1.5%)
	2	0	1 (0.7%)
鼻出血	- Any Grade -	0	3 (2.2%)
	1	0	3 (2.2%)
しゃっくり	- Any Grade -	0	2 (1.5%)
	1	0	2 (1.5%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
湿性咳嗽	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
低酸素症	- Any Grade -	2 (1.4%)	0
	3	2 (1.4%)	0
咽喉刺激感	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
急性呼吸窮迫症候群	- Any Grade -	0	1 (0.7%)
	5	0	1 (0.7%)
胸膜炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
喉頭出血	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
肺浸潤	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
鼻閉	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
鼻漏	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
喀血	- Any Grade -	1 (0.7%)	0
	1	1 (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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
臨床検査			
- Overall -	- Any Grade -	18 (12.7%)	16 (11.9%)
	1	12 (8.5%)	7 (5.2%)
	2	3 (2.1%)	3 (2.2%)
	3	3 (2.1%)	5 (3.7%)
	4	0	1 (0.7%)
体重減少	- Any Grade -	6 (4.2%)	6 (4.4%)
	1	4 (2.8%)	5 (3.7%)
	2	2 (1.4%)	1 (0.7%)
アスパラギン酸アミノトランスフェラーゼ増加	- Any Grade -	4 (2.8%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
	3	3 (2.1%)	0
好中球数減少	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	0
	3	0	3 (2.2%)
	4	0	1 (0.7%)
アラニンアミノトランスフェラーゼ増加	- Any Grade -	3 (2.1%)	0
	2	1 (0.7%)	0
	3	2 (1.4%)	0
ヘモグロビン減少	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
血中アルカリホスファターゼ増加	- Any Grade -	2 (1.4%)	0
	2	1 (0.7%)	0
	3	1 (0.7%)	0
血中クレアチニン増加	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0

Percentages are based on N in the column headings.
事象名：MedDRA ver. 18.0
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Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
血中ビリルビン増加	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
白血球数減少	- Any Grade -	0	2 (1.5%)
	3	0	2 (1.5%)
Ｃ－反応性蛋白増加	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
リンパ球数減少	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
血中アルブミン減少	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
好酸球数増加	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
糸球体濾過率減少	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
心電図ＱＴ延長	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
体温上昇	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
感染症および寄生虫症			
- Overall -	- Any Grade -	11 (7.7%)	17 (12.6%)
	1	3 (2.1%)	4 (3.0%)
	2	5 (3.5%)	10 (7.4%)
	3	3 (2.1%)	1 (0.7%)
	4	0	1 (0.7%)
	5	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
肺炎	- Any Grade -	3 (2.1%)	3 (2.2%)
	2	0	2 (1.5%)
	3	3 (2.1%)	1 (0.7%)
口腔カンジダ症	- Any Grade -	1 (0.7%)	4 (3.0%)
	1	1 (0.7%)	3 (2.2%)
	2	0	1 (0.7%)
結膜炎	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	0
	2	0	1 (0.7%)
口腔真菌感染	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
上気道感染	- Any Grade -	2 (1.4%)	0
	2	2 (1.4%)	0
爪囲炎	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
敗血症	- Any Grade -	0	2 (1.5%)
	4	0	1 (0.7%)
	5	0	1 (0.7%)
せつ	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
カンジダ感染	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
下気道感染	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
気管支炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
帯状疱疹	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
爪感染	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
膿尿	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
皮下組織膿瘍	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
鼻咽頭炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
副鼻腔炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
慢性副鼻腔炎	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
毛包炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
眼障害			
- Overall -	- Any Grade -	6 (4.2%)	10 (7.4%)
	1	6 (4.2%)	6 (4.4%)
	2	0	4 (3.0%)
流涙増加	- Any Grade -	1 (0.7%)	7 (5.2%)
	1	1 (0.7%)	4 (3.0%)
	2	0	3 (2.2%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
眼乾燥	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
霧視	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
眼そう痒症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
硝子体浮遊物	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
複視	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
血管障害			
- Overall -	- Any Grade -	6 (4.2%)	7 (5.2%)
	1	5 (3.5%)	4 (3.0%)
	2	0	1 (0.7%)
	3	1 (0.7%)	2 (1.5%)
低血圧	- Any Grade -	2 (1.4%)	3 (2.2%)
	1	2 (1.4%)	2 (1.5%)
	3	0	1 (0.7%)
ほてり	- Any Grade -	1 (0.7%)	1 (0.7%)
	1	1 (0.7%)	1 (0.7%)
高血圧	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	0
	3	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
潮紅	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
頚静脈血栓症	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
静脈炎	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)
静脈狭窄	- Any Grade -	1 (0.7%)	0
	3	1 (0.7%)	0
心臓障害			
- Overall -	- Any Grade -	5 (3.5%)	1 (0.7%)
	1	1 (0.7%)	0
	2	3 (2.1%)	1 (0.7%)
	5	1 (0.7%)	0
心嚢液貯留	- Any Grade -	2 (1.4%)	1 (0.7%)
	2	2 (1.4%)	1 (0.7%)
頻脈	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
心不全	- Any Grade -	1 (0.7%)	0
	5	1 (0.7%)	0
精神障害			
- Overall -	- Any Grade -	6 (4.2%)	0
	1	3 (2.1%)	0
	2	3 (2.1%)	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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
不眠症	- Any Grade -	4 (2.8%)	0
	1	2 (1.4%)	0
	2	2 (1.4%)	0
うつ病	- Any Grade -	2 (1.4%)	0
	1	1 (0.7%)	0
	2	1 (0.7%)	0
内分泌障害			
- Overall -	- Any Grade -	5 (3.5%)	0
	2	4 (2.8%)	0
	3	1 (0.7%)	0
甲状腺機能低下症	- Any Grade -	5 (3.5%)	0
	2	4 (2.8%)	0
	3	1 (0.7%)	0
耳および迷路障害			
- Overall -	- Any Grade -	1 (0.7%)	2 (1.5%)
	1	1 (0.7%)	1 (0.7%)
	2	0	1 (0.7%)
耳痛	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
耳そう痒症	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
聴力低下	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
外科および内科処置			
- Overall -	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
脱毛術	- Any Grade -	0	2 (1.5%)
	2	0	2 (1.5%)
肝胆道系障害			
- Overall -	- Any Grade -	2 (1.4%)	0
	1	2 (1.4%)	0
肝炎	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
肝臓痛	- Any Grade -	1 (0.7%)	0
	1	1 (0.7%)	0
傷害、中毒および処置合併症			
- Overall -	- Any Grade -	1 (0.7%)	1 (0.7%)
	2	1 (0.7%)	1 (0.7%)
処置後腫脹	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
創部分泌	- Any Grade -	1 (0.7%)	0
	2	1 (0.7%)	0
注入に伴う反応	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Related Adverse Events by Intensity (CTCAE Grades 1-5) (GO28753:POPLAR)
Protocol: GO28753
Population: Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term	Grade	atezolizumab 1200 mg q3w IV (N=142)	Docetaxel (N=135)
腎および尿路障害			
- Overall -	- Any Grade -	0	2 (1.5%)
	2	0	1 (0.7%)
	3	0	1 (0.7%)
急性腎不全	- Any Grade -	0	1 (0.7%)
	3	0	1 (0.7%)
腎不全	- Any Grade -	0	1 (0.7%)
	2	0	1 (0.7%)
免疫系障害			
- Overall -	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
過敏症	- Any Grade -	0	2 (1.5%)
	1	0	1 (0.7%)
	2	0	1 (0.7%)
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 -	0	1 (0.7%)
	1	0	1 (0.7%)
腫瘍熱	- Any Grade -	0	1 (0.7%)
	1	0	1 (0.7%)

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.
Data Cut-off: 8 May 2015; SDTM Data Extracted: 16 Jul 2015.

Program: /opt/BIOSTAT/prod/cdt7692j/aet04r.sas / Output: /opt/BIOSTAT/prod/cdt7692j/j28753a/reports/aet04r_GO28753_SE.out
17NOV2016 13:38

［5.3.5.3-1 aet04r_GO28753_SE を再掲］

2.7.6.2.1.5　BIRCH 試験

表 2.7.6.2.1.5-1　すべての有害事象（BIRCH 試験）

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 -	617 (93.6%)	127 (91.4%)	246 (92.1%)	244 (96.4%)
	1	109 (16.5%)	22 (15.8%)	45 (16.9%)	42 (16.6%)
	2	237 (36.0%)	47 (33.8%)	93 (34.8%)	97 (38.3%)
	3	225 (34.1%)	50 (36.0%)	89 (33.3%)	86 (34.0%)
	4	27 (4.1%)	6 (4.3%)	9 (3.4%)	12 (4.7%)
	5	19 (2.9%)	2 (1.4%)	10 (3.7%)	7 (2.8%)
一般・全身障害および投与部位の状態					
- Overall -	- Any Grade -	406 (61.6%)	80 (57.6%)	158 (59.2%)	168 (66.4%)
	1	195 (29.6%)	40 (28.8%)	77 (28.8%)	78 (30.8%)
	2	165 (25.0%)	34 (24.5%)	58 (21.7%)	73 (28.9%)
	3	42 (6.4%)	6 (4.3%)	21 (7.9%)	15 (5.9%)
	4	1 (0.2%)	0	1 (0.4%)	0
	5	3 (0.5%)	0	1 (0.4%)	2 (0.8%)
疲労	- Any Grade -	203 (30.8%)	45 (32.4%)	74 (27.7%)	84 (33.2%)
	1	100 (15.2%)	22 (15.8%)	38 (14.2%)	40 (15.8%)
	2	88 (13.4%)	20 (14.4%)	29 (10.9%)	39 (15.4%)
	3	15 (2.3%)	3 (2.2%)	7 (2.6%)	5 (2.0%)
発熱	- Any Grade -	107 (16.2%)	18 (12.9%)	45 (16.9%)	44 (17.4%)
	1	76 (11.5%)	14 (10.1%)	29 (10.9%)	33 (13.0%)
	2	26 (3.9%)	4 (2.9%)	13 (4.9%)	9 (3.6%)
	3	5 (0.8%)	0	3 (1.1%)	2 (0.8%)
無力症	- Any Grade -	71 (10.8%)	13 (9.4%)	24 (9.0%)	34 (13.4%)
	1	33 (5.0%)	8 (5.8%)	10 (3.7%)	15 (5.9%)
	2	29 (4.4%)	3 (2.2%)	11 (4.1%)	15 (5.9%)
	3	9 (1.4%)	2 (1.4%)	3 (1.1%)	4 (1.6%)

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