23 April 2026
EMADOC-1700519818-2944627
Human Medicines Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Tecentriq

Atezolizumab

Procedure no: EMA/PAM/0000327007

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

Status of this report and steps taken for the assessment			
Current step	**Description**	**Planned date**	**Actual Date**
☐	Submission deadline	10 February 2026	10 February 2026
☐	Start date	23 February 2026	23 February 2026
☐	CHMP Rapporteur AR	30 March 2026	1 April 2026
☐	CHMP comments	13 April 2026	N/A
☐	Updated CHMP Rapporteur AR	16 April 2026	N/A
☒	CHMP outcome	23 April 2026	23 April 2026

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1. Introduction

On 3 February 2026, the MAH submitted a completed paediatric study for Tecentriq, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended. Study BO41932 was not part of an approved Paediatric Investigational Plan (PIP) for Tecentriq (atezolizumab).

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that BO41932 (TAPISTRY) is a standalone study.

2.2. Information on the pharmaceutical formulation used in the study

Atezolizumab was administered by intravenous (IV) infusion at a fixed dose of 1200 mg.

2.3. Clinical aspects

2.3.1. Introduction

Study BO41932 is a Phase II, global, multicentre, open-label, multicohort study designed to evaluate the efficacy and safety of targeted therapies or immunotherapy as single agents or in rational, specified combinations, in patients with unresectable, locally advanced or metastatic solid tumours determined to harbour specific oncogenic genomic alterations or who are Tumour Mutational Burden (TMB)-high as identified by a validated next generation sequencing (NGS) assay. Cohort D was specifically designed to evaluate atezolizumab in adults and paediatric patients (from birth to < 18 years).

However, Study BO41932 was not part of an approved Paediatric Investigational Plan (PIP) for Tecentriq (atezolizumab).

While the study BO41932 is still ongoing, the LPLV for Cohort D occurred on 15 July 2025. Thus, the final analysis for Cohort D from the first enrolled patient (5 February 2021) to LPLV for Cohort D presented in the final clinical study report (CSR) for Cohort D (Study BO41932 Synopsis CSR) is submitted now with this package to ensure the sharing of information regarding the paediatric patient is not delayed until the completion of the study.

The MAH submitted a final report for:

• BO41932 (TAPISTRY – Cohort D) Tumour-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational For You (TAPISTRY) Phase II Platform Trial.

2.3.2. Clinical study

BO41932 (TAPISTRY – Cohort D) Tumour-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational For You (TAPISTRY) Phase II Platform Trial.

Description

TAPISTRY is a Phase II, global, multicentre, open label, multicohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in patients with unresectable, locally advanced or metastatic solid tumours determined to

harbour specific oncogenic genomic alterations or who are tumour mutational burden (TMB) high as identified by a validated next generation sequencing (NGS) assay.

The overarching structure of the TAPISTRY study is a platform interventional study in which patients with solid tumours are treated with a drug or drug regimen tailored to their NGS assay results at screening.

This CSR reports the methods and results for patients with TMB-high (≥ 16 and ≥ 13 mutations per megabase) tumours assigned to Cohort D who received atezolizumab.

Methods

Study participants

150 patients (150 patients were enrolled in the study; of which 148 patients received at least one dose of study treatment). This study enrolled patients aged ≥ 18 years and paediatric patients (any patients < 18 years old) with TMB-high (≥ 13 mutations per megabase) advanced or metastatic solid tumours.

Treatments

Atezolizumab was administered by intravenous (IV) infusion at a fixed dose of 1200 mg for patients aged ≥ 18 years, and 15 mg/kg (maximum 1200 mg) for patients aged <18 years on Day 1 of each 21-day cycle until unacceptable toxicity or loss of clinical benefit as determined by the investigator. For patients who receive the 15 mg/kg dose, the dose administered was within 5% of the calculated dose to accommodate for any rounding that may need to occur.

Patients in Cohort D received atezolizumab until disease progression, loss of clinical benefit, unacceptable toxicity or consent withdrawal.

Objectives and Endpoints

Objectives	Endpoints	Statistical Analyses
Primary Efficacy Objective		
• To evaluate the efficacy of atezolizumab in patients with TMB-high (☐ 16 mutations per megabase) advanced or metastatic solid tumours (for tumour types that are assessed by RECIST v1.1)	• IRC-assessed ORR based on confirmed (☐ 4 weeks after initial documentation of response) objective response (per RECIST v1.1)	• An estimate of the ORR and its 95% CI was calculated (estimated using the Clopper-Pearson method) for comparison with the expected ORR with standard of care treatment.
Secondary Efficacy Objectives		
• To evaluate the efficacy of atezolizumab in patients with TMB-high (☐ 16 and ☐ 13 mutations per megabase) advanced or metastatic solid tumours (for tumour types that are assessed by RECIST v1.1)	• For TMB-high (☐ 13 mutations per megabase) tumours, IRC-assessed ORR based on confirmed (☐ 4 weeks after initial documentation of response) objective response (per RECIST v1.1)	• The secondary efficacy endpoints included: – ORR for the TMB-high (☐ 13 mutations per megabase) cohort, IRC-assessed duration of response (DOR), clinical benefit rate (CBR), and PFS per RECIST v1.1; investigator-assessed ORR, DOR, CBR, and PFS per RECIST v1.1; – IRC- and investigator-assessed time to CNS progression per RECIST v1.1;
	• IRC-assessed DOR, CBR, and PFS per RECIST v1.1	
	• INV-assessed ORR, DOR, CBR, and PFS per RECIST v1.1	

Objectives	Endpoints	Statistical Analyses
	• IRC- and INV-assessed time to CNS progression per RECIST v1.1	– IRC- and investigator-assessed CNS-ORR, CNS-DOR, CNS-CBR, and CNS-PFS per RANO in patients with primary CNS tumours at baseline; – IRC- and investigator-assessed ORR, DOR, CBR, and PFS per INRC;
	• OS	
Objectives	**Endpoints**	**Statistical Analyses**
• To evaluate the efficacy of atezolizumab in patients with TMB-high primary CNS tumours at baseline	• IRC-assessed CNS-ORR, CNS-DOR, CNS-CBR, and CNS-PFS per RANO	– IRC- and investigator-assessed intracranial (IC)-ORR, IC-DOR, IC-CBR, and IC-PFS per RECIST v1.1 in patients with CNS metastases at baseline; – Overall survival (OS); and – EORTC scores for both TMB-high cohorts
	• INV-assessed CNS-ORR, CNS-DOR, CNS-CBR, and CNS-PFS per RANO	
• To evaluate the efficacy of atezolizumab in patients with TMB-high advanced or metastatic neuroblastoma	• IRC-assessed ORR, DOR, CBR, and PFS per INRC	
	• INV-assessed ORR, DOR, CBR, and PFS per INRC	
• To evaluate the efficacy of atezolizumab in the subgroup of patients with TMB-high solid tumours with CNS metastases at baseline	• IRC-assessed IC-ORR, IC-DOR, IC-CBR, IC-PFS rate per RECIST v1.1	
	• INV-assessed IC-ORR, IC-DOR, IC-CBR, IC-PFS per RECIST v1.1	
• To evaluate the impact of atezolizumab on PROs of function and symptoms in patients with TMB-high advanced or metastatic solid tumours	• Descriptive endpoints of time to confirmed deterioration, change from baseline, proportion of patients with a clinical meaningful change on the Global Health Status, Physical Functioning, and Role Functioning scores from the EORTC QLQ-C30	
	• Descriptive endpoint of time to confirmed symptom onset or worsening from tumour-related symptom scores from the EORTC QLQ-C30 and EORTC IL71	
Objectives	**Endpoints**	**Statistical Analyses**
Safety Objective		
• To evaluate the safety and tolerability of atezolizumab in patients with TMB-high solid tumours	• Incidence, type, and severity of adverse events (based on the NCI CTCAE v5.0), including serious adverse events	• Descriptive statistics of patient numbers and percentages, severity was graded according to NCI CTCAE v5.0
Pharmacokinetic Objective		
• To characterize the pharmacokinetics of atezolizumab	• Serum concentration of atezolizumab at specified timepoints	• PK analyses are not available because the cohort was closed before the bioanalysis of PK samples were completed.

Objectives	Endpoints	Statistical Analyses
Immunogenicity Objectives		
• To evaluate the immune response to atezolizumab	• Incidence of ADAs during the study relative to the prevalence of ADAs at baseline	• Immunogenicity analyses are not available because the cohort was closed before the bioanalysis of ADA samples were completed.
• To evaluate the potential effects of ADAs	• Relationship between ADA status and efficacy, safety, or pharmacokinetic endpoints	

ADA ☐ anti-drug antibody; CBR ☐ clinical benefit rate; CSR ☐ Clinical Study Report; ctDNA ☐ circulating tumour DNA; DOR ☐ duration of response; EORTC ☐ European Organization for Research and Treatment of Cancer; EORTC IL71☐European Organization for Research and Treatment of Cancer Item Library 71; IC ☐ intracranial; INRC ☐ International Neuroblastoma Response Criteria; INV ☐ investigator; IRC ☐ Independent Review Committee; NCI CTCAE v5.0 ☐ National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0; NGS ☐ next-generation sequencing; ORR ☐ objective response rate; OS ☐ overall survival; PFS ☐ progression-free survival; PK = pharmacokinetics; RANO ☐ Response Assessment in Neuro-Oncology; RECIST v1.1 ☐ Response Evaluation Criteria in Solid Tumours, Version 1.1; TMB ☐ tumour mutational burden.

PRO objectives/endpoints are not included in this CSR due to the synoptic nature of this report.

Results

Participant flow

As of the LPLV of 15 July 2025, a total of 150 patients were enrolled in Cohort D; of which 98.7% (148 patients) received at least one dose of atezolizumab. A total of 148 patients discontinued from study treatment and all patients (i.e., 150 patients) discontinued from study. The most common reasons (≥10% of patients) for study treatment discontinuation were progressive disease (35.8% patients); physician decision (25.7% patients) and cohort terminated by Sponsor (10.1% patients). The most common reasons (≥10% of patients) for study discontinuation were death (62.0% patients) and cohort terminated by Sponsor (26.7% patients). A total of 114 patients who had received treatment participated in long-term survival follow-up. Median duration of survival follow up was 14.4 months (range: 0-47 months).

Populations analysed

There were three analysis populations:

Intent to Treat (ITT) Population (150 patients): The ITT Population consists of all patients enrolled in Cohort D.

Safety Evaluable Population (148 patients): The safety evaluable population is defined as all enrolled patients who received at least one dose of study treatment.

Efficacy Evaluable (EE) Population (129 patients): The efficacy evaluable population is defined as all enrolled patients who: have tumours that express the biomarker definition per protocol, primary tumour is an extracranial solid tumour, measurable disease by RECIST v1.1 per IRC, not previously treated with protocol mentioned exclusion criteria with agents of the same molecular targets, have received at least one dose of study treatment, and Eastern Cooperative Oncology Group Performance Status (ECOG PS) defined by the cohort-specific eligibility criteria.

Protocol deviations

A total of 40 of 150 enrolled patients (26.7%) had at least one major protocol deviation. The most frequent protocol deviations (that occurred in ≥2% of patients) were:

- Other proc. deviation for safety and/or efficacy (5.3% patients)

- Failure to report SAEs or pregnancy per protocol, informed consent form (ICF)/assent - other (e.g. procedural issues), and omission of baseline tumour assessments (4% patients each)
- Omission of lab test req. by protocol, and tumour assessment not done or out of window (2.7% patients each)
- Continuation of study Tx in conflict with protocol (2% patients)

Demographic and other baseline characteristics.

Demographic Data (Safety Evaluable Population)

Of 148 treated patients in the safety evaluable population, 56.1% were male. The median age reported was 63 years with majority of patients (60.8%) in the 18-65 years of age category. The median weight at baseline was 69 kg. The majority of patients were "not Hispanic/Latino" (85.1% patients) by ethnicity and were "White" (62.2% patients) by race. The percentage of patients with an ECOG status at baseline of 0, 1 and 2 were 28.6%, 70.7% and 0.7%, respectively. The median number of mutations per megabase at enrolment was 24.5.

Baseline Disease Characteristics (Safety Evaluable Population)

The most frequent (≥ 5% of patients) types of cancer were colorectal cancer (29.1% patients); breast cancer and gastroesophageal cancer (8.8% patients each); hepatobiliary cancer and prostate cancer (6.1% patients each) and occult primary or cancer of unknown primary (5.4% patients). The median time from initial diagnosis to study start was 22.6 months (range: 1-252 months). The majority of patients (95.3%) had metastatic disease. The following proportions of patients by metastasis type at study entry were observed: liver: 46.6%, lung: 39.2%, bone: 25.0%, and central nervous system (CNS): 7.4%.

Exposure

The median treatment duration was 3.5 months (range: 0.0-46.8 months) with atezolizumab in safety evaluable population. The median number of cycles were 6 (range: 1.0-68.0) and 53 patients (35.8% patients) received more than 10 cycles. The median dose intensity (defined as the sum of actual dose divided by the planned dose) was 99.4% (range: 50.7%-107.7%).

Efficacy results

Cohort D of Study BO41932 met its primary endpoint. The IRC assessed- ORR (primary endpoint) in 'the TMB-high (≥16 mutations per megabase) efficacy evaluable population was 24.1% (95% CI: 16.53, 33.10) with a lower bound of the associated 95% CI that excluded 10%. Summary of efficacy results are presented in Table 1 and Table 2.

This corresponded to 27 responders (5 of complete response and 22 of partial response) among the 112 TMB-high (≥ 16 mutations per megabase) efficacy evaluable patients. These responses were observed in following tumour types: colorectal cancer (6 of 35 patients); gastroesophageal cancer (4 of 11 patients); hepatobiliary cancer (1 of 9 patients); occult primary or cancer of unknown primary (2 of 6 patients); prostate cancer (2 of 6 patients); non-melanoma skin cancer (1 of 5 patients); endometrial/uterine cancer (2 of 4 patients); neuroendocrine and adrenal cancer (2 of 4 patients); non-small cell lung cancer (2 of 4 patients); pancreatic cancer (2 of 4 patients); sarcoma (2 of 4 patients); and cervical cancer (1 of 3 patients).

The median survival -follow-up duration in the TMB-high (≥ 16 mutations per megabase) efficacy evaluable population was 13.7 months (range: 1-47 months).

Table 1. Overview of Efficacy Results by RECIST v1.1 (EE Population)

Endpoints	Atezolizumab TMB High	
	IRC-assessed	INV-assessed
Primary Efficacy Endpoint		
IRC assessed ORR by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Responders (%)	27 (24.1%)	NA
95% CI	(16.53, 33.10)	NA
Secondary Efficacy Endpoints		
IRC and INV assessed ORR by RECIST 1.1 (≥13 mutations per megabase) (N=129)		
Responders (%)	28 (21.7%)	31 (24.0%)
95% CI	(14.93, 29.82)	(16.95, 32.34)
INV assessed ORR by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Responders (%)	NA	30 (26.8%)
95% CI	NA	(18.86, 35.98)
IRC and INV assessed DOR by RECIST 1.1 (≥13 mutations per megabase) (N=129)		
Responders	28	31
Median DOR,-months (95% CI)	NE (20.76, NE)	40.64 (40.64, NE)
IRC and INV assessed DOR by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Responders	27	30
Median DOR,-months (95% CI)	NE (20.76, NE)	40.64 (40.64, NE)
IRC and INV assessed PFS by RECIST 1.1 (≥13 mutations per megabase) (N=129)		
Patients with event (%)	103 (79.8%)	100 (77.5%)
Median time to PFS event - months (95% CI)	2.69 (1.54, 4.21)	2.83 (1.87, 4.44)
IRC and INV assessed PFS by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Patients with event (%)	86 (76.8%)	83 (74.1%)
Median time to PFS event - months (95% CI)	2.96 (1.68, 5.45)	3.94 (2.56, 5.45)
IRC and INV assessed CBR by RECIST 1.1 (≥13 mutations per megabase) (N=129)		
Responders (%)	39 (30.2%)	42 (32.6%)
95% CI	(22.46, 38.94)	(24.57, 41.36)
IRC and INV assessed CBR by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Responders (%)	37 (33.0%)	39 (34.8%)
95% CI	(24.44, 42.56)	(26.07, 44.40)
IRC and INV assessed Time to CNS Progression by RECIST 1.1 (≥13 mutations per megabase) (N=129)		

Endpoints	Atezolizumab TMB High	
	IRC-assessed	INV-assessed
Patients with event (%)	79 (61.2%)	79 (61.2%)
Median time to CNS Progression - months (95% CI)	10.09 (8.11, 16.39)	10.35 (8.28, 16.49)
IRC and INV assessed Time to CNS Progression by RECIST 1.1 (≥16 mutations per megabase) (N=112)		
Patients with event (%)	67 (59.8%)	67 (59.8%)
Median time to CNS Progression - months (95% CI)	10.35 (8.28, 20.96)	10.35 (8.44, 20.96)
Assessor-Independent Endpoint		
OS (≥13 mutations per megabase) (N=129)		
Patients with event (%)	79 (61.2%)	
Median time to OS event - months (95% CI)	15.64 (9.43, 21.55)	
OS (≥16 mutations per megabase) (N=112)		
Patients with event (%)	67 (59.8%)	
Median time to OS event - months (95% CI)	16.39 (9.43, 21.98)	

CBR=clinical benefit rate; CNS=central nervous system; DOR=duration of response; EE=efficacy evaluable; IRC=Independent Review Committee; INV=investigator; NA=not applicable; ORR=objective response rate; OS=overall survival; PFS=progression free survival; RECIST 1.1=Response Evaluation Criteria in Solid Tumors, Version 1.1; TMB=tumor mutational burden

Table 2. Overview of Efficacy Results by RANO (CNS Evaluable Population)

Endpoints	Atezolizumab All Grades (N = 5)	
	IRC-assessed	INV-assessed
Secondary Efficacy Endpoints		
IRC and INV assessed ORR by RANO (≥16 mutations per megabase)		
Responders (%)	0	0
95% CI	(0.00, 52.18)	(0.00, 52.18)
IRC and INV assessed DOR* by RANO (≥16 mutations per megabase)		
Responders	NA	NA
Median DOR-months (95% CI)	NA	NA
IRC and INV assessed PFS by RANO (≥16 mutations per megabase)		
Patients with event (%)	5 (100%)	5 (100%)
Median time to PFS event - months (95% CI)	1.41 (1.31, NE)	1.41 (1.38, NE)
IRC and INV assessed CBR by RANO (≥16 mutations per megabase)		
Responders (%)	0	1 (20.0%)
95% CI	(0.00, 52.18)	(0.51, 71.64)

CBR = clinical benefit rate; CNS = central nervous system; DOR = duration of response; EE = efficacy evaluable; IRC = Independent Review Committee; INV = investigator;; NA = not applicable; NE = not evaluable; ORR = objective response rate; OS = overall survival; PFS = progression free survival; RANO = Response Assessment in Neuro-Oncology; TMB = tumor mutational burden

*Please note, no observations met the reporting criteria for inclusion in this output.

Safety results

Overall, the safety results observed in Cohort D were consistent with the known safety profile of atezolizumab and no new safety signals were identified. An overview of key safety data is provided in Table 3.

Table 3. Overview of Safety Results (SE Population)

Overview of Deaths and Adverse Events, Cohort D, Safety Evaluable Population
Protocol: BO41932 - Clinical Cutoff Date: Jul 15, 2025

	ATEZOLIZUMAB (N=148)
Total number of patients with at least one AE	138 (93.2%)
Total number of AEs	1300
Total number of deaths	93 (62.8%)
Total number of patients withdrawn from treatment due to an AE	3 (2.0%)
Total number of patients withdrawn from study due to an AE	0
Total number of patients with at least one	
AE with fatal outcome	6 (4.1%)
Serious AE	49 (33.1%)
Related Serious AE	9 (6.1%)
AE leading to dose reduction/interruption	50 (33.8%)
AE leading to dose reduction	0
AE leading to dose interruption	50 (33.8%)
Related AE leading to dose reduction/interruption	15 (10.1%)
Related AE leading to dose reduction	0
Related AE leading to dose interruption	15 (10.1%)
AE leading to withdrawal from treatment	6 (4.1%)
Serious AE leading to withdrawal from treatment	4 (2.7%)
Related AE leading to withdrawal from treatment	3 (2.0%)
AE leading to withdrawal from study	6 (4.1%)
Serious AE leading to withdrawal from study	6 (4.1%)
Related AE leading to withdrawal from study	0
Related AE	80 (54.1%)
Grade 3-5 AE	67 (45.3%)
Related Grade 3-5 AE	14 (9.5%)

The number of patients withdrawn from treatment/study due to an AE is derived from the reason for discontinuation on the disposition CRF. The number of patients with at least one AE leading to withdrawal from treatment/study is derived from the Action taken on the Adverse Event CRF.
Snapshot: Sep 18, 2025

Analysis of all Adverse Events

Overall, 138 of 148 patients (93.2% patients) treated with atezolizumab experienced at least one AE of any grade. The most frequently reported AEs by system organ class (SOC) (≥25% of patients) were gastrointestinal disorders (54.7% patients); general disorders and administration site conditions (48.0% patients); infections and infestations (39.9% patients); musculoskeletal and connective tissue disorders (36.5% patients); metabolism and nutrition disorders (35.1% patients); blood and lymphatic system disorders, and investigations (32.4% patients each); and skin and subcutaneous tissue disorders (27.7% patients). The most frequently reported AEs by preferred term (PT) (≥ 15% patients) were fatigue (24.3% patients); anaemia (20.9% patients); diarrhoea (17.6% patients); pyrexia (17.6% patients); and decreased appetite (16.9% patients).

Adverse Events Related to Study Treatment

A total of 80 of 148 patients (54.1%) treated with atezolizumab experienced at least one AE which was considered related to study treatment by investigator. The most frequently reported treatment related AEs by SOC (≥ 10% of patients) were skin and subcutaneous tissue disorders (20.9% patients); general disorders and administration site conditions (20.3% patients); gastrointestinal disorders (15.5% patients); endocrine disorders (13.5% patients); and investigations (12.8% patients). The most frequently reported treatment related AEs by PT (≥ 5% of patients) were pruritus (11.5%

patients); fatigue (10.8% patients); hypothyroidism (10.1% patients); diarrhoea (6.1% patients); alanine aminotransferase increased, aspartate aminotransferase increased and decreased appetite (5.4% patients each).

Adverse Events by Intensity

Overall, 45.3% of patients treated with atezolizumab had at least one Grade 3-5 AE and 9.5% of patients had at least one treatment related Grade 3-5 AE. The most common Grade 3-5 AEs by PT (≥ 2% of patients) were anaemia (6.8% patients); fatigue, alanine aminotransferase increased (3.4% patients); abdominal pain, pneumonia (2.7% patients each); and ascites, diarrhoea, aspartate aminotransferase increased, acute kidney injury (2.0% patients each). The most common treatment related Grade 3-5 AEs by PT (≥ 1% of patients) were abdominal pain and fatigue (1.4% patients each). A total of 4.1% of patients (6 patients) reported 6 Grade 5 AEs; cardiac failure, cardio-respiratory arrest, myocardial infarction, death, sepsis, and renal failure, and all these AEs were considered unrelated to study treatment.

Deaths

A total of 93 deaths were reported in Cohort D. The most common reasons for deaths were progressive disease (84.9% [79 patients]), followed by adverse events (6.5% [6 patients]), other (5.4% [5 patients]), and missing/unknown (3.2% [3 patients]).

Serious Adverse Events

Overall, 33.1% of patients treated with atezolizumab had at least one SAE and 6.1% of patients had at least one treatment related SAE. The most common SAEs by SOC (≥5% of patients) were gastrointestinal disorders and infections and infestations (8.8% patients each); and general disorders and administration site conditions (5.4% patients). The most common SAEs by PT (≥ 2% of patients) were pyrexia (2.7% patients); pneumonia and acute kidney injury (2.0% patients each). The most common treatment related SAE by PT (≥ 1% of patients) was pyrexia (1.4% patients).

The number of patients withdrawn from treatment/study due to an AE is derived from the reason for discontinuation on the disposition CRF. The number of patients with at least one AE leading to withdrawal from treatment/study is derived from the action taken on the adverse event CRF.

Adverse Events That Led to Dose Modification (Dose Interruption)

Overall, 33.8% of patients treated with atezolizumab had at least one AE that led to dose interruption. The most frequent AEs by PT that lead to dose interruption (≥ 2% of patients) were COVID-19 (5.4% patients); upper respiratory tract infection and pyrexia (2.7% patients each); respiratory tract infection, urinary tract infection, abdominal pain, diarrhoea, asthenia, fatigue, and anaemia (2.0% patients each).

Selected Adverse Events

Selected AEs for additional analysis were chosen on the basis of prior experience with atezolizumab. Overall, 50.7% of patients reported 283 Selected AEs. The most common Selected AEs by category (≥5% of patients) were:

- Immune-Mediated Hepatitis (Diagnosis and Lab Abnormalities): 20.9% patients
- Immune-Mediated Hepatitis (Lab Abnormalities): 19.6% patients
- Immune-Mediated Rash: 13.5% patients
- Immune-Mediated Hypothyroidism: 12.8% patients

- COVID-19: 11.5% patients
- Confirmed COVID-19: 11.5% patients
- Immune-Mediated Hepatitis (Diagnosis): 6.8% patients

Immune-Mediated Hepatitis (Diagnosis and Lab Abnormalities)

Overall, 20.9% of patients reported 80 AEs of immune-mediated hepatitis (diagnosis and lab abnormalities). The most frequent AEs by PT (≥5% of patients) in this category were alanine aminotransferase increased and aspartate aminotransferase increased (10.1% patients each).

Immune-Mediated Hepatitis (Lab Abnormalities)

Overall, 19.6% of patients reported 75 AEs of immune-mediated hepatitis (lab abnormalities). The most frequent AEs by PT (≥5% of patients) in this category were alanine aminotransferase increased and aspartate aminotransferase increased (10.1% patients each).

Immune-Mediated Hypothyroidism

Overall, 12.8% of patients reported 22 AEs of immune-mediated hypothyroidism. The most frequent AE by PT (≥ 5% of patients) in this category was hypothyroidism (11.5% patients).

COVID-19

Overall, 11.5% of patients reported 20 COVID-19 AEs. All the events were non-serious (Grade 1 or 2) and reported as not related to study drug. The AE duration ranged from 2-32 days. All the events reported event outcome as recovered (11 AEs recovered without any treatment, while 9 AEs recovered with treatment). In 9 AEs the event led to drug interruption, while none of the events led to drug withdrawal.

Potential Hy's Law Cases (Laboratory Criteria)

Two patients potentially met Hy's law laboratory criteria.

2.3.3. Discussion on clinical aspects

The applicant concludes that Cohort D of Study BO41932 met its primary endpoint, and atezolizumab demonstrated antitumor activity in the efficacy evaluable population across a range of tumour types. Overall, the safety results observed in Cohort D were consistent with the known safety profile of atezolizumab and no new safety signals were identified. There was minor impact on the Cohort D of the study due to the COVID-19 pandemic.

3. Overall conclusion and recommendation

The MAH has provided a final synopsis clinical study report for study BO41932 (TAPISTRY Cohort D); a Tumour-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational For You (TAPISTRY) Phase II Platform Trial. This is not a part of a PIP. The MAH has also informed that this final report is provided in synopsis format due to sponsor decision to not pursue further development of atezolizumab in the indication. Thus, the information and results provided is noted and nothing further is required.

☒ **Fulfilled:**

No regulatory action required.

Annex. Line listing of all the studies included in the development program

Clinical studies

Product Name: Active substance:

Study title	Study number	Date of completion	Date of submission of final study report
(TAPISTRY – Cohort D) Tumour-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational For You (TAPISTRY) Phase II Platform Trial.	BO41932	COHORT D 15 July 2025	3 Feb 2026