TECENTRIQ®
Konzentrat zur Herstellung einer Infusionslösung, 1200mg/20ml, 840mg/14ml
Zul.-Nr. 66’152

Public Risk Management Plan (RMP) Summary

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Roche Pharma (Schweiz) AG
Gartenstrasse 9
CH-4052 Basel
pharma.schweiz@roche.com
www.roche.ch/pharma
Tel. +41 61 715 41 11

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of “Tecentriq” is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of “Tecentriq” in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. “Roche Pharma (Schweiz) AG” is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Tecentriq”.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR TECENTRIQ (ATEZOLIZUMAB)

This is a summary of the risk management plan (RMP) for Tecentriq. The RMP details important risks of Tecentriq, how these risks can be minimized, and how more information will be obtained about Tecentriq's risks and uncertainties (missing information).

Tecentriq's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tecentriq should be used.

This summary of the RMP for Tecentriq should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tecentriq's RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Tecentriq contains atezolizumab as the active substance and it is given by intravenous route of administration.

Tecentriq contains the active ingredient atezolizumab and is administered for treatment by intravenous infusion. The recommended dosage is either 840 mg every two weeks, 1,200 mg every three weeks or 1,680 mg every four weeks depending on the indication.

Monotherapy

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC)

- after prior platinum-containing chemotherapy, or
- who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression ≥ 5%.

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC should also have received targeted therapies before receiving Tecentriq.

Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumours have a PD-L1 expression ≥50% tumour cells (TC) or ≥10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC.

Tecentriq as monotherapy is indicated as adjuvant treatment following complete resection and platinum-based chemotherapy for adult patients with NSCLC with a high risk of recurrence whose tumours have PD-L1 expression on ≥50% of tumour cells (TC) and who do not have EGFR mutant or ALK-positive NSCLC.

Combination Therapy

Tecentriq, in combination with bevacizumab, is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC who do not have EGFR mutant or ALK-positive NSCLC.

Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC. In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies.

Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease.

Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Further information about the evaluation of Tecentriq's benefits can be found in Tecentriq's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage (https://www.ema.europa.eu/en/medicines/human/EPAR/tecentriq).

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Tecentriq, together with measures to minimize such risks and the proposed studies for learning more about Tecentriq's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In the case of Tecentriq, these measures are supplemented with ***additional risk-minimization*** measures mentioned under relevant risks below.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed: including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute ***routine pharmacovigilance activities***.

If important information that may affect the safe use of Tecentriq is not yet available, it is listed under 'Missing Information' below.

II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Tecentriq are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Tecentriq. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information about the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	Immune-mediated adverse reactions Infusion-related reactions
Important potential risks	Attenuated efficacy or reduced tolerability in patients with anti-drug antibodies Embryo-fetal toxicity
Missing information	Long term use

II.B SUMMARY OF IMPORTANT RISKS

Important identified risk: Immune-mediated adverse reactions

Important identified risk: Hepatitis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	There are no identified risk factors for the development of immune-mediated hepatitis in atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Pneumonitis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	General factors that may be associated with an increased risk of drug-induced ILD include: older age, male sex, pre-existing lung disease, smoking, prior radiation therapy, prior or concomitant treatment with medications with known pulmonary toxicity (e.g., some antimicrobial, anti-inflammatory and cardiovascular agents, biologics, and chemotherapeutics), inflammatory conditions (e.g., rheumatoid arthritis and inflammatory bowel disease). The underlying malignant disease itself may also increase the risk of pneumonitis and be a confounder of diagnosis (Barber et al. 2011; Schwaiblmair et al. 2012). There are currently no known risk factors that may predispose individual patients to develop immunemediated pneumonitis following treatment with atezolizumab.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use

	Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Colitis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	There are currently no known risk factors that may predispose individual patients to develop immunemediated colitis following treatment with atezolizumab.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Pancreatitis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	Female sex, younger age, and pre-existing inflammatory bowel disease may be associated with an increased risk of drug-induced pancreatitis (Vinklerova et al. 2010; Nitsche et al. 2012). There are currently no known risk factors that may predispose individual patients to develop immunemediated pancreatitis following treatment with atezolizumab.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration

	Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Endocrinopathies (Diabetes Mellitus, Hypothyroidism, Hyperthyroidism, Adrenal Insufficiency, and Hypophysitis)	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	An Italian study of adults between age 30 and 49 years found that the risk of type 1 diabetes was almost two times higher in males compared with females (rate ratio [RR] 1.70 [95% CI 1.21, 2.38]) (Bruno et al. 2005). There are currently no known risk factors that may predispose individual patients to develop immune-mediated diabetes following treatment with atezolizumab. There are no known risk factors associated with the development of immune-mediated hypo- or hyperthyroidism, adrenal insufficiency, or hypophysitis in individual atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Neuropathies (Guillain-Barré Syndrome and Myasthenic Syndrome/Myasthenia Gravis, and Facial Paresis)	
Evidence for linking the risk to the	**Guillain-Barré Syndrome and Myasthenic**

medicine	**Syndrome/Myasthenia Gravis** Clinical trial data **Facial Paresis** Based on a comprehensive analysis of all the cases retrieved from the Roche global drug safety database reported with facial paresis in patients who received treatment with atezolizumab, as well as available data from the clinical database, FAERS and EV databases, preclinical studies, published literature and considering the plausible mechanism of action and the known class effect of similar-in-class drugs, a causal association between atezolizumab and facial paresis has been established.
Risk factors and risk groups	There are no known risk factors associated with the development of immune-mediated neuropathies in atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Myelitis	
Evidence for linking the risk to the medicine	Based on a comprehensive analysis of all the cases retrieved from the Roche global drug safety database reported with myelitis and related events in patients who received treatment with atezolizumab, as well as available data from the clinical database, FAERS and EV databases, preclinical studies, published literature and considering the plausible mechanism of action and the known class effect of similar-in-class drugs, a causal association between atezolizumab and myelitis has been established.
Risk factors and risk groups	There are no identified risk factors for the development of immune-mediated myelitis in atezolizumab treated patients.

Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Meningoencephalitis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	There are no known risk factors associated with the development of immune-mediated meningoencephalitis in atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Myocarditis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	There are no known risk factors associated with the development of immune-mediated myocarditis in atezolizumab-treated patients
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the

	following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Nephritis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	Risk factors include certain infections, drugs (including antibiotics, non-steroidal anti-inflammatory drugs, proton pump inhibitors) and autoimmune diseases such as Sjögren's syndrome, and immunoglobulin G4 related disease (Muriithi et al. 2014). The risk factors that may predispose individual patients to developing immune-mediated nephritis following therapy with immune checkpoint inhibitors are unknown
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Myositis	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	Like other autoimmune diseases, genes and environment/lifestyle factors are likely to contribute to susceptibility to myositis. Multiple independent associations

	within the HLA 8.1 ancestral haplotype are the strongest genetic risk factors for idiopathic inflammatory myopathies. Epidemiological data support a role for infections, prior lung disease, physical exertion, collagen implants, exposure to ultraviolet radiation and smoking in the development of inflammatory myopathies. Females were found to be more prone to develop polymyositis and dermatomyositis, while males were more prone to develop inclusion body myositis. Drugs such as statins, D-penicillamine, interferon-α, and procainamide were found to be associated with myositis. The risk of developing myositis is found to increase with age and peaks in patients aged between 50 to 79 years (Svensson et al. 2017).
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Severe Cutaneous Adverse Reactions	
Evidence for linking the risk to the medicine	Based on a comprehensive analysis of all the cases retrieved from the Roche global drug safety database reported under the Standardized MedDRA Query (SMQ) (narrow) 'severe cutaneous adverse reactions' in patients who received treatment with atezolizumab as well as available data from the clinical database, literature (Zhao et al. 2018; Raschi et al. 2019; Jimenez et al. 2020), and EudraVigilance database with a cut-off date of 31 July 2020 and considering the plausible mechanism of action and background of Severe Cutaneous Adverse Reactions (SCARs) as a known class effect, a causal association between atezolizumab and SCARs has been established. As such, SCARs was updated from a potential risk to an important identified risk.

Risk factors and risk groups	There are no known risk factors associated with the development of SCARs in atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Direct Healthcare Professional Communication (DHPC): To inform healthcare professionals that immune-mediated SCARs which were previously known to be potentially associated with use of Tecentriq (atezolizumab), are now considered to be an identified risk.
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** Metrics on the distribution and receipt of the DHPC will be taken to assess the effectiveness of this risk minimization activity.

Important identified risk: Pericardial Disorders	
Evidence for linking the risk to the medicine	Based on a comprehensive analysis of all the cases retrieved from the Roche global drug safety database reported with the PTs autoimmune pericarditis, cardiac tamponade, pericarditis, pericarditis constrictive, pericardial disease and pericardial effusion in patients who received treatment with atezolizumab as well as available data from the clinical database, FDA Adverse Event Reporting System (FAERS) and EudraVigilance (EV) databases, published literature with a cut-off date of 29 April 2022 and considering the plausible mechanism of action and the class effect of similar-in-class drugs, a causal association between atezolizumab and pericardial disorders has been established.
Risk factors and risk groups	The development of immune-mediated pericardial disorders may be higher in patients with lung, breast and oesophageal carcinoma due to direct local extension to the parietal pericardium and in patients treated with chest radiotherapy (Burazor et al. 2013).
Risk minimization measures	**Routine risk minimization measures:**

	Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Hemophagocytic Lymphohistiocytosis	
Evidence for linking the risk to the medicine	Following an analysis of new cases of hemophagocytic lymphohistiocytosis (HLH) reported in the global safety database within the period between 18 May 2022 and 17 October 2022, one confirmed literature spontaneous case of HLH was identified with sufficient supportive diagnostic information (bone marrow biopsy, laboratory results, imaging, and autopsy) without alternative explanations for diagnosis or attribution identified. Based on potential mechanism of action, class effect of similar-in-class drugs, and considering that HLH is a rare, severe, and potentially fatal condition, a causal association between atezolizumab and HLH has been established.
Risk factors and risk groups	There are no identified risk factors for the development of HLH in atezolizumab treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 –Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important identified risk: Infusion-Related Reactions	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	Treatment with monoclonal antibodies is associated with an increased risk for infusion-related reactions. (Keating et al. 2014; Thompson et al. 2014). There are no known risk factors associated with the development of IRRs in atezolizumab-treated patients.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.2 Posology and method of administration Section 4.4 Special Warnings and Precautions for Use Section 4.8 – Undesirable effects Relevant information for patient in PIL **Additional risk minimization measures:** Patient cards
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important potential risk: Attenuated efficacy or reduced tolerability in patients with anti-drug antibodies	
Evidence for linking the risk to the medicine	Clinical trial data
Risk factors and risk groups	Risk factors for the development of ADAs are currently unknown.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.8 – Undesirable effects **Additional risk minimization measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Important potential risk: Embryo-fetal toxicity	
Evidence for linking the risk to the medicine	Literature and nonclinical studies

Risk factors and risk groups	The at-risk group for experiencing atezolizumab-related embryo-fetal toxicity includes female patients of child-bearing potential and developing fetuses who are exposed to atezolizumab during gestation.
Risk minimization measures	**Routine risk minimization measures:** Proposed measures are described in the E.U. SmPC under the following sections: Section 4.6 Fertility, pregnancy and lactation Section 5.3 Preclinical safety data **Additional risk minimization measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Missing Information: Long-term use	
Risk minimization measures	**Routine risk minimization measures:** Proposed text in E.U. SmPC None **Additional risk minimization measures:** Not applicable
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** Study MO29983

ADA=anti drug antibody; DHPC=Direct Healthcare Professional Communication; E.U.=European Union; EV=Eudravigilance; FAERS=FDA Adverse Event Reporting System; HLH=hemophagocytic lymphohistiocytosis; PIL= Product Information Leaflet; RMP=Risk Management Plan; SCAR=severe cutaneous adverse reaction; SmPC= Summary of Product Characteristics.

II.C POST-AUTHORISATION DEVELOPMENT PLAN

II.C.1 Studies which are conditions of the marketing authorization

The following studies are conditions of the marketing authorization:

GO29293 (IMvigor210): A Phase II, multicenter, single-arm study of atezolizumab in patients with locally advanced or metastatic urothelial bladder cancer.

Purpose of the study:

- To evaluate efficacy of atezolizumab in patients with locally advanced or metastatic UC as measured by ORR (primary objective), PFS, DOR, OS and 1-year OS
- To evaluate safety and tolerability of atezolizumab
- To evaluate the incidence of ADAs against atezolizumab and to explore the potential relationship of the immunogenicity response with pharmacokinetics, safety, and efficacy

WO30070 (IMvigor130): A Phase III, multicenter, randomized, placebo-controlled study of atezolizumab (anti-PD-L1 antibody) as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma

Purpose of the study:

- To evaluate the efficacy of atezolizumab plus platinum-based chemotherapy compared with placebo plus platinum-based chemotherapy on the basis of PFS and OS
- To evaluate the efficacy of atezolizumab given as either monotherapy or in combination with platinum-based chemotherapy compared with placebo in combination with platinum-based chemotherapy on the basis of various secondary endpoints
- To evaluate the efficacy of atezolizumab monotherapy compared with placebo plus platinum-based chemotherapy on the basis of OS
- To evaluate the safety and tolerability of atezolizumab given as either monotherapy or in combination with platinum-based chemotherapy compared with placebo plus platinum-based chemotherapy

II.C.2 Other studies in post-authorization development plan

MO29983 (SAUL): An open-label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract.

Purpose of study:

- To evaluate the safety of atezolizumab based on the following endpoints: Nature, severity, duration, frequency and timing of adverse events (AEs) and changes in vital signs, physical findings, and clinical laboratory results during and following atezolizumab administration.