独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Atezolizumab (genetical recombination)

November 26, 2025

Non-proprietary name

Atezolizumab (genetical recombination)

Brand name (marketing authorization holder)

Tecentriq for Intravenous Infusion 840 mg, Tecentriq for Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)

Japanese market launch

Tecentriq for Intravenous Infusion 840 mg: November 2019

Tecentriq for Intravenous Infusion 1200 mg: April 2018

Indications

<Common to both preparations>

○ Unresectable, advanced or recurrent non-small cell lung cancer

○ Postoperative adjuvant treatment for PD-L1 positive non-small cell lung cancer

○ Extensive stage small cell lung cancer

○ Unresectable alveolar soft part sarcoma

○ Recurrent or refractory extranodal NK/T-cell lymphoma/nasal type

< Tecentriq for Intravenous Infusion 1200 mg >

○ Unresectable hepatocellular carcinoma

< Tecentriq for Intravenous Infusion 840 mg >

○ PD-L1 positive, hormone receptor negative and HER2 negative inoperable or recurrent breast cancer

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Summary of revisions

"Haemolytic anaemia" should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS section.

Investigation results and background of the revision

Cases involving haemolytic anaemia were evaluated. Cases in which a causal relationship between atezolizumab (genetical recombination) and haemolytic anaemia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving haemolytic anaemia reported in Japan

A total of 16 cases have been reported to date (including 11 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported.

*: Cases collected in the PMDA's safety database for drugs

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).