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)

January 10, 2024

Non-proprietary name

Atezolizumab (genetical recombination)

Brand name (marketing authorization holder)

Tecentriq for Intravenous Infusion 840 mg, 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

<Tecentriq for Intravenous Infusion 1200 mg>

• 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 hepatocellular carcinoma

<Tecentriq for Intravenous Infusion 840 mg>

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

Summary of revisions

“Myelitis” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

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Cases involving myelitis were evaluated. Cases for which a causal relationship between atezolizumab (genetical recombination) and myelitis 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 myelitis reported in Japan and overseas

A total of 6 cases have been reported in Japan to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported in Japan to date.
A total of 16 cases have been reported overseas to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).
One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

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).