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 16, 2021

Non-proprietary name

Atezolizumab (genetical recombination)

Branded name (Marketing authorization holder)

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

Indications

<Tecentriq for Intravenous Infusion 840 mg>

· PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or metastatic breast cancer

<Tecentriq for Intravenous Infusion 1200 mg>

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

· Extensive-stage small cell lung cancer

· Unresectable hepatocellular carcinoma

Summary of revisions

1. Precaution for sclerosing cholangitis should be added to the language concerning hepatic impairment in the IMPORTANT PRECAUTIONS section.
2. “Sclerosing cholangitis” should be added to the language concerning hepatic impairment and hepatitis in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of sclerosing cholangitis have been reported in patients treated with atezolizumab (genetical recombination) in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 10 cases involving sclerosing cholangitis have been reported to date (including 4 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

(Japanese market launch: April 2018)

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).

Pharmaceuticals and Medical Devices Agency

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