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)
Avelumab (genetical recombination)
Cemiplimab (genetical recombination)

March 5, 2025

Non-proprietary name

a. Atezolizumab (genetical recombination)
b. Avelumab (genetical recombination)
c. Cemiplimab (genetical recombination)

Brand name (marketing authorization holder)

a. Tecentriq for Intravenous Infusion 840 mg, 1200 mg (Chugai Pharmaceutical Co., Ltd.)
b. Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd)
c. Libtayo I.V. Infusion 350 mg (Regeneron Japan KK)

Japanese market launch

a. Tecentriq for Intravenous Infusion 840 mg: November 2019
Tecentriq for Intravenous Infusion 1200 mg: April 2018
b. November 2017
c. March 2023

Indications

a.

<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

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<Tecentriq for Intravenous Infusion 840 mg>

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

<Common to both preparations>

•Unresectable alveolar soft part sarcoma

b.

•Radically unresectable Merkel cell carcinoma

•Radically unresectable or metastatic renal cell carcinoma

•Maintenance treatment of radically unresectable urothelial carcinoma following chemotherapy

c.

Advanced or recurrent cervical cancer that has progressed after cancer chemotherapy

Summary of revisions

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

Investigation results and background of the revision

Cases involving immune thrombocytopenia were evaluated. 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 for the following reasons: Cases for which a causal relationship between immune thrombocytopenia and atezolizumab (genetical recombination) or avelumab (genetical recombination) was reasonably possible have been reported. Although no cases for which a causal relationship between cemiplimab (genetical recombination) and the event was reasonably possible have been reported at this point, revision of PRECAUTIONS was considered to be necessary also for cemiplimab (genetical recombination), taking into consideration the descriptions in overseas product labeling, etc.

Reference: Number of cases[*1] and patient mortalities involving immune thrombocytopenia reported in Japan and overseas

a. A total of 32 cases have been reported in Japan to date (including 12 cases for which a

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causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported in Japan to date. (A causal relationship between the drug and the death subsequent to the event could not be established for this case.)

A total of 29 cases have been reported overseas to date.*2

One instance of patient mortality has been reported overseas to date.

b. No cases have been reported in Japan to date.

A total of 10 cases have been reported overseas to date (including 1 case for which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and the death subsequent to the event could not be established for this case.)

c. No cases have been reported in Japan to date.

One case has been reported overseas to date. (A causal relationship between the drug and the event could not be established for this case.)

One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and the death subsequent to the event could not be established for this case.)

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

*2 The causality assessment was not performed by the expert advisors.

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).

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