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

Durvalumab (genetical recombination), avelumab (genetical recombination)

July 20, 2022

Non-proprietary name

a. Durvalumab (genetical recombination)

b. Avelumab (genetical recombination)

Brand name (Marketing authorization holder)

a. Imfinzi Injection 120 mg, 500 mg (AstraZeneca K.K.)

b. Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd)

Indications

a.

·Maintenance treatment of locally-advanced, unresectable non-small cell lung cancer following definitive chemoradiotherapy

·Extensive stage small cell lung cancer

b.

·Unresectable Merkel cell carcinoma

·Radically unresectable or metastatic renal cell carcinoma

·Maintenance treatment of radically unresectable urothelial carcinoma following chemotherapy

Summary of revisions

“Encephalitis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of encephalitis reported in Japan and overseas were evaluated. Cases for which a

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causal relationship of encephalitis to durvalumab (genetical recombination) or avelumab (genetical recombination) was reasonably possible have been reported in Japan and overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

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

a.

A total of 10 cases have been reported in Japan to date (including 5 cases for which a causal relationship between the drug and event was reasonably possible).

A total of 3 patient mortalities have been reported in Japan to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

A total of 21 cases have been reported overseas to date (including 10 cases for which a causal relationship between the drug and event was reasonably possible).

A total of 8 patient mortalities have been reported overseas to date (including 1 case for which a causal relationship between the drug and death subsequent to the event was reasonably possible).

b.

A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

1 case has been reported overseas to date. (A causal relationship between the drug and event was reasonably possible for this case.)

No patient mortalities have been reported to date.

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).