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Summary of Investigation Results

Durvalumab (genetical recombination)

March 30, 2021

Non-proprietary name

Durvalumab (genetical recombination)

Branded name (Marketing authorization holder)

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

Indications

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

Extensive stage small cell lung cancer

Summary of revisions

“Immune thrombocytopenic purpura” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

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

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

A total of 15 cases involving immune thrombocytopenic purpura 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.

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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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