独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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

Tarlatamab (genetical recombination)

September 17, 2025

Non-proprietary name

Tarlatamab (genetical recombination)

Brand name (marketing authorization holder)

Imdelltra For I.V. Infusion 1mg, 10 mg (Amgen K.K.)

Japanese market launch

April 2025

Indications

Small cell lung cancer that has progressed after cancer chemotherapy

Summary of revisions

Statements that cases involving cytokine release syndrome that resulted in death have been reported should be added to precautions regarding cytokine release syndrome and neurologic events (including immune effector cell-associated neurotoxicity syndrome) in 1.WARNINGS.

Investigation results and background of the revision

Cases involving cytokine release syndrome that resulted in death were evaluated. A case in which a causal relationship between death following cytokine release syndrome and tarlatamab (genetical recombination) was reasonably possible has 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.

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Reference: Number of patient deaths* involving cytokine release syndrome reported in Japan

A total of 3 patient deaths have been reported to date (including 1 case in which a causal relationship between the drug and the death following the event was reasonably possible).

*Cases collected in the PMDA's safety database for drugs

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).