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
Tirzepatide

July 20, 2023

Non-proprietary name

Tirzepatide

Brand name (marketing authorization holder)

Mounjaro Subcutaneous Injection 2.5 mg Ateos, 5 mg Ateos, 7.5 mg Ateos, 10 mg Ateos, 12.5 mg Ateos, 15 mg Ateos (Eli Lilly Japan K.K.)

Japanese market launch

2.5mg, 5 mg: April 2023

7.5 mg, 10 mg, 12.5 mg, 15 mg: June 2023

Indications

Type 2 diabetes mellitus

Summary of revisions

“Anaphylaxis, angioedema” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving anaphylaxis reported in Japan and overseas and those involving angioedema reported overseas were evaluated. Cases for which a causal relationship between tirzepatide and anaphylaxis was reasonably possible have been reported in Japan and overseas. Also, cases for which a causal relationship between tirzepatide and angioedema was reasonably possible have been reported overseas. As a result of consultation with expert advisors regarding the causality assessment of the cases and the

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving anaphylaxis or angioedema reported in Japan and overseas

Cases involving anaphylaxis
One case has been reported in Japan to date. (A causal relationship between the drug and event was reasonably possible for this case.)
No patient mortalities have been reported in Japan to date.
A total of 15 cases have been reported overseas to date (including 8 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported overseas to date.

Cases involving angioedema
No cases have been reported in Japan to date.
A total of 9 cases have been reported overseas to date (including 6 cases† for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported overseas to date.

*: Cases collected in the PMDA's database for adverse drug reactions, etc. reports
†: Three cases evaluated as angioedema occurring as an anaphylactic symptom are included.

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).