This English version is intended to be a reference material Interventional Cardiology convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Vedolizumab (genetical recombination)

December 17, 2024

Non-proprietary name

Vedolizumab (genetical recombination)

Brand name (marketing authorization holder)

Entyvio for I.V. Infusion 300 mg, Entyvio Pens for S.C. Injection 108 mg, Entyvio Syringes for S.C. Injection 108 mg (Takeda Pharmaceutical Company Limited)

Japanese market launch

November 2018 (for I.V. Infusion), June 2023 (for S.C. Injection)

Indications

<Entyvio for I.V. Infusion 300 mg>

•Treatment and maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments)

•Treatment and maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments)

<Entyvio Pens for S.C. Injection 108 mg, Entyvio Syringes for S.C. Injection 108 mg>

•Maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments)

•Maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments)

Summary of revisions

“Interstitial lung disease” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Pharmaceuticals and Medical Devices Agency

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

This English version is intended to be a reference material Interventional Cardiology convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Investigation results and background of the revision

Cases involving interstitial lung disease were evaluated. Cases for which a causal relationship between vedolizumab (genetical recombination) and interstitial lung disease was reasonably possible have 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.

Reference: Number of cases*† and patient mortalities involving interstitial lung disease reported in Japan

A total of 25 cases have been reported to date (including 6 cases for which a causal relationship between the drug and the event was reasonably possible).

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

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

†: Cases retrieved by the following conditions

•Retrieved by MedDRA ver.27.1 SMQ “interstitial lung disease (broad)”

•Cases for which the diagnostic basis for interstitial lung disease (chest x-ray, chest CT scan, KL-6 level, bronchoalveolar lavage, etc.) is mentioned

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).

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