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

Ixekizumab (genetical recombination)

June 15, 2021

Non-proprietary name

Ixekizumab (genetical recombination)

Branded name (Marketing authorization holder)

Taltz Subcutaneous Injection Autoinjectors 80 mg, Taltz Subcutaneous Injection Syringes 80 mg (Eli Lilly Japan K.K.)

Indications

Treatment of the following diseases in patients who have had an inadequate response to conventional therapies:

Psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis

Ankylosing spondylitis, non-radiographic axial spondyloarthritis

Summary of revisions

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

Investigation results and background of the revision

Since cases of interstitial pneumonia have been reported in patients treated with ixekizumab (genetical recombination) in Japan, the necessity of a precaution was discussed.

Although the relationship between the drug and event is not necessarily clear considering the onset mechanism of this event, etc., MHLW/PMDA, in consultation with expert advisors and based on the evaluation of the cases reported in Japan, concluded that a precaution

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

regarding this event in the Clinically Significant Adverse Reactions section was necessary.

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

A total of 8 cases involving interstitial pneumonia 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.

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