

Mochida obtains marketing approval for etanercept biosimilar in Japan

This material is an English translation of the press release issued on January 19, 2018 in Japanese, and the Japanese release is given priority regarding content and interpretation.

January 19, 2018

Mochida Pharmaceutical Co., Ltd.
AYUMI Pharmaceutical Corporation

Mochida Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) and AYUMI Pharmaceutical Corporation (Headquarters: Tokyo, Japan, President: Hikaru Ouchi, hereinafter: AYUMI) announced that Mochida obtained marketing approval for Etanercept BS「MA」 (etanercept biosimilar, Development code: LBEC0101) from the Japanese Ministry of Health, Labour and Welfare (MHLW) on January 19.

Etanercept BS「MA」 is an etanercept biosimilar which Mochida has developed in Japan based on a collaboration agreement with LG Chem, Ltd., Korea. All types of preparation are available for self-injection.

Based on a collaboration agreement between Mochida and AYUMI, Etanercept BS「MA」 will be distributed by AYUMI in Japan. Expected launch date will be announced at the NHI Price Listing.

As the first etanercept biosimilar in Japan, Mochida and AYUMI believe that Etanercept BS「MA」 will contribute to improving the Quality of Life and to reducing the financial burden of patients with rheumatoid arthritis and juvenile idiopathic arthritis.

【References】

Summary of the marketing approval

Generic Name : Etanercept (genetical recombination) [Etanercept Biosimilar 1]
Approved Date : January 19, 2018
Manufactured and Distributed : Mochida Pharmaceutical Co., Ltd.
Distributed : AYUMI Pharmaceutical Corporation

[vial]

Brand name : Etanercept BS 10 mg for S.C. Inj.「MA」
Etanercept BS 25 mg for S.C. Inj.「MA」

Indications : The following diseases which do not show sufficient response to the existing therapies:
Rheumatoid arthritis (including inhibition of progression of structural joint damage) and polyarticular-course juvenile idiopathic arthritis

Dosage and Administration : For treatment of rheumatoid arthritis: In general, for adults, dissolve 10 to 25 mg of etanercept (genetical recombination) [etanercept biosimilar1] into 1 mL of water for injection at a time, and subcutaneously inject once a day on two different days in the same week; or dissolve 25 to 50 mg into 1 mL of water for injection at a time, and subcutaneously inject once a day, once a week.
For treatment of active, polyarticular-course juvenile idiopathic arthritis: In general, for children, inject subcutaneously 0.2 to 0.4 mg/kg of etanercept (genetical recombination) [etanercept biosimilar1] once a day on two different days in the same week. Each dose for children should not exceed 25 mg.

[syringe/pen]

Brand name : Etanercept BS 25 mg Syringe 0.5mL for S.C. Inj.「MA」
Etanercept BS 50 mg Syringe 1.0mL for S.C. Inj.「MA」
Etanercept BS 50 mg PEN 1.0mL for S.C. Inj.「MA」

Indication : Rheumatoid arthritis (including inhibition of progression of structural joint damage) which do not show sufficient response to the existing therapies

Dosage and Administration : In general, for adults, 10 to 25 mg of etanercept (genetical recombination) [etanercept biosimilar1] at a time, and subcutaneously inject once a day on two different days in the same week; or 25 to 50 mg at a time, and subcutaneously inject once a day, once a week.