

## The NHI Drug Price Listing and Launch of Etanercept Biosimilar in Japan

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This material is an English translation of the press release issued on May 30, 2018 in Japanese, and the Japanese release is given priority regarding content and interpretation.

May 30, 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 Etanercept BS「MA」 (etanercept biosimilar, Development code: LBEC0101) has been launched in Japan as the NHI (National Health Insurance) Drug Price has been listed today.

Etanercept BS「MA」 is the first etanercept biosimilar in Japan which Mochida has developed 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」 is supplied to AYUMI by Mochida and distributed by AYUMI in Japan. As an additional preparation, 25mg PEN is currently being developed.

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】

Generic Name : Etanercept (genetical recombination) [Etanercept Biosimilar 1]  
Approved Date : January 19, 2018  
NHI Drug Price Listing Date : May 30, 2018  
Launch Date : May 30, 2018  
Manufacturer/ Distributor : Mochida Pharmaceutical Co., Ltd.  
Distributor : AYUMI Pharmaceutical Corporation

### [vial]

Brand name and NHI Drug Price : Etanercept BS 10 mg for S.C. Inj.「MA」 3,697 Yen  
Etanercept BS 25 mg for S.C. Inj.「MA」 9,099 Yen

Ingredients and Contents : Lyophilized powder for injection to be dissolved before using  
Etanercept (genetical recombination) [Etanercept biosimilar 1]  
10 mg / 25 mg per 1 vial

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.

Package : 4 vials

### [syringe/pen]

Brand name and NHI Drug Price : Etanercept BS 25 mg Syringe 0.5mL for S.C. Inj.「MA」 9,249 Yen  
Etanercept BS 50 mg Syringe 1.0mL for S.C. Inj.「MA」 18,134 Yen  
Etanercept BS 50 mg PEN 1.0mL for S.C. Inj.「MA」 18,190 Yen  
※Etanercept BS 50 mg PEN 1.0 mL for S.C.Inj.「MA」 is a kit consisting of a syringe that comes with a fixed needle and an injector (autoinjector).

Ingredients and Contents : Injection solution  
Etanercept (genetical recombination) [Etanercept biosimilar 1]  
25 mg/0.5 mL solution in a single-dose prefilled syringe  
Etanercept (genetical recombination) [Etanercept biosimilar 1]  
50 mg/1.0 mL solution in a single-dose prefilled syringe  
Etanercept (genetical recombination) [Etanercept biosimilar 1]  
50 mg/1.0 mL solution in a single-dose prefilled autoinjector

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.

Package : Etanercept BS 25 mg Syringe 0.5mL for S.C. Inj.「MA」 4 syringes  
Etanercept BS 50 mg Syringe 1.0mL for S.C. Inj.「MA」 2 syringes  
Etanercept BS 50 mg PEN 1.0mL for S.C. Inj.「MA」 2 kits