The NHI Drug Price Listing and Launch of Adalimumab Biosimilar in Japan

This material is an English translation of the press release issued on November 25, 2021 in Japanese, and the Japanese release is given priority regarding content and interpretation.

November 25, 2021

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, CEO: Kiyonori Karasawa, hereinafter: AYUMI) announced that Adalimumab BS MA (adalimumab biosimilar, Development code: LBAL) has been launched in Japan as the NHI (National Health Insurance) Drug Price has been listed today.

Adalimumab BS MA is an adalimumab biosimilar which Mochida has developed in Japan. Including the first 80mg syringe preparation of adalimumab biosimilar in Japan, all types of preparation are available for self-injection. Adalimumab BS MA has been launched as the first adalimumab biosimilar which contains same concentration of the active ingredient as Humira® currently distributed in Japan.

Based on a collaboration agreement between Mochida and AYUMI, Adalimumab BS MA is supplied to AYUMI by Mochida and distributed and promoted by AYUMI in Japan. For the indications in gastroenterology field, Mochida will also promote Adalimumab BS MA. Mochida and AYUMI are also collaborating in the commercialization of Etanercept BS MA which has been launched in May 2018.

Mochida and AYUMI believe that Adalimumab BS MA will contribute to improving the Quality of Life and to reducing the financial burden of patients.

【References】

Generic Name	:	Adalimumab (genetical recombination) [Adalimumab Biosimilar 3]
Approval Date	:	March 23, 2021
NHI Drug Price Listing Date	:	November 25, 2021
Launch Date	:	November 25, 2021
Manufacturer / Distributor	:	Mochida Pharmaceutical Co., Ltd.
Distributor	:	AYUMI Pharmaceutical Corporation
Brand Name and NHI Drug Price	:	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL MA 20,604 Yen Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL MA 39,913 Yen Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL MA 77,392 Yen Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL MA 40,056 Yen
Ingredients and Contents	:	Injection solution Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] 20 mg/0.2 mL solution in a single-dose prefilled syringe Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] 40 mg/0.4 mL solution in a single-dose prefilled syringe Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] 80 mg/0.8 mL solution in a single-dose prefilled syringe Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] 40 mg/0.4 mL solution in a single-dose prefilled pen
Indication	:	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL MA Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL MA Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL MA The following disease which does not show sufficient response to the existing therapies: Polyarticular Juvenile Idiopathic Arthritis Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL MA Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL MA Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL MA Rheumatoid Arthritis (including inhibition of progression of structural joint damage) The following diseases which do not show sufficient response to the existing therapies: Plaque Psoriasis, Psoriatic Arthritis, Pustular Psoriasis Ankylosing Spondylitis Intestinal Behçet's Disease Remission induction and maintenance therapy for moderately or severely active Crohn's Disease (limited in case of inadequate response to existing therapies) Therapy for moderately or severely Ulcerative Colitis (limited in case of inadequate response to existing therapies)

Dosage and Administration	:	**Rheumatoid arthritis** Usually, to adults, 40 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection, once every other week. When its effect is insufficient, the dosage can be increased up to 80 mg at a time. **Plaque Psoriasis, Psoriatic Arthritis, Pustular Psoriasis,** Usually, to adults, 80 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection as initial dose, followed by 40 mg subcutaneously, once every other week. When its effect is insufficient, the dosage can be increased up to 80 mg at a time. **Ankylosing Spondylitis** Usually, to adults, 40 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection, once every other week. When its effect is insufficient, the dosage can be increased up to 80 mg at a time. **Polyarticular Juvenile Idiopathic Arthritis** Usually, for patients with body weight of 15 kg to less than 30 kg, 20 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection once every other week. For patients with the body weight of more than 30 kg, 40 mg is administered by subcutaneous injection once every other week. **Intestinal Behcet's Disease** Usually, to adults, 160 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection as initial dose, followed by 80 mg subcutaneously two weeks after the initial dose. After 4 weeks or later from the initial dose, 40 mg is administered by subcutaneous injection once every other week. **Crohn's Disease** Usually, to adults, 160 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection as initial dose, followed by 80 mg subcutaneously two weeks after initial dose. After four weeks or later from the initial dose, 40 mg is administered by subcutaneous injection once every other week. When its effect is reduced, the dosage can be increased up to 80 mg at a time. **Ulcerative Colitis** Usually, to adults, 160 mg of Adalimumab (genetical recombination) [Adalimumab Biosimilar 3] is administered by subcutaneous injection as initial dose, followed by 80 mg subcutaneously two weeks after initial dose. After four weeks or later from the initial dose, 40 mg is administered by subcutaneous injection once every other week.
Package	:	One prefilled syringe with 29 gauge fixed needle