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For Immediate Release

Bristol-Myers Squibb K.K.
Ono Pharmaceutical Co., Ltd.

BMSKK and ONO Submit Supplemental Applications of Orencia® for I.V. Infusion, Orencia® Syringe for S.C. Injection and Orencia® Autoinjector for S.C. Injection, a Selective T-cell Co-Stimulation Modulator, for Inhibition of Structural Damage of Joints in Rheumatoid Arthritis

Bristol-Myers Squibb K.K. (Head office: Shinjuku, Tokyo; Representative Director and President: Jean-Christophe Barland) and Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka; President, Representative Director and CEO, Gyo Sagara) announced today that the Companies submitted supplemental applications of "Orencia® for Intravenous Infusion 250mg", "Orencia® 125mg Syringe for Subcutaneous Injection 1mL" and "Orencia® 125mg Autoinjector for Subcutaneous Injection 1mL" (generic name: abatacept (genetical recombination), a selective T-cell co-stimulation modulator, to include the description of "inhibition of the structural damage of the joints" in the currently approved indication of rheumatoid arthritis for a partial change in approved items of the manufacturing and marketing approval in Japan.

The application is based on the results from a multicenter, randomized, double-blind, placebo-controlled, post-marketing clinical trial (IM101-338 study) conducted in Japan to meet the conditional approval for the indication of rheumatoid arthritis (which have had inadequate response to conventional treatment only) approved in July 2010, as well as a Phase 3b, multicenter, randomized, investigator-blinded, active-controlled clinical trial (IM101-235 study) conducted outside Japan.

In IM101-338 study, the efficacy and safety of abatacept in combination therapy with methotrexate were evaluated compared to methotrexate alone. The combination therapy of abatacept and methotrexate demonstrated a statistically significant difference in the primary endpoint, a change from baseline in modified Total Sharp Score (mTSS) at 24 weeks post-treatment, versus methotrexate alone. No new safety concerns were shown in the analysis of the safety in both trials, except for identified risks of abatacept.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an inflammatory autoimmune disease characterized by inflammation of joint synovium, causing swelling and pain of many joints. It is estimated that there are approximately 700,000 to 800,000 patients diagnosed with RA in Japan. This disease causes inflammation typically in small joints of the fingers, wrists and toes. If the disease progresses, bones and cartilage are gradually destructed. If larger joints such as hips, knees and elbows are destructed, this causes joint deformity and difficulty in movement of the body. These symptoms significantly reduce activities of daily living (ADL), and also significantly affect quality of life (QOL) of the patients.

About Orencia

Orencia is a genetically recombinant soluble fusion protein that consists of the extracellular domain of cytotoxic T-lymphocyte-antigen-4 (CTLA-4) linked to the Fc portion of human IgG1. Orencia is a biologic product that suppresses activation of T-cells by binding specifically with CD80 and CD86 on the surface of the antigen-presenting cells and improves signs and symptoms, physical functions, and health-related quality of life in patients with rheumatoid arthritis.

In Japan, Orencia Intravenous Infusion received manufacturing and marketing approval for the treatment of rheumatoid arthritis with inadequate response to existing therapies in July 2010, followed by approval for the subcutaneous syringe formulation in June 2013 and for the subcutaneous autoinjector formulation in February 2016. Orencia Intravenous Infusion was approved for the treatment of active polyarticular juvenile idiopathic arthritis in February 2018.

Orencia was first approved in the US in December 2005 as a treatment for rheumatoid arthritis, and is now approved in more than 50 countries worldwide.

Collaboration between Ono and BMSKK

Bristol-Myers Squibb (BMS) and Ono concluded a co-commercialization agreement for Orencia on September 21, 2011, and initiated co-promotion activities from June 4, 2013. The product was developed by both companies.

About Bristol-Myers Squibb K.K.

Bristol-Myers Squibb is a global bio-pharmaceutical company with a 130-year history, operating business around the world. With our mission to develop and deliver innovative medicines for patients with serious diseases and their families, we are focused on our R&D efforts on our core therapeutic areas: oncology, immunoscience, cardiovascular and fibrosis. Since its foundation in 1960, Bristol-Myers Squibb K.K. has been helping patients and their families in Japan and committed to delivering transformational therapies in areas of significant unmet medical needs to improve treatment of diseases and patients' lives.

For more information about Bristol-Myers Squibb K.K., visit us at https://www.bms.com/jp.

About Ono

Ono Pharmaceutical Co., Ltd., headquartered in Osaka, Japan, is an R&D-oriented pharmaceutical company committed to creating and developing innovative medicines in specific areas, especially the treatment of cancer and diabetes. For more detailed information, please visit the company's website at http://www.ono.co.jp/eng/.

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