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Supplemental Application of Orencia® (Abatacept) Intravenous Injection 250 mg a Selective T-cell Co-stimulation Modulator for Treatment of Juvenile Idiopathic Arthritis for a Partial Change in Approved Items of Manufacturing and Marketing Approval

Bristol-Myers Squibb K.K. (Head office: Shinjuku, Tokyo; Representative Director and President: Davide Piras: "BMSKK") and Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka; President, Representative Director and CEO, Gyo Sagara; "ONO") announced today that a supplemental application of Orencia[®] for Intravenous Infusion 250 mg (generic name: abatacept (genetical recombination), a selective T-cell co-stimulation modulator has been submitted for the treatment of active polyarticular juvenile idiopathic arthritis (JIA) for a partial change in approved items of manufacturing and marketing approval in Japan.

In Japan, the manufacturing and marketing approval of Orencia[®] for Intravenous Infusion 250 mg was obtained for the treatment of rheumatoid arthritis in July 2010.

The indication of JIA for Orencia for Intravenous infusion has been granted in the US and Europe, etc. In Japan, as a result of the evaluation by the "Review Committee on Unapproved and Off-labeled Drugs with High Medical Needs", it was concluded that the product has a high medical need for the treatment, and has been developed under the request from the Ministry of Health, Labour and Welfare (MHLW).

This application is based on the results of two clinical studies, a multi-national, multi-center, randomized, double-blind, placebo-controlled, Phase III study (IM101-033 study) in patients with active polyarticular JIA and a multi-center, open-label, Japan Phase III study (IM101-365 study) in patients with active polyarticular JIA.

Juvenile idiopathic arthritis (JIA) is arthritis of unknown etiology that begins under the age of 16 and persists for at least 6 weeks. In Japan, the prevalence of JIA is estimated at 10 - 15 cases per 100,000 pediatric population*. In the treatment of JIA, non-steroidal anti-inflammatory drugs (NSAIDs) and biologic products (i.e., IL-6 inhibitor and TNF α inhibitor) have been employed, but these drugs are not always effective to all patients. As some patients cannot continue the treatment with these drugs due to adverse drug reactions, a new treatment option with different mode of actions from those currently available drugs is expected.

*: Guidance on primary care for juvenile idiopathic arthritis 2015, The Pediatric Evaluation Committee of the Japan College of Rheumatology

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 modified 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 rheumatoid arthritis.

Collaboration between Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb

Bristol-Myers Squibb and Ono Pharmaceutical Co., Ltd. concluded a co-development and co-commercialization agreement of Orencia[®] on September 21, 2011 and initiated co-promotion activities from June 4, 2013.

About Bristol-Myers Squibb K.K.

Bristol-Myers Squibb K.K. is the Japanese subsidiary of Bristol-Myers Squibb Company (Headquarter: New York). Bristol-Myers Squibb is a global biopharmaceutical company with more than 150-years history and about 24,000 employees around the world. Bristol-Myers Squibb is committed to developing new medicines in high specialty disease areas, such as cancer, virus disease, cardiovascular disease, immune disease and so on, as a specialty biopharmaceutical company, combining the best of biotechnology with the best of a traditional pharmaceutical company. For more detailed information, please visit http://www.bms.co.jp.

About Ono Pharmaceutical Co., Ltd.

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 in the oncology and diabetes areas. For more detailed information, please visit the company's website at http://www.ono.co.jp/eng/index.html.

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