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Bristol-Myers K.K.
Public Affairs & Communications

Ono Pharmaceutical Co., Ltd.
Corporate Communications

Manufacturing and Marketing Approval of
Orencia® SC 125 mg Auto-injector 1 mL for Rheumatoid Arthritis Treatment

Bristol-Myers K.K. (Head office: Shinjuku, Tokyo; President: Davide Piras: "BMKK") and Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka; President: Gyo Sagara; "ONO") announced today that they have received the manufacturing and marketing approval of Orencia® Subcutaneous Injection 125 mg Auto-injector 1 mL (abatacept: genetically recombinant) for the treatment of rheumatoid arthritis.

This approval allows Orencia to make the new formulation of subcutaneous auto-injector available, in addition to the existing formulation of intravenous infusion and subcutaneous injection syringe.

Orencia® Subcutaneous Injection 125 mg Auto-injector 1 mL (OSA) is prefilled with a single dose in the device. By simply pressing the injection button which facilitates one-touch operation, the needle can be automatically inserted under the skin to deliver the drug. In addition, OSA is designed as the device with a non-slip surface to grip easily in size and a large viewing window to confirm whether the drug has been fully injected.

Many patients with rheumatoid arthritis find it difficult to inject themselves in subcutaneous injections due to tension and pain in the joints of the hands, and the OSA will help such patients to reduce their burden in self-injection.

In addition, OSA offers merits to physicians in providing a wider range of treatment options depending on patients' conditions, as well as to healthcare professionals, in charge of instruction on self-injection to patients, in further facilitating such instruction to them.

Bristol-Myers K.K. and Ono Pharmaceutical Co., Ltd. are committed to alleviating the symptoms and improving the quality of life in rheumatoid arthritis patients who are treated with Orencia.

Overview of Orencia® Subcutaneous Injection 125 mg Auto-injector 1 mL

Product name	Orencia Subcutaneous Injection 125 mg Auto-injector 1mL
Generic name	Abatacept (genetically recombinant)
Efficacy and effects	Rheumatoid arthritis (restricted to patients who have had an inadequate response to the existing treatment)
Administration and dose	Usually, for adults, inject intravenously Orencia Intravenous Injection (abatacept recombinant) as a loading dose on the first day of treatment, followed by subcutaneous injection of 125 mg of abatacept on the same day. After that, inject 125 mg of abatacept subcutaneously once a week. It is allowed to begin the course with subcutaneous injection at 125 mg of abatacept once a week.
Manufacturing and marketing approval date	February25, 2016
Manufacturer/distributor	Bristol-Myers K.K.
Distributor	Ono Pharmaceutical Co., Ltd.

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 biopharmaceutical product that suppresses activation of T-cells and improves signs and symptoms, physical functions, and health-related QOLs by binding specifically with CD80 and CD86 on the surface of the antigen-presenting cell. Orencia was first approved in the United States in December 2005 for the treatment of rheumatoid arthritis, and has since been launched in more than 50 countries around the world. The manufacturing and marketing approval for intravenous infusion was granted in Japan in July 2010. Orencia SC was approved in June 2013.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is one of autoimmune diseases characterized by causing joint inflammation and destruction with chronic pain, stiffness, and swelling. RA restricts the movement of body and decrease joint function. This disease more commonly occurs in women, accounting for 75%, than in men. It is estimated that there are currently 700,000 to 800,000 patients* in Japan. For more detailed information on rheumatoid arthritis, visit the Rheumatoid Arthritis Tea Room (http://www.bms.co.jp/ra/)

*: Report in August, 2013 by the Health Sciences Council in Ministry of Health, Labour and Welfare

Partnership with Ono Pharmaceutical Co., Ltd.

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 K.K.

Bristol-Myers K.K. is the Japanese affiliate of the Bristol-Myers Squibb Company (Headquarters: New York). Bristol-Myers Squibb is a global pharmaceutical 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 BioPharma company, combining the best of biotechnology with the best of a traditional pharmaceutical company. Thanks to the support from all patients and stakeholders, we celebrated our 55th anniversary last year. We continue to help and support all patients suffering from serious disease. 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 innovative medicines in specific areas. It focuses especially on the oncology and diabetes areas. For more detailed information about Ono, visit the company's website at http://www.ono.co.jp/eng/index.htmll.

Contacts:

Bristol-Myers K.K.	**Ono Pharmaceutical Co., Ltd.**
Public Affairs & Communications +81-3-6705-7013	Corporate Communications +81-6-6263-5670
Keisuke Goto Keisuke.Goto@bms.com	Yukio Tani, y.tani@ono.co.jp