May 25, 2016

Launch of Orencia® SC 125 mg Auto-injector 1 mL for Treatment of Rheumatoid Arthritis

Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka; President, Representative Director and CEO, Gyo Sagara; "ONO") and Bristol-Myers Squibb K.K. (Head office: Shinjuku, Tokyo; President: Davide Piras: "BMSKK") announced today that Orencia® Subcutaneous Injection 125 mg Auto-injector 1 mL (abatacept: genetically recombinant) has been launched for the treatment of rheumatoid arthritis.

The manufacturing and marketing approval of Orencia® Subcutaneous Injection 125 mg Auto-injector 1 mL (Orencia-AI) was obtained on February 25, 2016. This launch represents the new formulation of subcutaneous auto-injector available, in addition to the existing formulation of intravenous infusion and subcutaneous injection syringe.

Orencia-AI 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 without looking at the injection to deliver the drug. In addition, Orencia-AI is designed to be an easy-to-handle device for patients in function and shape with a non-slip surface to grip easily in size and a large viewing window to confirm whether the drug has been fully injected.

As rheumatoid arthritis is characterized by the tension, pain and deformity of the joints, many patients with rheumatoid arthritis have a difficulty in injecting by themselves due to such symptoms and complications. Orencia-AI is expected to help such patients having a trouble in self-injection due to joint deformity to reduce their burden in self-injection. In addition, Orencia-AI 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.

Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb K.K. 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)
Indications	Rheumatoid arthritis (restricted to patients who have had an inadequate response to the existing treatment)

Dosage and Administration	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	February 25, 2016
NHI price listed date	May 25, 2016
Launched date	May 25, 2016
Manufacturer/Distributor (Importer)	Bristol-Myers Squibb K.K.
Distributor	Ono Pharmaceutical Co., Ltd.
NHI price	¥28,233

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 quality of life 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 been marketed 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 syringe formulation 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

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 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, please visit the company's website at http://www.ono.co.jp/eng/index.htmll.

About Bristol-Myers Squibb K.K.

Bristol-Myers Squibb K.K. is the Japanese arm of Bristol-Myers Squibb Company (Headquarter: New York). Bristol-Myers Squibb is a global biopharmaceutical company with more than 150-years history and about 25,000 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. Thanks to the support from all patients and stakeholders, we celebrated our 55th anniversary in 2015. We continue to help and support all patients suffering from serious diseases. For more detailed information, please visit http://www.bms.co.jp/.

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