

June 28, 2013

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## **Rheumatoid Arthritis Drug ORENCIA<sup>®</sup> SC 125mg Syringe 1mL Approved for Production and Distribution**

Ono Pharmaceutical Co., Ltd. (Head Office: Osaka City; President and Representative Director: Gyo Sagara; “Ono”) and Bristol-Myers K.K. (Head Office: Shinjuku-ku, Tokyo; President & CEO: Emmanuel Blin; “BMKK”) announced that ORENCIA<sup>®</sup> Subcutaneous Injection 125mg/mL Syringe 1mL (generic name: abatacept (genetic recombination); “ORENCIA<sup>®</sup> SC”) was approved today by the Ministry of Health, Labour and Welfare to be manufactured and marketed with an indication for rheumatoid arthritis (limited to cases where existing treatments are inadequate).

Rheumatoid arthritis is a condition caused by the body attacking oneself, and is known for inducing joint inflammation by the excessively produced cytokines. ORENCIA<sup>®</sup> SC is a biologic therapy that inhibits secretion of cytokines by blocking the signal which activates T cells, resulting in an easing of joint inflammation. Since September 2010, ORENCIA<sup>®</sup> Intravenous Infusion 250mg (“ORENCIA<sup>®</sup> IV”) with the same indication has been manufactured and marketed by BMKK in Japan and used widely for the treatment of rheumatoid arthritis patients. Ono and BMKK commenced co-promotion of ORENCIA<sup>®</sup> IV on June 4, and ORENCIA<sup>®</sup> SC will also be co-promoted by the two companies.

ORENCIA<sup>®</sup> SC comes in a prefilled syringe with a needle cover, which is expected to reduce the risk of infection as the cover prevents needle sticks. The preparation takes into account the safety of both healthcare workers and rheumatoid arthritis patients. ORENCIA<sup>®</sup> SC can also be self-administered by the patient if that is judged as appropriate by physicians. Along with the preparation for intravenous infusion which is already on the market, the addition of a new formulation for subcutaneous injection is believed to allow patients to receive treatment tailored to their lifestyle and contribute to increased convenience.

In domestic phase II and III clinical trials for rheumatoid arthritis on which the effect of methotrexate administered was insufficient, ORENCIA<sup>®</sup> SC was shown to inhibit disease activity of rheumatoid arthritis and, moreover, improved body function.

Currently, ORENCIA<sup>®</sup> IV is marketed in over 50 countries around the world including the United States and Europe, and ORENCIA<sup>®</sup> SC has been approved in 40 countries including the United

States and Europe (as of May 2013).

### About rheumatoid arthritis (RA)

Rheumatoid arthritis is a chronic autoimmune disease characterized by inflammation of joint synovium. Major symptoms are pain and swelling of joints in hands and legs/feet. When inflammation of joint synovium progresses or is prolonged, joints being to destruct, causing advanced functional disability that interfere with daily routines and reduces quality of life (QOL). It is estimated that there are 700,000 to 800,000(\*) RA patients in Japan now. For further information on RA, please visit the Rheumatism Tea Room at <http://www.bms.co.jp/ra/index.html>.

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

### Overview of ORENCIA® SC 125mg Syringe 1mL

Product name ORENCIA® SC 125mg Syringe 1mL  
General name Abatacept (Genetic recombination)  
Approval date June 28, 2013  
for production/  
distribution  
Manufacturer/ Bristol-Myers K.K.  
distributor  
Distributor Ono Pharmaceutical Co., Ltd.  
Indication or Rheumatoid arthritis  
usage (only for patients with an inadequate response to prior conventional therapy)  
Dosage and Following an intravenous loading dose with the ORENCIA® IV, 125mg subcutaneous  
Administration injection of ORENCIA® SC should be given within the first administration day, followed by 125mg subcutaneous injections once weekly for adult patients. Weekly 125mg subcutaneous injections of ORENCIA® SC may also be initiated

### Collaboration between Ono and BMKK

Ono and BMKK concluded an agreement to jointly promote ORENCIA® in September 21, 2011, and, commenced co-promotion on June 4, 2013. The two companies have also been co-developing ORENCIA®. With ORENCIA® IV and ORENCIA® SC, we will further contribute to the treatment of rheumatoid arthritis.

### About Ono Pharmaceutical

Ono Pharmaceutical Co., Ltd. is a R&D-oriented pharmaceutical company specialized in creating innovative medicines in specific areas and is headquartered in Osaka, Japan. For more information about Ono, visit the company's website at [www.ono.co.jp](http://www.ono.co.jp).

### About Bristol Myers K.K.

Bristol Myers K.K. is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. The company has a passion for innovative science, R&D capacity for serious diseases with significant unmet medical needs, and outstanding competitiveness in the field of biologics. Our corporate strategy is to evolve into a "BioPharma" leader by combining the strengths of a traditional pharmaceutical company with the entrepreneurial spirit and agility of a successful biotech company. We will provide innovative medicines to meet unmet medical needs with more than 27,000 employees internationally. For further information, visit the company's website at <http://www.bms.co.jp>.

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