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Bristol-Myers K.K.

Ono Pharmaceutical Co., Ltd.

Public Affairs & Communications

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Bristol-Myers and Ono Pharmaceutical to Announce Lifting of Approval Conditions (Completion of PMS: "All-Case Surveillance") and Start of Co-Promotion

Bristol-Myers K.K. (Head Office: Shinjuku-ku, Tokyo; President & CEO: Emmanuel Blin; "BMKK") and Ono Pharmaceutical Co., Ltd. (Head Office: Osaka City; President and Representative Director: Gyo Sagara; "Ono") announced that BMKK has received a notification from the Ministry of Health, Labour and Welfare on the lifting of approval conditions for "ORENCIA® IV 250mg" (abatacept), a rheumatoid arthritis (RA) drug that BMKK manufactures and distributes. This notification pertains to the completion of post-marketing surveillance ("all-case surveillance"), which is the approval conditions of this drug.

All cases of ORENCIA®'s administration were required to be registered since its launch in September 2010 to evaluate its safety and efficacy. By the end of June 2011, the primary target of 4,000 cases underwent registration, and over 12,510 patients were treated with the drug as of May 2013. Following the completion of all-case surveillance of ORENCIA® IV 250 mg, RA patients will be offered more treatment options, based on the drug's safety and efficacy data obtained.

On September 21, 2011, the two companies entered into a collaboration agreement for ORENCIA®. Starting today, June 4, BMKK and Ono will begin co-promotion of "ORENCIA® IV 250mg". Both companies will further contribute to RA patients' treatment.

## **About ORENCIA® in Japan**

Rheumatoid arthritis is an autoimmune disease characterized by inflammation of the joints as a result of the over-expression of pro-inflammatory cytokines. ORENCIA® is a biologic therapy that works by inhibiting the T cell activation and suppressing the production of pro-inflammatory cytokines, which leads to the amelioration of the inflammation in joints of patients. ORENCIA® IV is available in more than 50 counties, and was launched in September 2010 in Japan where it is indicated for use of rheumatoid arthritis only for patients with an inadequate response to prior conventional therapy.

## 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.

#### About Ono Pharmaceutical

One 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.

### Contacts:

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