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**Fully Human Anti-PD-1 Antibody “Nivolumab (ONO-4538/BMS-936558)”  
Result from Phase II Study in Patients with Melanoma Presented  
at European Cancer Congress 2013**

Ono Pharmaceutical Co., Ltd (Head Office: Osaka City, President and Representative Director: Gyo Sagara, “Ono”) announced that the result from a Japanese phase II study of the fully human PD-1 immune checkpoint inhibitor antibody “Nivolumab (ONO-4538/BMS-936558)” in patients with advanced melanoma was presented at European Cancer Congress 2013 held in Amsterdam, the Netherlands. The results were presented by Dr. Naoya Yamazaki, Dermatology Division, Dermatologic Oncology, National Cancer Center Hospital.

In this Japanese phase II study in advanced melanoma patients with a history of chemotherapeutic regimens including dacarbazine, 22.9% of patients (35 out of 153) who received the drug at 2mg/kg showed an objective response (OR) by RECIST 1.1. Durable and ongoing responses were observed with a median progression-free survival of 172 days. Grade 3-4 treatment-related adverse events occurred in 17.1% of the patients and common treatment-related Grade 3-4 adverse events included  $\gamma$ -GTP increased (11.4%), AST increased (5.7%) and CRP increased (2.9%). No treatment-related deaths were reported.

Nivolumab, a fully human PD-1 immune checkpoint inhibitor antibody, is an investigational cancer immunotherapy generated under a research collaboration entered into in May 2005 between Ono Pharmaceutical Co., Ltd. and Medarex, Inc. When Medarex, Inc. was acquired by Bristol-Myers Squibb in 2009, Bristol-Myers Squibb succeeded its rights to develop and commercialize

Nivolumab in North America. Through the collaboration agreement entered into in September 2011 between Ono and Bristol-Myers Squibb, Ono granted Bristol-Myers Squibb exclusive rights to develop and commercialize Nivolumab in the rest of the world, except in Japan, Korea and Taiwan where Ono retained all rights to develop and commercialize the compound. Bristol-Myers Squibb is conducting Phase 3 studies in NSCLC, RCC and melanoma in the overseas countries and Phase 1 studies in HCV, Hematologic Malignancy and Hepatocellular Carcinoma. On the other hand, in Japan, Ono is conducting phase II studies in NSCLC and melanoma and a phase III study in RCC.