ONO PHARMACEUTICAL CO.,LTD.

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Second Phase III Study Shows Kyprolis® (Carfilzomib) Regimen Significantly Improves Overall Survival in Patients with Relapsed Multiple Myeloma

Patients Treated With the Kyprolis-Based Regimen Survived 7.9 Months Longer Than Patients on Lenalidomide and Dexamethasone

On July 12, 2017, Amgen (NASDAQ:AMGN) announced positive results from the final analysis of the Phase 3 ASPIRE trial. The study met the key secondary endpoint of overall survival (OS), demonstrating that Kyprolis® (carfilzomib), lenalidomide and dexamethasone (KRd) reduced the risk of death by 21 percent over lenalidomide and dexamethasone alone (Rd) (median OS 48.3 months for KRd versus 40.4 for Rd, HR = 0.79, 95 percent CI, 0.67 – 0.95). Per protocol patients received 18 cycles of Kyprolis with Rd, before continuing treatment with Rd alone to progression. The KRd regimen of twice-weekly Kyprolis administered at 27 mg/m^2 is currently approved in the U.S., European Union, Japan and other countries based on the primary analysis of progression-free survival (PFS) in the ASPIRE study.

Adverse events observed in this updated analysis were consistent with those previously reported for ASPIRE. The most common adverse events (greater than or equal to 20 percent) in the Kyprolis arm were diarrhea, anemia, neutropenia, fatigue, upper respiratory tract infection, pyrexia, cough, hypokalemia, thrombocytopenia, muscle spasms, pneumonia, nasopharyngitis, nausea, constipation, and bronchitis.

For further information, please refer to the following link for press release made by Amgen.

http://www.amgen.com/media/news-releases/2017/07/second-phase-3-study-shows-kyprolis-carfilzomib-regimen-significantly-improves-overall-survival-in-patients-with-relapsed-multiple-myeloma/

In September 2010, Ono Pharmaceutical Co., Ltd. (ONO) entered into an exclusive license agreement with U.S.-based Onyx Pharmaceuticals, Inc. (Onyx), now a wholly-owned subsidiary of Amgen, to develop and commercialize two products from Onyx's development program for proteasome inhibitors, Kyprolis (for injection) and oprozomib (orally administered) for all oncology indications in Japan.

ONO received the manufacturing and marketing approval of Kyprolis in July 2016 which was launched for the treatment of relapsed or refractory multiple myeloma in combination with lenalidomide and dexamethasone in August 2016 in Japan. ONO also received an approval of Kyprolis for a partial change in approved items of the manufacturing and marketing approval in May 2017 to expand a dosage and administration of Kyprolis in combination with dexamethasone at a dosage of 20 mg/m^2 in Cycle 1 on Day 1 and 2, and escalate to 56 mg/m^2 thereafter.

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