ONO PHARMACEUTICAL CO.,LTD.

September 1, 2017

Long-Term Analysis of Phase 3 Head-To-Head Study Confirms KYPROLIS® (Carfilzomib) Regimen Extends Overall Survival in Patients with Relapsed Multiple Myeloma

On August 30, 2017, Amgen (NASDAQ:AMGN) announced positive results from a post-hoc analysis requested by the U.S. Food and Drug Administration (FDA) of the Phase 3 head-to-head ENDEAVOR trial, which followed patients for at least three years after enrollment. The analysis evaluated overall survival (OS) and long-term safety of KYPROLIS® (carfilzomib) administered at 56 mg/m^2 twice weekly and dexamethasone (Kd) versus Velcade® (bortezomib) and dexamethasone (Vd) in patients with relapsed or refractory multiple myeloma. Kd reduced the risk of death by 24 percent over Vd (median OS 47.8 months for Kd versus 38.8 months for Vd, HR=0.76, 95 percent CI, 0.63-0.92; p=0.0017). This Kd regimen is currently approved in the U.S., European Union, Japan and other countries based on the primary analysis of progression-free survival in the ENDEAVOR study.

Adverse events observed in this updated analysis were consistent with those previously reported for ENDEAVOR. The most common adverse events (greater than or equal to 20 percent) in the KYPROLIS arm were anemia, diarrhea, pyrexia, hypertension, dyspnea, fatigue, cough, insomnia, upper respiratory tract infection, nausea, bronchitis, asthenia, back pain, thrombocytopenia, edema peripheral, headache and muscle spasms.

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

http://www.amgen.com/media/news-releases/2017/08/longterm-analysis-of-phase-3-headtohead-study-confirms-kyprolis-carfilzomib-regimen-extends-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 and Kyprolis was launched for the treatment of relapsed or refractory multiple myeloma in combination with lenalidomide and dexamethasone in August 2016 in Japan. In addition, ONO received a supplemental approval of Kyprolis 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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