ONO PHARMACEUTICAL CO.,LTD.

October 3, 2018

FDA Approves KYPROLIS® (Carfilzomib) Once-Weekly 70 mg/m^2 in Combination with Dexamethasone (Kd70) for Patients with Relapsed or Refractory Multiple Myeloma

This information is intended to notify the press release issued on October 1 (ET) by Amgen. Please click https://www.amgen.com/media/news-releases/ for the original press release by Amgen.

(1st paragraph of the press release)

THOUSAND OAKS, Calif. (Oct 1, 2018) – Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) to expand the Prescribing Information for KYPROLIS® (carfilzomib) to include a once-weekly dosing option in combination with dexamethasone (once-weekly Kd70) for patients with relapsed or refractory multiple myeloma. The approval is based on data from the Phase 3 A.R.R.O.W. trial, which demonstrated that KYPROLIS administered once-weekly at 70 mg/m^2 with dexamethasone achieved superior progression-free survival (PFS) and overall response rates (ORR), with a comparable safety profile, versus twice-weekly KYPROLIS administered at a dose of 27 mg/m^2 in combination with dexamethasone (twice-weekly Kd27). KYPROLIS is not approved for twice-weekly 27 mg/m^2 administration in combination with dexamethasone alone.

*: A.R.R.O.W. study is a global collaborative clinical study including Japan.

About Ono and Amgen Collaboration

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.

About Approval Status of Kyprolis 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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