

August 31, 2018

Amgen Submits Supplemental New Drug Application for KYPROLIS® (carfilzomib) Once-Weekly 70 mg/m² in Combination with Dexamethasone

This information is intended to notify the press release issued on August 27(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., August 27, 2018) – Amgen (NASDAQ: AMGN) today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to expand the Prescribing Information for KYPROLIS® (carfilzomib) to include a once-weekly dosing option in combination with dexamethasone (Kd) for patients with relapsed or refractory multiple myeloma. The sNDA is based on data from the Phase 3 A.R.R.O.W. trial, demonstrating KYPROLIS administered once-weekly at 70 mg/m² with dexamethasone (once-weekly Kd) achieved superior progression-free survival (PFS) and overall response rates (ORR), with a comparable safety profile versus the twice-weekly KYPROLIS at 27 mg/m² and dexamethasone (twice-weekly Kd).

*: 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/m² in Cycle 1 on Day 1 and 2, and escalate to 56 mg/m² thereafter.

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