ONO PHARMACEUTICAL CO.,LTD.

August 24, 2020

FDA Approves New KYPROLIS® (carfilzomib) Combination Regimen with DARZALEX® (daratumumab) and Dexamethasone in Both Once- and Twice-Weekly Dosing Regimens

This information is intended to notify the press release issued on August 20 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 20, 2020) – Amgen (NASDAQ:AMGN) today announced the U.S. Food and Drug Administration (FDA) has approved the expansion of the KYPROLIS® (carfilzomib) U.S. prescribing information to include its use in combination with DARZALEX® (daratumumab) plus dexamethasone (DKd) in two dosing regimens - once weekly and twice weekly - for the treatment of patients with relapsed or refractory multiple myeloma (R/R MM) who have received one to three previous lines of therapy.

*: This approval is based on the CANDOR study, a global clinical study including Japan, in R/R MM patients, etc.

About Ono and Amgen Collaboration

In September 2010, Ono Pharmaceutical Co., Ltd. (ONO) entered into an exclusive license agreement on a proteasome inhibitor, Kyprolis® (for injection) with U.S.-based Onyx Pharmaceuticals, Inc., now a wholly-owned subsidiary of Amgen, to develop and commercialize the product 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. In September 2019, ONO also obtained a supplemental approval of Kyprolis for additional dosage and administration in combination with dexamethasone at a dosage of 20 mg/m^2 only in Cycle 1 on Day 1, and escalate to 70 mg/m^2 once a week thereafter.

Contact:
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono.co.jp