ONO PHARMACEUTICAL CO.,LTD.

September 17, 2019

Amgen Announces Phase 3 CANDOR Study Combining Kyprolis® (Carfilzomib) and Darzalex® (Daratumumab) Meets Primary Endpoint of Progression-Free Survival

This information is intended to notify the press release issued on September 13 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. (September 13, 2019) – Amgen (NASDAQ:AMGN) today announced the Phase 3 CANDOR study evaluating KYPROLIS® (carfilzomib) in combination with dexamethasone and DARZALEX® (daratumumab) (KdD) compared to KYPROLIS and dexamethasone alone (Kd) met its primary endpoint of progression-free survival (PFS). The regimen resulted in a 37% reduction in the risk of progression or death in patients with relapsed or refractory multiple myeloma treated with KdD (HR=0.630; 95% CI: 0.464, 0.854; *p*=0.0014). The median PFS for patients treated with Kd alone was 15.8 months, while the median PFS for patients treated with KdD has not been reached by the cut-off date.

*: CANDOR study is a global 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.

In addition, ONO submitted a supplemental application of Kyprolis for additional dosage and administration of Kyprolis 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.

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