ONO PHARMACEUTICAL CO.,LTD.

October 25, 2017

Phase 3 A.R.R.O.W. Study of Once-Weekly Kyprolis® (Carfilzomib) Regimen Meets Primary Endpoint of Progression-Free Survival in Relapsed and Refractory Multiple Myeloma Patients

On October 23, 2017, Amgen (NASDAQ:AMGN) announced top-line results from a pre-specified interim analysis of the Phase 3 A.R.R.O.W. trial, which showed Kyprolis® (carfilzomib) administered once-weekly at the 70 mg/m^2 dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than Kyprolis administered twice-weekly at the 27 mg/m^2 dose with dexamethasone. The overall safety profile of the once-weekly Kyprolis regimen was comparable to that of the twice-weekly regimen.

The study included 478 patients with relapsed and refractory multiple myeloma who received two or three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent (IMiD). Patients in the trial treated with the once-weekly Kyprolis regimen achieved a statistically significant superior progression-free survival (PFS) with a median of 11.2 months compared to 7.6 months for those treated with the twice-weekly Kyprolis regimen (HR = 0.69, 95 percent CI, 0.54 – 0.88).

The most frequently reported treatment-emergent adverse events (greater than or equal to 20 percent) in either treatment arm were anemia, diarrhea, fatigue, hypertension, insomnia and pyrexia.

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

Please click here for the press release distributed by Amgen.

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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