ONO PHARMACEUTICAL CO.,LTD.

March 2, 2017

Phase III Head-to-Head Trial Showed KYPROLIS® (Carfilzomib) Significantly Improved Overall Survival Compared to Velcade® (Bortezomib) in Relapsed or Refractory Multiple Myeloma Patients

On February 28, 2017, Amgen (NASDAQ:AMGN) announced positive results from a planned overall survival (OS) interim analysis of the Phase III head-to-head ENDEAVOR trial. The study met the key secondary endpoint of OS, demonstrating that patients with relapsed or refractory multiple myeloma treated with KYPROLIS® (carfilzomib) and dexamethasone (Kd) lived 7.6 months longer than those treated with Velcade® (bortezomib) and dexamethasone (Vd) (median OS 47.6 months for Kd versus 40.0 for Vd, HR = 0.79, 95 percent CI, 0.65 – 0.96). This Kd regimen administered with 56 mg/m^2 KYPROLIS twice weekly is already approved in the U.S., European Union and other countries based on the primary analysis of progression-free survival (PFS) in the ENDEAVOR study. Adverse events observed in this updated analysis were consistent with those previously reported for ENDEAVOR.

*: ENDEAVOR trial is a global collaborative clinical study including Japan.

For further information, please refer to the following link for press release made by Amgen.

http://www.amgen.com/media/news-releases/2017/02/phase-3-headtohead-trial-showed-kyprolis-carfilzomib-significantly-improved-overall-survival-compared-to-velcade-bortezomib-in-relapsed-or-refractory-multiple-myeloma-patients/

In Japan, 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, in September 2010 to develop and commercialize two products from Onyx's development program for proteasome inhibitors, carfilzomib (for injection) and oprozomib (orally administered) for all oncology indications.
ONO received the manufacturing and marketing approval of Kyprolis on July 4, 2016 which was launched for the treatment of relapsed or refractory multiple myeloma on August 31, 2016 in Japan. ONO also submitted an application of Kyprolis for a partial change in approved items of the manufacturing and marketing approval on August 25, 2016 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.

Contact
ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp