

September 28, 2016

Amgen Announces Top-line Results from Phase III Kyprolis® (Carfilzomib) CLARION Study in Newly Diagnosed Multiple Myeloma Patients

On September 27, 2016, Amgen (NASDAQ:AMGN) announced top-line results of the Phase III CLARION trial, which evaluated an investigational regimen of KYPROLIS® (carfilzomib), melphalan and prednisone (KMP) versus Velcade® (bortezomib), melphalan and prednisone (VMP) for 54 weeks in patients with newly diagnosed multiple myeloma who were ineligible for hematopoietic stem-cell transplant. The trial did not meet the primary endpoint of superiority in progression-free survival (PFS) (median PFS 22.3 months for KMP versus 22.1 months for VMP, HR = 0.91, 95 percent CI, 0.75 - 1.10). While the data for overall survival, a secondary endpoint, are not yet mature, the observed hazard ratio (KMP versus VMP) was 1.21 (95 percent CI, 0.90 - 1.64). Neither result was statistically significant.

Overall, the adverse events in the KMP arm were consistent with the known safety profile of KYPROLIS. The incidence of Grade 3 or higher adverse events was 74.7 percent in the KMP arm and 76.2 percent in the VMP arm. Fatal treatment-emergent adverse events occurred in 6.5 percent of KMP patients and 4.3 percent of VMP patients. The incidence of Grade 2 or higher peripheral neuropathy, a secondary endpoint, was 2.5 percent in the KMP arm and 35.1 percent in the VMP arm.

CLARION 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/2016/09/amgen-announces-topline-results-from-phase-3-kyprolis-carfilzomib-clarion-study-in-newly-diagnosed-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/m² in Cycle 1 on Day 1 and 2, and escalate to 56 mg/m² thereafter.

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