January 22, 2016

FDA Approves NEW Kyprolis® (Carfilzomib) COMBINATION THERAPY for the treatment of patients with Relapsed Or Refractory multiple myeloma

THOUSAND OAKS, Calif. (Jan. 21, 2016) – Amgen (NASDAQ:AMGN) announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) of Kyprolis® (carfilzomib) for Injection in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. The FDA also approved Kyprolis as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. This FDA decision converts to full approval the initial accelerated approval Kyprolis received in July 2012 as a single agent.

For further information, visit the link below to the website for press release distributed by Amgen.
http://www.amgen.com/media/news-releases/2016/01/fda-approves-new-kyprolis-carfilzomib-combination-therapy-for-the-treatment-of-patients-with-relapsed-or-refractory-multiple-myeloma/

In Japan, ONO entered into an exclusive license agreement with Onyx, a wholly-owned subsidiary of Amgen, in September 2010 to develop and commercialize two compounds from Onyx's proteasome inhibitor development program, carfilzomib (for injection) and oprozomib (orally administered) for all oncology indications. ONO submitted Manufacturing and Marketing Approval Application for "carfilzomib for Injection (ONO-7057)", to seek an indication for relapsed or refractory multiple myeloma in August 2015.

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