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FDA Acceptance of New Drug Application for Carfilzomib in Relapsed and Refractory Multiple Myeloma in the U.S.

Onyx Pharmaceuticals, Inc. ("Onyx") announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) submission for carfilzomib, a next generation proteasome inhibitor, for the potential treatment of patients with relapsed and refractory multiple myeloma.

Attached is the press release made by Onyx for your information.

In Japan, Ono is conducting a Phase 1/2 study evaluating carfilzomib in patients with relapsed/refractory multiple myeloma, in accordance with the license agreement* between Onyx and Ono signed in September 2010.

* Ono entered into an exclusive license agreement with Onyx to develop and commercialize two compounds from Onyx's proteasome inhibitor development program, carfilzomib (for injection) and ONX 0912 (orally administered) for all oncology indications in Japan. The compounds are both in clinical development by Onyx outside of Japan.

Onyx Pharmaceuticals Announces FDA Acceptance of New Drug Application for Carfilzomib for the Treatment of Relapsed and Refractory Multiple Myeloma

South San Francisco, CA – November 29, 2011– Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) announced today that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) submission for carfilzomib, a next generation proteasome inhibitor, for the potential treatment of patients with relapsed and refractory multiple myeloma.

"The FDA's acceptance of the new drug application submission for carfilzomib marks an important milestone for bringing this promising therapy one step closer to patients with few remaining treatment options," said Ted Love, M.D., executive vice president, research and development and technical operations at Onyx Pharmaceuticals. "We believe that the efficacy and safety data make carfilzomib an appropriate candidate for accelerated approval in the relapsed and refractory treatment setting, and we look forward to hearing back from the FDA in the next few weeks regarding priority versus standard review."

About the Phase 2b 003-A1 Study

The submission is based on the 003-A1 study, an open-label, single-arm Phase 2b trial. The trial evaluated 266 heavily-pretreated patients with relapsed and refractory multiple myeloma who had received at least two prior therapies, including bortezomib and either thalidomide or lenalidomide. Refractory disease was defined as less than or equal to a 25 percent response or progression during therapy, or progression within 60 days after completion of therapy.[1] The primary endpoint was overall response rate. Secondary endpoints included duration of response, clinical benefit rate, overall survival, time-to-progression, progression-free survival, and safety. Safety data from additional carfilzomib studies were also included in the submission.

Carfilzomib Development Program

Carfilzomib is being studied in several clinical trials either as a single-agent or in combination with other therapies, including:

- A Phase 3 clinical trial, known as the ASPIRE trial, is evaluating the combination of lenalidomide and low dose dexamethasone with or without carfilzomib in patients with relapsed multiple myeloma who have received one to three prior therapies. The company has an agreement with the FDA on a Special Protocol Assessment (SPA) on the design and planned analysis of the ASPIRE trial.

- A Phase 3 clinical trial, called the FOCUS trial to support registration in Europe, is evaluating single-agent carfilzomib in patients with relapsed and refractory myeloma who have received three or more prior therapies.

- A Phase 2 clinical trial, known as the 004 study, is evaluating single-agent carfilzomib in patients with relapsed and/or refractory multiple myeloma who have received one to three prior therapies.

- A Phase 1b/2 study, known as the 006 study, is evaluating carfilzomib in combination with lenalidomide and low dose dexamethasone in patients with relapsed and/or refractory myeloma.

- A Multiple Myeloma Research Consortium (MMRC) Phase 1/2 study is evaluating carfilzomib in combination with lenalidomide and low dose dexamethasone in newly diagnosed patients. This study is supported by Onyx Pharmaceuticals, MMRC, and Celgene Corporation.

- A Phase 1/2 study being conducted by Onyx's partner Ono Pharmaceutical Co., Ltd is evaluating carfilzomib in Japanese patients with relapsed/refractory multiple myeloma.

- An expanded access program is underway in partnership with the Multiple Myeloma Research Foundation for eligible patients in the U.S., with relapsed and refractory multiple myeloma for whom no satisfactory treatment alternatives are available.

About Multiple Myeloma

Multiple myeloma is the second most common hematologic cancer and results from an abnormality of plasma cells, usually in the bone marrow. In the United States, more than 50,000 people are living with multiple myeloma and approximately 20,000 new cases are diagnosed annually.[ii] Worldwide, more than 180,000 people are living with multiple myeloma and approximately 86,000 new cases are diagnosed annually.[iii]

About Onyx Pharmaceuticals, Inc.

Based in South San Francisco, California, Onyx Pharmaceuticals, Inc. is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer and other serious diseases. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx-pharm.com.

[i] Anderson et al. Clinically relevant end points and new drug approvals for myeloma. *Leukemia.* 2008. 22:231

[ii] National Cancer Institute, Surveillance Epidemiology and End Results, 2007 Facts and Figures

[iii] International Agency for Research on Cancer, GLOBOCAN 2002 database