ONO PHARMACEUTICAL CO.,LTD.

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

Onyx Pharmaceuticals, Inc. ("Onyx") announced that it has completed the New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) under the accelerated approval process 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 Submits New Drug Application for Carfilzomib in Relapsed and Refractory Multiple Myeloma

South San Francisco, CA– September 28, 2011 – Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that it has completed the New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) under the accelerated approval process for carfilzomib, a next generation proteasome inhibitor, for the potential treatment of patients with relapsed and refractory multiple myeloma. In addition, Onyx has requested priority review of the application, which reduces the time the FDA takes to review a new drug application.

"We believe the efficacy and safety data within the NDA submission provide a compelling basis for accelerated approval of carfilzomib in the relapsed and refractory treatment setting," said Ted W. Love, M.D., Executive Vice President, Research and Development and Technical Operations at Onyx Pharmaceuticals. "While important strides have been made in treating patients with multiple myeloma in the last decade, this disease remains uniformly fatal, underscoring the need for new treatment options."

The rolling submission of the NDA began in January 2011, after carfilzomib was granted Fast Track designation by the FDA, and the company submitted the pre-clinical portion of the application. The Fast Track designation process was developed by the FDA to facilitate the development, and expedite the review of drugs to treat serious or life-threatening diseases with an unmet medical need.

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 additional 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 greater than three 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, 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 at the University of Michigan Comprehensive Cancer Center, evaluating carfilzomib in combination of lenalidomide and low dose dexamethasone in newly diagnosed patients. This study is sponsored by Onyx Pharmaceuticals, MMRC, Celgene Corporation and the University of Michigan Comprehensive Cancer Center.

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

- An expanded access program launched 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.[2] Worldwide, more than 180,000 people are living with multiple myeloma and approximately 86,000 new cases are diagnosed annually.[3]

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.

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[1] Anderson et al. Clinically relevant end points and new drug approvals for myeloma. *Leukemia.* 2008. 22:231
[2] National Cancer Institute, Surveillance Epidemiology and End Results, 2007 Facts and Figures
[3] International Agency for Research on Cancer, GLOBOCAN 2002 database