Press Releases

Onyx Pharmaceuticals Announces Positive Complete Results from Carfilzomib Phase 2b Study

24 Percent Overall Response Rate and Duration of Response Exceeding Eight Months in Heavily Pretreated Advanced Multiple Myeloma Patients; Median Overall Survival 15.5 months

Investor Teleconference with Carfilzomib Trial Investigators Today at 10:00 a.m. ET

Emeryville, CA. — Dec. 07, 2010

Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced positive complete results from the Phase 2b 003-A1 study of single-agent carfilzomib, a next generation proteasome inhibitor, in patients with relapsed and refractory multiple myeloma. Carfilzomib achieved an overall response rate (ORR) (partial response or greater) of 24.1 percent and a median duration of response (DOR) of 8.3 months in patients who entered the study after receiving a median of five prior lines of therapy (corresponding to a median of 13 anti-myeloma agents) and whose disease was refractory to their last therapeutic regimen. In addition, patients enrolled in the study had progressive disease upon entering the trial. The clinical benefit rate (CBR) (minimal response or greater) in the study population was 34.2 percent. The median overall survival (OS) was 15.5 months. Overall survival for responding patients (≥ minimal response) has not yet been reached; however, based on current data is expected to exceed 19 months.

Seventy-seven percent of patients had grade 1/2 peripheral neuropathy (PN) upon entry into the study. New or worsening of PN was uncommon and Grade 3 PN occurred in less than 1 percent of patients. There were no Grade 4 PN events. A subset analysis of patients with PN (n= 202) on study was also presented at ASH. Efficacy responses in patients with baseline PN were comparable to those seen in the full study population with an ORR of 24 percent and CBR of 34 percent. Based on the full 003-A1 results, Onyx plans to submit a New Drug Application (NDA) filing as early as mid-2011 for potential accelerated approval in the U.S.

These data are being presented today at the 52nd American Society of Hematology Annual Meeting in Orlando by David Siegel, M.D., Ph.D., Division Chief for Myeloma at John Theurer Cancer Center at Hackensack University Medical Center. The results will also be included in the 2011 Highlights of ASH meetings, taking place January through April.

“There is a significant need for new treatment options for these patients with refractory multiple myeloma who have exhausted all other options,” said Dr. Siegel. “This heavily pretreated patient population has received all classes of approved and commonly used myeloma therapies, and the durable responses and tolerability demonstrate carfilzomib’s potential as a promising treatment.”

In the overall study population, no new or unexpected toxicities were observed. The most common Grade 3/4 adverse events were thrombocytopenia (27 percent), anemia (22 percent), lymphopenia (18 percent), and neutropenia (10 percent).

In a subset analysis of patients who were refractory to bortezomib in their last line of therapy (n=128), carfilzomib achieved an ORR of 19 percent and CBR of 31 percent. In patients who had received only one prior bortezomib regimen (n=122), the ORR was 30 percent and the CBR was 40 percent.

“We believe that carfilzomib has the potential to be an important new treatment option for patients with relapsed and refractory myeloma,” said Michael G. Kauffman, M.D., Ph.D., Chief Medical Officer of Onyx Pharmaceuticals. “We are particularly encouraged by the activity and very low rates of peripheral neuropathy observed in this study.”

Two hundred and sixty-six patients with relapsed and refractory multiple myeloma were enrolled in the study, and 257 patients were evaluable for response. The primary endpoint was ORR. Secondary endpoints included CBR, DOR, OS, time to progression (TTP), progression free survival (PFS), and safety.

Trial Design
The 003-A1 study was an open-label, single-arm Phase 2b trial. The trial evaluated 266 heavily-pretreated patients with relapsed and refractory multiple myeloma whose disease was refractory to their last treatment regimen and who had received at least two prior therapies, including bortezomib, either thalidomide or lenalidomide, an alkylating agent, glucocorticoids and an anthracycline. Refractory disease was defined as ≤ 25 percent response or progression during therapy, or progression within 60 days after completion of therapy.[i] Patients received carfilzomib at 20mg/m2 for the first cycle followed by 27mg/m2 thereafter for up to 12 cycles. Patients who completed the 12 cycles were eligible to enter an extension study. Responses and progression were determined according to the International Myeloma Working Group (IMWG) criteria. The trial was conducted in collaboration with the Multiple Myeloma Research Consortium (MMRC) and at additional sites in the U.S. and Canada.

ASH Investor Teleconference
Investigators will discuss data presentations surrounding carfilzomib in relapsed and/or refractory multiple myeloma, as featured at the 52nd American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, Florida. The teleconference will begin at 10:00 a.m. ET on December 7, 2010. The live webcast will be available at:

http://www.onyx-pharm.com/view.cfm/32/Event-Calendar

or by dialing 847-585-4405 and using the passcode 28465587. A replay of the presentation will be available on the Onyx website or by dialing 630-652-3042 and using the passcode 28465587# later in the day. The replay will be available on the Onyx website through December 21, 2010.

About the Carfilzomib Development Program
Carfilzomib is a selective, next generation proteasome inhibitor that has shown encouraging results in a broad clinical trial program in multiple myeloma.

The carfilzomib development program includes a large, randomized international Phase 3 clinical trial, known as the ASPIRE trial, studying the combination of lenalidomide and low dose dexamethasone with or without carfilzomib in patients with relapsed multiple myeloma. The company has an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) and received Scientific Advice from the European Medicines Agency (EMA) on the design and planned analysis of the ASPIRE trial. A second Phase 3 clinical trial, called the FOCUS trial, is evaluating carfilzomib in patients with relapsed and refractory myeloma in Europe. Carfilzomib is also being evaluated in advanced solid tumors.

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.

Onyx Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of people with cancer. The company, in collaboration with Bayer HealthCare Pharmaceuticals Inc., is developing and marketing Nexavar® (sorafenib) tablets, a small molecule drug that is currently approved for the treatment of liver cancer and advanced kidney cancer. Additionally, Nexavar is being investigated in several ongoing trials in a variety of tumor types. Beyond Nexavar, Onyx has established a development pipeline of anticancer compounds at various stages of clinical testing, including carfilzomib, a selective proteasome inhibitor, that is currently being evaluated in multiple clinical trials for the treatment of patients with relapsed or relapsed/refractory multiple myeloma and solid tumors. ONX 0801, an alpha-folate receptor targeted inhibitor of thymidylate synthase, and ONX 0912, an oral proteasome inhibitor, are currently in Phase 1 testing. For more information about Onyx, visit the company's website at **www.onyx-pharm.com**.

Forward Looking Statements

This news release contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include without limitation, statements regarding the progress and results of the clinical development, safety, regulatory processes, commercialization efforts or commercial potential of carfilzomib. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including risks related to the development and commercialization of pharmaceutical products. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Reference should be made to Onyx's Annual Report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission under the heading "Risk Factors" and Onyx's Quarterly Reports on Form 10-Q for a more detailed description of such factors. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

[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

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