Press Releases

Onyx Pharmaceuticals Announces Plans to Amend Phase 3 FOCUS Study for European Registration

U.S. NDA Filing Expected to be Completed as Early as Mid-Year

Emeryville, CA. — Mar. 28, 2011

Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced its plans to expand the Phase 3 European clinical trial FOCUS, which is evaluating the efficacy and tolerability of carfilzomib, a selective next-generation proteasome inhibitor. The FOCUS trial is designed to support the registrational filing with the European Medicines Agency (EMA) in patients with relapsed and refractory myeloma.

The FOCUS (Car**F**il**z** **O**mib for Advan**C**ed Refractory M**U**ltiple Myeloma European **S**tudy) trial modification includes two key enhancements to the study: changing the primary end point to overall survival (OS) from progression-free survival (PFS) and correspondingly increasing patient enrollment to 300 from 84. These modifications are supported by overall survival data from the Phase 2b 003-A1 study evaluating single-agent carfilzomib in patients with relapsed and refractory multiple myeloma announced at the American Society of Hematology (ASH) meeting in December 2010. The company expects to review these data with the EMA and is moving forward with plans to do so.

"Given the encouraging carfilzomib data reported to date, including the 003-A1 survival data, Onyx decided to make this change to demonstrate a potential mortality benefit for carfilzomib," said Ted Love, M.D., executive vice president, research and development and technical operations at Onyx. "We plan to upsize the trial at the currently active sites by leveraging the momentum we are seeing in enrollment as well as by adding additional sites, as appropriate."

Focus Trial Design
As modified, the Phase 3 FOCUS study will be a randomized 300-patient trial evaluating carfilzomib versus best supportive care of low dose steroids plus cytoxan (optional), in patients with relapsed and refractory multiple myeloma following treatment with at least three prior therapies. Patients are being randomized to receive carfilzomib (20mg/m2 on days 1 and 2 of cycle 1 only, then 27mg/m^2 subsequently). The primary endpoint is overall survival with secondary endpoints including PFS, overall response rate (ORR), clinical benefit rate (CBR) and duration of response (DOR), as well as safety. The study design incorporates planned interim analyses on the primary endpoint.

Onyx on Track for Submission of NDA in the U.S.
In January, Onyx announced that the U.S. Food and Drug Administration (FDA) had granted fast track designation for carfilzomib. Onyx has initiated a rolling submission of a New Drug Application (NDA) for potential accelerated approval of carfilzomib in the U.S. Through the Fast Track designation, Onyx is eligible to submit the carfilzomib NDA on a rolling basis, allowing Onyx to begin the NDA filing process immediately and giving the FDA an opportunity to review the completed sections of the registration application. Onyx has now submitted the non-clinical section of the carfilzomib NDA with the FDA and commenced its rolling NDA process. Onyx intends to complete its submission of the NDA for potential accelerated approval of carfilzomib in the U.S. as early as mid-2011.

About the Carfilzomib Development Program
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. Carfilzomib is also being evaluated in a broad investigator sponsored trial program including 1st line multiple myeloma, combination studies, lymphoma and other malignancies.

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[i]. Worldwide, more than 180,000 people are living with multiple myeloma and approximately 86,000 new cases are diagnosed annually[ii].

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 in various settings 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 press 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 clinical development and regulatory processes related to carfilzomib, and potential benefits of the modification of the FOCUS Phase 3 study. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: Onyx may never receive marketing approval for carfilzomib; failures or delays in Onyx's clinical trials; if approved, Onyx may be unsuccessful in launching, maintaining adequate supply of or obtaining reimbursement for carfilzomib; serious adverse side

effects, if they are associated with carfilzomib; competition; government regulation; and protection of Onyx's intellectual property. Any statements contained in this report 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, 2010, filed with the Securities and Exchange Commission under the heading "Risk Factors" 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] National Cancer Institute, Surveillance Epidemiology and End Results, 2007 Facts and Figures

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

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