July 23, 2012

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Carfilzomib, a proteasome inhibitor,
has been granted FDA accelerated approval

Onyx Pharmaceuticals, Inc. ("Onyx") announced that U.S. Food and Drug Administration's (FDA) has granted accelerated approval of carfilzomib (ONO-7057), a proteasome inhibitor, indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

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

In Japan, Ono is conducting a Phase 1/2 study 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 oprozomib (orally administered) for all oncology indications in Japan. The compounds are both in clinical development by Onyx outside of Japan.

Onyx Pharmaceuticals Receives FDA Accelerated Approval of Kyprolis™ (carfilzomib) for Injection

Onyx Launches Comprehensive Patient Support Program

Onyx to Host Conference Call Today at 1:00 p.m. ET

South San Francisco, CA – July 20, 2012 – Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of Kyprolis™ (carfilzomib) for Injection, a proteasome inhibitor, indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies, including bortezomib and an immunomodulatory agent, and have demonstrated disease progression on or within 60 days of completion of the last therapy. The indication for Kyprolis is based on response rate. Currently, no data are available for Kyprolis that demonstrate an improvement in progression-free survival or overall survival.

“Today’s approval is a significant milestone for Onyx and, most importantly, for patients with advanced myeloma who have few treatment options available to them,” said N. Anthony Coles, M.D., President and Chief Executive Officer of Onyx Pharmaceuticals. “We deeply appreciate the hundreds of patients who participated in the Kyprolis clinical studies that led to this accelerated approval, and recognize the many clinicians across the country and researchers here at Onyx for their dedication in bringing this promising new medicine to patients. We are committed to continuing the clinical development of Kyprolis across earlier stages of multiple myeloma treatment.”

The approval was based on the results of the Phase 2b 003-A1 study, a single-arm, multicenter clinical trial that enrolled 266 patients with multiple myeloma, who had received a median of five prior anti-myeloma regimens. The primary efficacy endpoint was overall response (ORR) and determined by an Independent Review Committee using the International Myeloma Working Group (IMWG) criteria. ORR was 22.9% and median response duration was 7.8 months.

Safety data were evaluated in 526 patients with relapsed and/or refractory multiple myeloma who received single-agent carfilzomib. There were 37 deaths on study, or 7% of patients. The most common causes of death, other than disease progression, were cardiac (5 patients), end-organ failure (4 patients), and infection (4 patients). Important warnings and precautions include cardiac arrest, congestive heart failure, myocardial ischemia; pulmonary hypertension, pulmonary complications, infusion reactions, infusion reactions, tumor lysis syndrome, thrombocytopenia, hepatic toxicity and embryo-fetal toxicity. The most common serious adverse reactions were pneumonia, acute renal failure, pyrexia, and congestive heart failure. The most common adverse reactions (incidence of 30% or greater) observed in clinical trials of patients with multiple myeloma were fatigue, anemia, nausea, thrombocytopenia, dyspnea, diarrhea, and

pyrexia. Serious adverse reactions were reported in 45% of patients.

Full prescribing information is available at http://www.onyx.com.

“This approval provides a new treatment option for the significant unmet need that exists in patients with multiple myeloma who have progressed after use of available treatments,” said Dr. David Siegel, Chief of the Division of Multiple Myeloma at John Theurer Cancer Center at Hackensack University Medical Center. “The single-agent activity of Kyprolis provides clinicians the opportunity to help these patients who until now had no effective options.”

Enrollment has been completed for the Phase 3 confirmatory clinical trial, known as the ASPIRE trial. The company has an agreement with the FDA on a Special Protocol Assessment (SPA) for this trial.

Onyx also announced the availability of Onyx Pharmaceuticals 360™ (Onyx 360), a comprehensive patient and caregiver support and services program, designed to help patients navigate the treatment journey, including reimbursement and payment support, treatment support and referrals to third-party organizations for day-to-day and emotional support. Dedicated Oncology Nurse Advocates are available Monday through Friday from 9:00 a.m. to 8:00 p.m. Eastern Standard Time at 1-855-ONYX-360 (1-855-669-9360) to assist patients, caregivers and healthcare providers.

Conference Call Details

Onyx’s management team will host a webcast and conference call to discuss today’s approval. The call will be held on July 20, 2012 at 1:00 p.m. Eastern Time (10:00 a.m. Pacific Time).

To access a live audio webcast of the conference call, log onto the company’s website at: http://www.onyx.com/investors/event-calendar.

To access the live conference call on July 20, 2012, dial (847) 585-4405 and use the passcode 32934688. A replay of the call will be available on the Onyx website or by dialing (630) 652-3042 and using the passcode 32934688# approximately two hours after the conference call concludes through August 03, 2012.

Important Safety Information Regarding Kyprolis™ (carfilzomib) for Injection

Death due to cardiac arrest has occurred within a day of Kyprolis administration. Patients with New York Heart Association Class III and IV heart failure, myocardial infarction in the preceding 6 months, and conduction abnormalities uncontrolled by medications were not eligible for the clinical trials. These patients may be at greater risk for cardiac complications.

Pulmonary arterial hypertension (PAH) was reported in 2% of patients treated with Kyprolis and was Grade 3 or greater in less than 1% of patients. Dyspnea was reported in 35% of patients

enrolled in clinical trials. Grade 3 dyspnea occurred in 5%; no Grade 4 events, and 1 death (Grade 5) was reported.
Infusion reactions, characterized by a spectrum of systemic symptoms including fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina can occur immediately following or up to 24 hours after administration of Kyprolis. Administration of dexamethasone prior to Kyprolis reduces the incidence and severity of reactions. Tumor lysis syndrome (TLS) occurred following Kyprolis administration in < 1% of patients. Patients with multiple myeloma and a high tumor burden should be considered to be at greater risk for TLS.

Thrombocytopenia following Kyprolis administration resulted in a dose reduction in 1% of patients and discontinuation of treatment with Kyprolis in < 1% of patients.

Cases of hepatic failure, including fatal cases, have been reported (< 1%). Kyprolis can cause elevations of serum transaminases and bilirubin.

There are no adequate and well-controlled studies in pregnant women using Kyprolis. Females of reproductive potential should be advised to avoid becoming pregnant while being treated with Kyprolis.

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 220,000 people are living with multiple myeloma and approximately 100,000 new cases are diagnosed annually [ii].

About the Kyprolis™ (carfilzomib) for Injection Development Program

Kyprolis is approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

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

- A global Phase 3 clinical trial, known as the ASPIRE trial, has completed enrollment and is evaluating the combination of lenalidomide and low-dose dexamethasone with or without Kyprolis 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) and has received Scientific Advice from the European Medicines Agency (EMA) on the design and planned analysis of the trial.

- A Phase 3 clinical trial, known as the FOCUS trial, is evaluating single-agent Kyprolis in patients with relapsed and refractory myeloma who have received three or more prior therapies. The trial is designed to facilitate regulatory approvals around the world.
- A global head-to-head Phase 3 clinical trial, known as the ENDEAVOR trial, is evaluating the combination of Kyprolis and low-dose dexamethasone versus the combination of bortezomib and low-dose dexamethasone.
- A Phase 1/2 study being conducted by Onyx's partner Ono Pharmaceutical Co., Ltd. is evaluating Kyprolis in Japanese patients with relapsed/refractory multiple myeloma.

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. 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.com.

[i] American Cancer Society, Cancer Facts & Figures 2012
[ii] International Agency for Research on Cancer, GLOBOCAN 2010