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Proteolix Announces Positive Data from Two Ongoing Phase 2 Clinical Trials of Carfilzomib in Multiple Myeloma at the 50th Annual Meeting of the American Society of Hematology

Carfilzomib Demonstrates Promising Single-Agent Anti-Tumor Activity in Relapsed and Refractory Myeloma Patients

South San Francisco, California, December 9, 2008 – Proteolix, Inc. today announced positive clinical data demonstrating that the company's lead product, carfilzomib, has single-agent activity and promotes durable responses in patients with relapsed and refractory multiple myeloma. Carfilzomib is the first in a new class of specific proteasome inhibitors being developed by Proteolix for the treatment of hematologic malignancies and solid tumors.

Sundar Jagannath, M.D., Chief of the Multiple Myeloma Program, Bone Marrow and Blood Stem Cell Transplantation at St. Vincent's Comprehensive Cancer Center in New York, and Ravi Vij, M.D., Associate Professor of Medicine, Division of Oncology, Section of Bone Marrow Transplantation at Washington University School of Medicine, presented data from two ongoing Phase 2 clinical trials of carfilzomib in relapsed and refractory multiple myeloma patients during the Novel Therapies for Myeloma and Related Disorders oral session at the 50th Annual Meeting of the American Society of Hematology (ASH). Both Phase 2 clinical trials are being conducted by Proteolix in collaboration with the Multiple Myeloma Research Consortium (MMRC).

Activity in Relapsed and Refractory Multiple Myeloma Patients

Dr. Jagannath presented data from an ongoing, open-label, multi-center study of single-agent carfilzomib in multiple myeloma patients. All patients in this trial were refractory to their last treatment. Of 39 evaluable patients, ten (26%) achieved partial or minor responses and an additional 16 (41%) achieved stable disease. Importantly, responses have also been durable with median treatment duration of 240 days, or approximately eight months.

"Patients enrolled in this Phase 2 trial have previously failed bortezomib, lenalidomide, thalidomide, and stem cell transplant. Carfilzomib as a single-agent is well tolerated and has demonstrated encouraging activity," said Dr. Jagannath.

The most common adverse events reported have been fatigue, anemia and thrombocytopenia. Patients with impaired renal function tolerated the drug and responses were independent of renal status. Treatment with carfilzomib was associated with a low incidence of peripheral neuropathy, a common side effect associated with the approved proteasome inhibitor, bortezomib. Exacerbation of pre-existing peripheral neuropathy was rare and did not result in dose reductions or discontinuation of therapy. Overall, carfilzomib was generally well tolerated and toxicities were manageable.

These data were presented by Dr. Jagannath in an oral presentation titled Initial Results of PX-171-003, an Open-Label, Single-Arm, Phase 2 Study of Carfilzomib in Patients with Relapsed and Refractory Multiple Myeloma (MM) (Abstract #864).

Carfilzomib Activity in Relapsed Patients by Prior Exposure to Bortezomib

A second presentation by Dr. Vij described interim results from a Phase 2 clinical trial of single-agent carfilzomib in multiple myeloma patients designed to evaluate response rates based on patients' bortezomib treatment history. Patients enrolled in this trial received one to three prior therapies, such as bortezomib, thalidomide, lenalidomide or stem cell transplantation and had subsequently relapsed. A total of 31 patients have been enrolled in this study and are currently evaluable for response.

Of fourteen evaluable bortezomib-naïve patients, eight (57%) achieved responses, including one patient with a complete response, two with very good partial responses and five with partial responses. Four additional patients achieved stable disease. Among seventeen patients who have received prior treatment with bortezomib, three (18%) achieved partial responses, one patient achieved a minor response, and ten patients achieved stable disease. The median time to disease progression has not yet been established for this study.

According to Dr. Vij, "Single-agent carfilzomib has shown impressive and durable activity, notably among patients who have failed transplantation and have not yet received treatment with a proteasome inhibitor. The emerging safety profile makes this an attractive option in patients who have pre-existing neuropathy. Continued evaluation of carfilzomib in less heavily pre-treated patients is warranted given these promising findings."

Carfilzomib was generally well tolerated among relapsed patients and toxicities were manageable. The most common adverse events were fatigue, anemia and neutropenia. Two cases of tumor lysis syndrome were observed among bortezomib-naïve patients, and with additional monitoring and management guidelines no further events have been reported. No treatment-emergent Grade 3 or 4 peripheral neuropathy was reported in this study.

Dr. Vij presented these interim data from a study of relapsed patients in a presentation titled Initial Results of PX-171-004, an Open-Label, Single-Arm, Phase 2 Study of Carfilzomib in Patients with Relapsed Multiple Myeloma (MM) (Abstract #865).
"We are encouraged by the data that show that carfilzomib is active and has been successful in providing durable responses in patients who have relapsed or who do not respond to currently available treatment options," said Lori A. Kunkel, M.D., Proteolix's Chief Medical Officer. "We believe carfilzomib may have broad application in the treatment of hematologic malignancies and solid tumors."

Supporting Preclinical Data

In addition to the two oral presentations of Phase 2 clinical data, Proteolix scientists presented results of preclinical studies that further characterize the mechanism and safety profile of carfilzomib. These data were presented on Sunday, December 7 in two poster presentations: Non-Proteasomal Targets of Proteasome Inhibitors Bortezomib and Carfilzomib (Abstract #2657) and The Selective Proteasome Inhibitor Carfilzomib is Well Tolerated in Experimental Animals with Dose Intensive Administration (Abstract #2765).

Carfilzomib acts by inhibiting the proteasome with a high degree of selectivity and is structurally and mechanistically distinct from bortezomib. Preclinical studies designed to assess and compare the off-target activity of bortezomib and carfilzomib indicate that carfilzomib has minimal activity on proteases other than the proteasome. In contrast, bortezomib targets several serine proteases including Cathepsin G, an enzyme whose inhibition may play a role in neuropathic pain. Proteolix researchers believe that these observations may translate into a different and possibly superior safety profile for carfilzomib as compared to bortezomib. In support of this notion, chronic administration of carfilzomib is well tolerated in rats and monkeys with no signs of the significant behavioral and histological neurotoxicities that have been described for bortezomib.

About Multiple Myeloma

According to the American Cancer Society, in 2008, approximately 19,900 new cases of multiple myeloma will be diagnosed in the United States. Newly diagnosed patients have treatment options that include combination chemotherapeutic agents and stem cell transplantation. While many patients respond to treatment, most eventually relapse and require subsequent treatment. Few patients are ultimately cured of their disease.

About Carfilzomib

Carfilzomib is the first in a new class of highly specific proteasome inhibitors. Carfilzomib produces specific and sustained inhibition of the proteasome, leading to apoptosis in cancer cells with minimal off-target effects. In Phase 1 and Phase 2 clinical trials, carfilzomib has demonstrated single-agent activity in hematologic and solid tumors, including multiple myeloma and renal cancer.
Proteolix is currently conducting a comprehensive clinical development program evaluating carfilzomib for the treatment of multiple myeloma, including two ongoing Phase 2 clinical trials of single-agent carfilzomib, one in heavily pre-treated relapsed patients who have failed to respond to prior treatment, and a second in relapsed patients stratified by prior treatment with bortezomib. A Phase Ib clinical trial of carfilzomib in combination with lenalidomide and dexamethasone in patients with relapsed multiple myeloma is also ongoing. In addition, based on promising Phase 1 results, Proteolix is conducting a single-agent Phase 2 clinical trial of carfilzomib in patients with recurrent or advanced solid tumors. For the latest information regarding ongoing carfilzomib clinical trials, please visit www.clinicaltrials.gov.

About Proteolix

Founded in December 2003, Proteolix, Inc. is a privately-held biopharmaceutical company, headquartered in South San Francisco, dedicated to discovering, developing and commercializing novel therapeutics that target protein degradation pathways for cancer and autoimmune diseases. Proteolix's lead product, carfilzomib, is the first in a new class of highly specific proteasome inhibitors, and is currently in multiple Phase 2 clinical studies to evaluate its safety and efficacy in hematologic and solid tumor malignancies. Proteolix is also developing a pipeline of novel proteasome inhibitors, including an oral proteasome inhibitor and a selective immunoproteasome inhibitor.

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