



Press Release

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THE MULTIPLE MYELOMA RESEARCH CONSORTIUM (MMRC) AND PROTEOLIX INITIATE PHASE 2 CLINICAL TRIAL INVESTIGATING CARFILZOMIB FOR THE TREATMENT OF MULTIPLE MYELOMA

Phase 2 Study to Explore the Efficacy of Novel Proteasome Inhibitor in Patients with Relapsed and Refractory Multiple Myeloma

SOUTH SAN FRANCISCO, Calif. & NORWALK, Conn., August 15, 2007 – The Multiple Myeloma Research Consortium (MMRC) and Proteolix, Inc. today announced the enrollment of the first patient in a multi-center Phase 2 clinical trial to study Proteolix's potent and selective proteasome inhibitor, carfilzomib (PR-171), in patients with relapsed and refractory multiple myeloma. Ten MMRC Member Institutions will participate in the study, under the MMRC leadership of Melissa Alsina, MD, H. Lee Moffitt Cancer Center & Research Institute. The nine additional sites are the City of Hope, Emory University, Cancer Center at Hackensack University Medical Center, Mayo Clinic, Princess Margaret/University Health Network, Saint Vincent's Comprehensive Cancer Center, University of Michigan, and Washington University.

The MMRC is the only research model of its kind that brings together 13 leading academic institutions to accelerate the development of novel and combination treatments for multiple myeloma, an incurable cancer of the plasma cell.

“Proteasome inhibitors are an important class of drugs for the treatment of multiple myeloma and we are proud to work with Proteolix to advance the clinical development of carfilzomib,” said Kathy Giusti, Founder and Chief Executive Officer of the MMRC. “This trial and the others the MMRC are facilitating underscore our commitment to bring better, more effective treatments to myeloma patients as quickly as possible.”

The trial will evaluate the overall response rate (ORR) for two cycles of carfilzomib in patients with multiple myeloma who have previously received specific FDA-approved therapies, have relapsed after two or more of such therapies, and are refractory to the most recently received therapy. Secondary objectives of this study include safety and tolerability, clinical benefit response (CBR), time to progression (TTP), duration of response (DOR), progression-free survival, and best ORR throughout the study. Patients enrolled in the trial will receive carfilzomib twice weekly for three weeks every 28 days.

“Based on promising laboratory and clinical data, we believe that carfilzomib holds promise in treating patients with multiple myeloma, including those for whom other treatments have failed,” said Sundar Jagannath, M.D., Saint Vincent's Comprehensive Cancer Center, where the first patient was enrolled. “We are excited to bring this compound into the MMRC as a critical step in bringing this new treatment to patients.”

In the coming weeks, the MMRC and Proteolix will also begin enrolling an open-label, single-arm, Phase 2 study of carfilzomib in patients with relapsed multiple myeloma, who will be stratified by bortezomib (Velcade®, Millennium Pharmaceuticals, Inc.) history.

About Carfilzomib

Carfilzomib is a structurally- and mechanistically-novel proteasome inhibitor that exhibits a high level of selectivity for the unique N-terminal threonine active sites within the proteasome. Carfilzomib is similar to bortezomib in that it is a potent inhibitor of the proteasome chymotrypsin-like activity, but unlike bortezomib, carfilzomib has shown minimal cross-reactivity with the other catalytic sites within the proteasome or across other protease classes. Phase 1 clinical studies confirmed that patients who have relapsed or progressed following multiple therapies can still achieve durable anti-tumor responses with carfilzomib. In addition to the two Phase 2 single-agent trials in myeloma and ongoing studies in lymphoma, a clinical trial in solid tumors and a trial exploring carfilzomib in combination with an FDA-approved agent will be initiated by the end of the year.

“The Phase 1 data consistently demonstrate carfilzomib anti-tumor activity in myeloma patients who have failed multiple lines of therapy, and we are excited to be moving our clinical program forward. We are very pleased that the MMRC sponsorship has made the rapid initiation of our Phase 2 trials possible and has enabled us to reach out to a larger group of myeloma patients. The thoughtful scientific expertise and collaborative effort of this group have helped speed development of new agents in the field of multiple myeloma,” said Lori A. Kunkel, M.D., Chief Medical Officer of Proteolix, Inc.

About the Multiple Myeloma Research Consortium (MMRC)

The Multiple Myeloma Research Consortium (MMRC) is a 509(a)3 non-profit organization that integrates leading academic institutions to accelerate drug development in multiple myeloma. It is led from MMRC offices in Norwalk, Conn., and comprises 13 Member Institutions: City of Hope, Dana-Farber Cancer Institute, Emory University's Winship Cancer Institute, the Cancer Center at Hackensack University Medical Center, H. Lee Moffitt Cancer Center & Research Institute, Mayo Clinic, Ohio State University, Roswell Park Cancer Institute, Saint Vincent's Comprehensive Cancer Center of Saint Vincent Catholic Medical Centers of New York, University Health Network (Princess Margaret Hospital), University of Chicago, University of Michigan, and Washington University. In addition to these trials with Proteolix, the MMRC is supporting six other clinical trials exploring several investigative agents.

The MMRC was founded in 2004 by Kathy Giusti, a myeloma patient, and with the help of the scientific community. The MMRC is a sister organization to the Multiple Myeloma Research Foundation (MMRF), the world's leading funder of multiple myeloma research. The MMRC is widely recognized as an optimal research model to rapidly address critical challenges in drug development and to explore opportunities in the today's most promising research areas—genomics, compound validation, and clinical trials. The MMRC is the only consortium to join academic institutions through membership agreements, customized IT systems, and an integrated tissue bank. For more information, please visit <http://www.themmr.org>.

About Proteolix

Proteolix, Inc. is a biopharmaceutical company dedicated to discovering, developing and marketing pharmaceutical products that target certain cancers and immunological conditions by inhibiting the proteasome and thereby disrupting protein turnover in cells. In addition to its lead product candidate, carfilzomib (PR-171), which is delivered intravenously and is currently in multiple clinical trials to evaluate its safety and efficacy in different types of cancer, Proteolix is developing next generation proteasome inhibitors, including an oral proteasome inhibitor and a selective immunoproteasome inhibitor, to expand the therapeutic potential of this new target class. Proteolix is headquartered in South San Francisco. For more information, please visit the Company's website at www.proteolix.com.

MMRC Contact: Anne Quinn Young, Program Director, 203-652-0212

Proteolix Contact: Stephen R. Brady, Executive Director of Business & Legal Affairs, 650-615-7521