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First Patient Dosed in Phase I Study of Prothena's Therapeutic Antibody for Treatment of AL Amyloidosis

NEOD001 Enters Clinic With Orphan Designation and Potential to Meet Significant Unmet Need

DUBLIN, Ireland, April 23, 2013 (GLOBE NEWSWIRE) -- Prothena Corporation plc (Nasdaq:PRTA), a clinical stage biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases, today announced the successful first patient dosing in a Phase 1 clinical trial of its antibody therapeutic candidate, NEOD001. The study will evaluate the safety and tolerability of NEOD001 in patients with AL amyloidosis.

NEOD001 is a monoclonal antibody that targets AL and AA amyloid for the potential treatment of amyloidoses, diseases in which misfolded proteins accumulate in the body's organs, causing progressive damage to affected organs and untimely death in many patients.

"We are pleased to initiate this Phase 1 clinical trial for NEOD001 and advance our research pipeline into the clinic," said Dale Schenk, PhD, President and Chief Executive Officer of Prothena. "Our preclinical experience to date with NEOD001 has indicated its potential in this disease area, where limited treatment options exist for patients suffering with amyloidosis. If proven to be safe and effective in clinical trials, our approach has the potential to provide a novel therapy for this orphan disease with significant unmet medical need."

In 2012, NEOD001 was granted orphan drug designation for both AL and AA amyloidoses by the U.S. Food and Drug Administration (FDA), and in 2013, NEOD001 was granted orphan designation by the European Medicines Agency for the treatment of AL amyloidosis, the most common form of systemic amyloidosis. There are no currently approved treatments for AL amyloidosis that directly target the potentially toxic forms of the misfolded AL protein. Today, patients are typically treated by attempting to reduce the source of the amyloid-causing proteins.

"Our goal with NEOD001 is to provide an improved therapy for patients with amyloidoses, and this is an important milestone for both patients and Prothena," said Gene Kinney, PhD, Chief Scientific Officer and Head of Research and Development of Prothena. "The orphan drug designations we have received in the U.S. and EU recognize the rarity of this disease and will help us advance the development of our potential treatment for these patients."

The multi-center Phase 1 clinical trial is designed to evaluate the safety and tolerability of NEOD001 in patients with AL amyloidosis and to determine a recommended dose for testing in Phase 2 trials.

About NEOD001

NEOD001 is a monoclonal antibody that specifically targets the amyloid that accumulates in both AL and AA forms of amyloidosis. If proven safe and effective in clinical trials for AL amyloidosis, the approach has the potential to be a first-in-class agent for this orphan disease with a significant unmet medical need.

NEOD001 was granted orphan drug designation by the FDA in 2012 and by the European Medicines Agency in 2013. An Investigational New Drug application, or IND, for NEOD001 in systemic amyloidosis (AL and AA forms of amyloidosis) was filed and accepted by the FDA in 2012.

NEOD001 is being developed by Onclave Therapeutics Limited, a wholly-owned subsidiary of Prothena. More information on the Phase 1 clinical trial for NEOD001 is available on www.clinicaltrials.gov.

About AL Amyloidosis

Systemic amyloidoses are a complex group of diseases caused by tissue deposition of misfolded proteins that result in progressive organ damage. The most common type, AL amyloidosis or primary amyloidosis, involves a hematological disorder caused by plasma cells that produce misfolded AL protein resulting in deposits of abnormal AL protein (amyloid), in the tissues and organs of individuals with this disease. There are no currently approved treatments for AL amyloidosis that directly target potentially toxic forms of the AL protein (amyloid).

AL amyloidosis is a rare disorder. It is estimated that about 15,000 patients in the U.S. and Europe suffer from AL amyloidosis.

1,200 to 3,200 new cases of AL amyloidosis are reported each year in the United States. Both the causes and origins of AL amyloidosis remain poorly understood.

About Prothena

Prothena Corporation plc (Nasdaq:PRTA) is a clinical stage biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion, particularly on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease-causing proteins. These potential therapies have a broad range of indications, including AL and AA forms of amyloidosis, Parkinson's disease and related synucleinopathies, and novel cell adhesion targets involved in inflammatory disease and metastatic cancers. For more information, please visit www.prothena.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to, among other things, the conduct of our Phase 1 clinical trial for NEOD001, the potential to advance such product candidate through further clinical trials and our ability to receive regulatory approval for such product candidate in one or more indications, including with orphan drug designations. These forward-looking statements are identified by their use of terms and phrases such as "anticipate," "believe," "could," "should," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "target," "will" and similar terms and phrases, including references to assumptions. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to known and unknown risks, uncertainties and other factors including, but not limited to the risks and uncertainties described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 29, 2013, the "Risk Factors" section of our Quarterly Reports on Form 10-Q that we file with the SEC from time to time, as well as the following risks: our ability to obtain additional financing; our ability to successfully complete research and development of our drug candidates and the size of the markets for those drug candidates; our ability to develop and commercialize products before competitors or that are superior to the alternatives developed by such competitors; our ability to protect our patents and other intellectual property; any loss of key employees; the impact of our separation from Elan and risks relating to our ability to operate effectively as a stand-alone, publicly traded company, including, without limitation, our ability to achieve benefits from our separation; restrictions on our taking certain actions due to tax rules and covenants with Elan; changes in our cost structure, management, financing and business operations following the separation and distribution; growth in costs and expenses; our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements; disruptions in the U.S. and global capital and credit markets; fluctuations in foreign currency exchange rates; the failure to comply with anti-kickback, false claims and other applicable laws in the United States; extensive government regulation; risks from potential environmental liabilities; the volatility of our share price; general changes in U.S. generally accepted accounting principles and International Financial Reporting Standards as adopted by the European Union; and business disruptions caused by information technology failures or events beyond our control. Prothena undertakes no obligation to update publicly any forward-looking statements contained in this press release as a result of new information, future events or changes in Prothena's expectations.

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