December 15, 2014

Prothena Receives FDA Fast Track Designation for NEOD001, a Monoclonal Antibody for the Treatment of Patients With AL Amyloidosis

- **First Investigational Immunotherapy for AL Amyloidosis to Receive FDA Fast Track Designation**
- **Follows Recent Initiation of The VITAL Amyloidosis Study, a Global Phase 3 Registrational Trial of NEOD001 for Patients with AL Amyloidosis**

DUBLIN, Ireland, Dec. 15, 2014 (GLOBE NEWSWIRE) -- Prothena Corporation plc (Nasdaq:PRTA), a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel antibodies for the potential treatment of diseases that involve amyloid or cell adhesion, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to NEOD001, a novel monoclonal antibody for the potential treatment of AL amyloidosis. This is the first investigational immunotherapy specifically targeting the disease-causing protein in AL amyloidosis to receive Fast Track designation.

The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. The purpose of the Fast Track designation is to make important new drugs available to patients earlier. The Fast Track program also provides a company with the ability to submit sections of the Biologics License Applications (BLA) for review before the company submits the complete BLA. This enables the FDA to review sections of the BLA as they are received, rather than waiting until every section of the application is completed, and also allows for Priority Review, shortening the standard review of the final BLA to six months. A drug program with Fast Track designation permits the company to have early and frequent communications with the FDA in the development and review of the product candidate, potentially leading to faster drug approval.

"The amyloidosis community has long hoped for a drug or treatment that would remove the amyloid deposits from the involved organs," said Muriel Finkel, President of the Amyloidosis Support Groups Inc. "Prothena's published results, and those recently presented, as well as excitement generated from amyloidosis patients, provide us hope that NEOD001 may offer us this very solution for our AL amyloidosis patients."

"We believe this progressive disease is significantly underdiagnosed and often misdiagnosed," commented Isabelle Lousada, Board Chairman of the Amyloidosis Foundation. "Until now, there have been no therapeutics developed specifically to treat patients with AL amyloidosis. Treatment has been limited to unapproved use of chemotherapeutic agents, which do not address the underlying cause of the disease and may have significant side effects. We welcome Prothena's dedication to pursuing a safe and effective therapy, and are encouraged by the safety profile of NEOD001 and the organ response rate results seen to date."

VITAL Phase 3 Registrational Trial Design

The international, multi-center, randomized, double-blind, placebo-controlled Phase 3 study continues Prothena's commitment to provide disease-modifying therapeutic alternatives for patients suffering from AL amyloidosis. The trial is designed to support global regulatory approvals and to enroll approximately 230 newly-diagnosed, treatment-naïve patients with cardiac dysfunction. Patients will be randomized on a 1:1 basis to receive 24 mg/kg of NEOD001 or placebo via infusion every 28 days, with both arms receiving concurrent standard of care therapy. The composite primary endpoint is event-based, with all-cause mortality or cardiac hospitalizations as qualifying events. The trial allows for an interim analysis to assess the primary endpoint for efficacy and futility.

"In addition to Fast Track, we have previously received orphan drug designation in both the U.S. and EU for AL amyloidosis. Collectively, this recognition of NEOD001 underscores the critical need for a disease-modifying immunotherapy specifically designed to treat patients with AL amyloidosis," said Gene Kinney, PhD, Chief Scientific Officer and Head of Research and Development of Prothena. "We are delighted to have recently initiated our VITAL Phase 3 clinical trial for NEOD001 in patients with AL amyloidosis. We will continue to work closely with the FDA and European regulatory authorities to bring this therapy to patients in the most expeditious manner possible."

About NEOD001

NEOD001 is a humanized monoclonal antibody that specifically targets the circulating soluble amyloid and deposited insoluble amyloid that accumulates in both the AL and AA forms of amyloidosis. The ongoing multi-center Phase 1/2 clinical trial is

evaluating the safety, tolerability, pharmacokinetics and immunogenicity of NEOD001 in patients with AL amyloidosis and persistent organ dysfunction. The study is also evaluating exploratory biomarkers for cardiac, renal and hepatic function. The VITAL Amyloidosis Study, a double-blind, placebo-controlled Phase 3 trial, will evaluate NEOD001 in newly-diagnosed, treatment-naïve patients with AL amyloidosis, and will assess all-cause mortality and cardiac hospitalizations in addition to biomarker, functional and quality of life endpoints. For more information on both the Phase 1/2 and VITAL Phase 3 trials, please visit www.clinicaltrials.gov, and search identifiers NCT01707264 (Phase 1/2) and NCT02312206 (VITAL Phase 3).

About AL Amyloidosis

Systemic amyloidoses are a complex group of progressive 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 approved treatments for AL amyloidosis that directly target potentially toxic forms of the AL protein. AL amyloidosis is a rare disorder and it is estimated that about 15,000 patients in the U.S. and Europe suffer from AL amyloidosis. Both the causes and origins of AL amyloidosis remain poorly understood. For more information on AL amyloidosis, please visit the websites of the Amyloidosis Support Group and the Amyloidosis Foundation.

About Prothena

Prothena Corporation plc is a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel antibodies for the potential treatment of diseases that involve amyloid or cell adhesion. The Company focuses on therapeutic monoclonal antibodies directed specifically to disease-causing proteins and its antibody-based product candidates target a number of potential indications, including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002) and novel cell adhesion targets involved in psoriasis and other inflammatory diseases (PRX003).

For more information, please visit the Company's website at www.prothena.com.

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things, the design of the VITAL Phase 3 study for NEOD001; the potential clinical benefit of NEOD001; and the potential for faster FDA approval of NEOD001. These statements are based on estimates, projections and assumptions that may prove not to be accurate, and 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, uncertainties and other factors described in the "Risk Factors" sections of our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 7, 2014, and our subsequent Quarterly Reports on Form 10-Q filed with the SEC. 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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