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First-In-Human Assessment of PRX002, Prothena's Anti-Alpha Synuclein Antibody for Parkinson's Disease, Published in Movement Disorders Journal

Data Previously Presented in 2015 at 19th International Congress of Parkinson's Disease and Movement Disorders

DUBLIN, Ireland, Dec. 13, 2016 (GLOBE NEWSWIRE) -- Prothena Corporation plc (Nasdaq:PRTA), a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel protein immunotherapies, today announced the publication of previously disclosed clinical results from a Phase 1 single ascending dose study in healthy volunteers of PRX002, a monoclonal antibody for the potential treatment of Parkinson's disease and other related synucleinopathies, in the peer-reviewed journal Movement Disorders. PRX002, also known as RG7935, is the focus of a worldwide collaboration between Prothena and Roche.

The data, which was previously presented in June 2015 as part of the late breaking oral session at the 19th International Congress of Parkinson's Disease and Movement Disorders, demonstrated that PRX002 was generally safe and well-tolerated in healthy volunteers, meeting the primary objective of the study. Further, results from this study showed that administration of PRX002 led to a mean reduction of free serum alpha-synuclein levels of up to 96.5 percent within one hour of the completion of infusion. These overall results were statistically significant ($p < 0.0001$). Reduction of free serum alpha-synuclein was shown to be robust, rapid, and dose- and time-dependent after a single dose.

The Phase 1 double-blind, placebo-controlled, single ascending dose study enrolled 40 healthy volunteers across five escalating dose cohorts to receive either PRX002 or placebo. No serious adverse events or hypersensitivity reactions were reported. PRX002 demonstrated favorable pharmacokinetic properties. The most common treatment emergent adverse events were headache, nausea, vessel puncture site pain, viral infection, and viral upper respiratory tract infection. In this study, all PRX002-related adverse events were mild, no dose limiting toxicities were observed and no anti-drug antibodies were detected.

About Alpha-synuclein

Alpha-synuclein is a protein found in neurons and is a major component of pathology that characterizes several neurodegenerative disorders including Parkinson's disease, dementia with Lewy bodies, and multiple system atrophy, which collectively are termed synucleinopathies. While the normal function of alpha-synuclein is not well understood, the protein generally occurs in a soluble form. In synucleinopathies, the alpha-synuclein protein can misfold and aggregate to form soluble aggregates and insoluble fibrils that contribute to disease pathology. There is increasing evidence that this disease-causing alpha-synuclein can be propagated and transmitted from neuron to neuron, resulting in an infection-like spread of neuronal death. Recent studies in cellular and animal models suggest that the spread of alpha-synuclein-associated neurodegeneration can be disrupted by targeting aberrant forms of alpha-synuclein.

About PRX002 (RG7935)

PRX002 is a monoclonal antibody under development for the potential treatment of Parkinson's disease. PRX002 targets alpha-synuclein and is designed to slow the progressive neurodegeneration associated with alpha-synuclein misfolding and/or the cell-to-cell transmission of the aggregated pathogenic forms of alpha-synuclein found in Parkinson's disease and other synucleinopathies. Prior to initiating clinical trials, Prothena demonstrated the efficacy of PRX002 in various cellular and animal models of alpha-synuclein-related disease. In multiple transgenic mouse models of Parkinson's disease, passive immunization with 9E4, the murine version of PRX002, reduced the appearance of alpha-synuclein pathology, protected synapses and improved performance in behavioral testing. In December 2013 Prothena and Roche entered into a worldwide collaboration to develop and commercialize antibodies that target alpha-synuclein, including PRX002. Prothena has an option to co-promote PRX002 in the U.S., where the companies share all development and commercialization costs, as well as profits, on a 30/70 basis (30 percent Prothena, 70 percent Roche). Outside the U.S., Roche will have sole responsibility for developing and commercializing PRX002 and will pay Prothena up to double-digit royalties on net sales. A Phase 2 clinical study of PRX002 in patients with Parkinson's disease is expected to begin in 2017.

About Parkinson's Disease

Parkinson's disease is a progressive degenerative disorder of the central nervous system (CNS) that affects one in 100

people over age 60. With an estimated seven to 10 million patients living with Parkinson's disease worldwide, it is the second most common neurodegenerative disorder after Alzheimer's disease. The disease is characterized by the neuronal accumulation of aggregated alpha-synuclein in the CNS and peripheral nervous system that results in a wide spectrum of worsening progressive motor and non-motor symptoms. While diagnosis relies on motor symptoms classically associated with Parkinson's disease, non-motor symptoms may present many years earlier. Current treatments for Parkinson's disease are symptomatic and only address a subset of symptoms such as motor impairment, dementia, or psychosis. Symptomatic therapies do not target the underlying cause of the disease and lose effectiveness, often leading to debilitating side effects as the disease progresses.

About Prothena

Prothena Corporation plc is a global, late-stage clinical biotechnology company seeking to fundamentally change the course of progressive diseases with its clinical pipeline of novel therapeutic antibodies. Fueled by its deep scientific understanding built over decades of research in protein misfolding and cell adhesion — the root causes of many serious or currently untreatable amyloid and inflammatory diseases — Prothena is establishing a fully integrated research, development and commercial focus and has advanced several drug candidates into clinical studies while pursuing discovery of additional novel therapies. Our pipeline of antibody-based product candidates targets a number of potential indications including AL amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002), inflammatory diseases, including psoriasis and psoriatic arthritis (PRX003), and ATTR amyloidosis (PRX004). 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, plans for and the timing of initiating a Phase 2 clinical study of PRX002; and the design of PRX002 and its potential as a disease modifying treatment for Parkinson's disease. 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 February 25, 2016 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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