Prothena Announces Achievement of $60 Million Milestone From Roche for First Patient Dosed in Phase 2b Study of Prasinezumab in Early Parkinson's Disease

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DUBLIN, Ireland, May 10, 2021 (GLOBE NEWSWIRE) -- Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical company with a robust pipeline of novel investigational therapeutics built on protein dysregulation expertise, today announced that the Company has earned a $60 million milestone from its worldwide collaboration with Roche based on the first patient dosed in the Phase 2b PADOVA study of prasinezumab in patients with early Parkinson's disease. Prothena has previously received $75 million in payments from Roche as part of this collaboration.

Prasinezumab is the first anti-alpha synuclein antibody to advance into late-stage clincal development. Results from the Phase 2 PASADENA study, reported in September 2020, demonstrated signals of efficacy on multiple pre-specified secondary and exploratory clinical endpoints, including measures of motor function and biomarkers, in patients with early Parkinson's disease. These signals of efficacy add to the growing body of evidence that optimally targeting an appropriate epitope within pathogenic proteins, such as alpha-synuclein and abeta, results in clinically meaningful benefits for patients. Roche's advancement of prasinezumab into this Phase 2b PADOVA study is an important step forward for this first-in-class compound, with the potential to slow the progression of Parkinson's disease and positively impact the lives of millions of patients.

Phase 2b PADOVA Study Design

Based on positive signals of efficacy consistent with disease modification in the Phase 2 PASADENA study, prasinezumab is being advanced into the Phase 2b PADOVA study to further assess the efficacy and safety of prasinezumab in an expanded patient population. PADOVA is a Phase 2b, randomized, double-blind, placebo-controlled, multicenter study designed to evaluate the efficacy and safety of prasinezumab in patients with early Parkinson's disease who are on stable symptomatic medication. The study will enroll approximately 575 patients, who will be randomized to receive either prasinezumab or placebo via intravenous infusion every 4 weeks. The primary endpoint is time to meaningful progression on motor signs of the disease, as assessed by ≥ 5 point increase from baseline in the Movement Disorder Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III score.

For more information on the Phase 2b PADOVA study, please visit clinicaltrials.gov and search NCT # 04777331.

About Parkinson's Disease

Parkinson's disease is a progressive degenerative disorder of the entire nervous system that affects one in 100 people over age 60. An estimated seven to 10 million people are 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. There are currently no treatments available that target the underlying cause of the disease and can slow its progression.

About Alpha-synuclein

Alpha-synuclein, a protein found in neurons and other cells, is a major component of the pathology that characterizes several neurodegenerative disorders including Parkinson's disease, dementia with Lewy bodies, and multiple system atrophy, which collectively are termed synucleinopathies. The understanding of the normal physiological function of alpha-synuclein is limited, but evidence indicates that soluble forms of the protein may interact with other proteins and certain intracellular membranes. In synucleinopathies, the alpha-synuclein protein appears to be abnormally aggregated intracellularly, which contributes to disease pathology. There is increasing evidence that certain aggregated forms of alpha-synuclein can be transmitted from neuron to neuron, resulting in a propagation of pathology that causes neuronal dysfunction and loss. Recent studies in cellular and animal models of synucleinopathy suggest that the spread of alpha-synuclein-associated neuronal pathology can be disrupted by targeting aberrant forms of alpha-synuclein.

About Prasinezumab

Prasinezumab is a humanized monoclonal antibody that targets a carboxyl terminal epitope of alpha-synuclein, a protein found in neurons that can aggregate and spread from cell to cell, resulting in the neuronal dysfunction and loss that causes Parkinson's disease. Prasinezumab is designed to block the cell-to-cell transmission of the aggregated, pathogenic forms of alpha-synuclein in Parkinson's disease, thereby slowing clinical decline. Prior to initiating clinical trials, the efficacy of prasinezumab was evaluated in various cellular and animal models of alpha-synuclein-related disease. In alpha-synuclein transgenic mice, the murine version of prasinezumab reduced the appearance of alpha-synuclein pathology, protected synapses and halted the worsening of behavioral phenotypes. In December 2013, Prothena and Roche entered into a worldwide collaboration to develop and commercialize antibodies that target alpha-synuclein, including prasinezumab. Prothena has an option to co-promote prasinezumab 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 has sole responsibility for developing and commercializing prasinezumab and has agreed to pay Prothena up to double-digit royalties on net sales. To date, Prothena has received $75 million and earned an additional $60 million of a total potential $600 million in milestone payments that includes clinical, regulatory and sales milestones. For more information on the Phase 2 PASADENA clinical study of prasinezumab in patients with early Parkinson's disease, visit clinicaltrials.gov and search NCT #03100149.

About Prothena

Prothena Corporation plc is a late-stage clinical company with a robust pipeline of novel investigational therapeutics built on protein dysregulation expertise with the potential to change the course of devastating rare peripheral amyloid and neurodegenerative diseases. Fueled by its deep scientific

expertise built over decades of research, Prothena is advancing a pipeline of therapeutic candidates for a number of indications and novel targets for which its ability to integrate scientific insights around neurological dysfunction and the biology of misfolded proteins can be leveraged. Prothena's pipeline includes both wholly-owned and partnered programs being developed for the potential treatment of diseases including AL amyloidosis, ATTR amyloidosis, Alzheimer's disease, Parkinson's disease and a number of other neurodegenerative diseases. For more information, please visit the Company's website at www.prothena.com and follow the Company on Twitter @ProthenaCorp.

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things, the treatment potential, design, and proposed mechanism of action of prasinezumab; plans for the Phase 2b PADOVA clinical study of prasinezumab; and amounts we might receive under our collaboration with Roche. 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 effects on our business of the worldwide COVID-19 pandemic and the risks, uncertainties and other factors described in the "Risk Factors" sections of our Prospectus Supplement filed pursuant to Rule 424(b)5 with the Securities and Exchange Commission (SEC) on March 24, 2021, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. We undertake 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 our expectations.

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