Prothena and Novo Nordisk Announce Acquisition Agreement for Prothena's ATTR Amyloidosis Programme

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- Prothena is eligible to receive development and sales milestone payments totalling up to 1.2 billion US dollars, including 100 million dollars in upfront and near-term clinical milestone payments
- Novo Nordisk will develop the phase 2 ready antibody PRX004 for the rare heart disease ATTR cardiomyopathy

DUBLIN, Ireland and BAGSVÆRD, Denmark, July 12, 2021 (GLOBE NEWSWIRE) -- Prothena Corporation plc (NASDAQ:PRTA) and Novo Nordisk A/S (Nasdaq Copenhagen: NOVO B) today announced that the companies have entered into a definitive purchase agreement under which Novo Nordisk has acquired Prothena's clinical stage antibody PRX004 and broader ATTR amyloidosis programme.

PRX004 is a phase 2 ready anti-amyloid immunotherapy designed to deplete the amyloid deposits that are associated with the disease pathology of ATTR amyloidosis.

ATTR amyloidosis is a rare, progressive, and fatal disease characterised by the abnormal buildup of amyloid deposits composed of misfolded transthyretin protein in organs and tissues, most commonly the heart and/or nervous system.

Prothena has completed a phase 1 study with PRX004 in patients with hereditary forms of ATTR, in which PRX004 was found to be safe and well tolerated.

Novo Nordisk will initially focus on the clinical development of PRX004 in ATTR cardiomyopathy - an underdiagnosed and potentially fatal form of ATTR amyloidosis characterised by build-up of amyloid deposits in cardiac tissue.

Under the terms of the definitive purchase agreement, Novo Nordisk acquires Prothena's wholly-owned subsidiary and gains full worldwide rights to the intellectual property and related rights of Prothena's ATTR amyloidosis business and pipeline. Prothena is eligible to receive development and sales milestone payments totalling up to 1.2 billion US dollars including 100 million dollars in upfront and near-term clinical milestone payments.

"Today's announcement is consistent with our commitment to create a better future for patients in critical need of new treatment options. We are confident that Novo Nordisk will leverage its extensive expertise in developing treatments for those affected by cardiovascular diseases to advance this promising potential treatment to patients on an expedited timeline," said Hideki Garren, MD, PhD, chief medical officer of Prothena. "With Novo Nordisk's commitment to further develop PRX004 in ATTR cardiomyopathy, Prothena will continue to focus on our mission to advance our robust portfolio designed to address rare peripheral amyloid and neurodegenerative diseases. We also wish to extend our sincere thanks and appreciation to all the patients and investigators who participated in the PRX004 phase 1 study."

"With its innovative amyloid-depleting mechanism, PRX004 has the potential to offer a novel treatment option for ATTR cardiomyopathy – an often fatal disease with significant unmet medical need," said Marcus Schindler, chief scientific officer, EVP Research and Early Development at Novo Nordisk. "This acquisition is a testament to Prothena's pioneering work in ATTR amyloidosis and Novo Nordisk's dedication to advancing new disease-modifying therapies for the benefit of people with cardiovascular diseases which are the world's leading cause of death."

About PRX004

PRX004 is an investigational humanised monoclonal antibody designed to deplete amyloid associated with disease pathology that underlies hereditary and wild type ATTR amyloidosis (hATTR and wtATTR, respectively), without affecting the native, normal tetrameric form of the protein. It is generally accepted that at the time of diagnosis, affected organs in ATTR patients contain extracellular amyloid deposits that cause organ dysfunction. PRX004 has been shown in preclinical studies to promote clearance of insoluble amyloid fibrils through antibody-mediated phagocytosis and inhibit amyloid formation. This depleter mechanism of action has the potential to provide benefit for ATTR patients at high risk for early mortality due to amyloid deposition in vital organs.

Prothena has completed a Phase 1, open-label, multicenter dose-escalation study (NCT03336580). 21 patients with hereditary ATTR Amyloidosis (hATTR) were enrolled to receive PRX004 intravenously once every 28 days for up to 3 infusions in the dose escalation phase of the study. Patients were enrolled into 1 of the following 6 PRX004 dose cohorts: 0.1, 0.3, 1, 3, 10, and 30 mg/kg. Eligible patients who completed dose-escalation were provided the opportunity to enrol in the long-term extension (LTE) portion of the study. All 21 patients enrolled in the Phase 1 study successfully completed dose-escalation and 17 patients were subsequently enrolled in the LTE. PRX004 was found to be safe and well tolerated across all dose levels.

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, 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.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 45,800 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Forward-looking Statements

This press release contains forward-looking statements regarding the definitive purchase agreement and the development of PRX004, including the ability of Novo Nordisk to successfully research, develop and commercialize PRX004, the ability of Novo Nordisk to obtain regulatory approval to manufacture, market and sell the products in and outside of the United States and the ability for Novo Nordisk to achieve the requirements of the milestones set forth in the definitive purchase agreement in order for Prothena to be entitled to the milestone payments. These forward-looking statements involve risks and uncertainties. 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 Prothena's SEC filings, including the "Risk Factors" section of the Quarterly Report on Form 10-Q filed with the SEC on May 11, 2021.

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