Prothena Receives FDA Fast Track Designation for PRX012, a Next-Generation Anti-Amyloid Beta Antibody Under Investigation for the Treatment of Alzheimer's Disease

- PRX012 is a potential best-in-class, subcutaneous anti-amyloid beta antibody therapy currently in a Phase 1 clinical study for the treatment of Alzheimer's disease

DUBLIN, Ireland, April 26, 2022 -- Prothena Corporation plc (NASDAQ: PRTA), a late-stage clinical biotechnology company with a robust pipeline of investigational therapeutics built on protein dysregulation expertise, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for PRX012, a potential best-in-class anti-amyloid beta (Aβ) antibody therapy currently being investigated in a Phase 1 clinical study for the treatment of Alzheimer's disease. The FDA's Fast Track designation program is designed to expedite the development and review of drugs intended to treat a serious condition, such as Alzheimer's disease, with evidence demonstrating the potential to address an unmet medical need.

"We welcome the FDA's decision to grant PRX012 Fast Track designation, which is designed to bring important new drugs to patients sooner, and we look forward to collaborating with the FDA to expedite the development of this investigational next-generation amyloid beta-targeting therapy for the millions of patients with Alzheimer's disease and their families," said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. "We are pleased the FDA has recognized the evidence demonstrating the potential for PRX012 to address an unmet need in the treatment of Alzheimer's disease. With its substantially higher binding strength that allows for simple subcutaneous administration, PRX012 is positioned to potentially lead a paradigm shift in Alzheimer's treatment."

A drug candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the drug candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

About PRX012

PRX012 is currently being investigated in a Phase 1 clinical study for the treatment of Alzheimer's disease. Preclinical data have demonstrated binding of PRX012 to beta amyloid plaques and oligomers with high avidity, allowing effective Aβ plaque occupancy at relatively lower dose ranges, optimal for subcutaneous delivery. Preclinical data have also demonstrated clearance of both pyroglutamate modified and unmodified Aβ plaque in brain tissue at concentrations of PRX012 estimated to be clinically achievable in the central nervous system with subcutaneous delivery.

About the Phase 1 SAD Study for PRX012

The Phase 1 PRX012 SAD study is a randomized, double-blind, placebo-controlled study to evaluate safety, tolerability, immunogenicity, and pharmacokinetics in healthy volunteers and patients with Alzheimer's disease. In this Phase 1 SAD study, healthy volunteers and patients will be randomized to receive a single subcutaneous injection of either PRX012 or placebo.

About Alzheimer's Disease

Alzheimer's disease is a fatal disease and the most common form of dementia causing increasingly serious symptoms, including confusion, disorientation, mood and behavioral changes, and difficulty speaking, swallowing, and walking. Approximately 50 million people worldwide are estimated to be living with Alzheimer's disease or other dementias. Alzheimer's disease is the most common neurodegenerative disorder. There is an urgent need for therapies that slow the progression and ultimately prevent Alzheimer's disease to address this global healthcare crisis. Prothena's Alzheimer's disease portfolio spans next generation antibody immunotherapy, small molecule, and vaccine approaches, geared toward building upon first generation treatments to advance the treatment paradigm.

About Prothena

Prothena Corporation plc is a late-stage clinical biotechnology company with expertise in protein dysregulation and a pipeline of investigational therapeutics with the potential to change the course of devastating neurodegenerative and rare peripheral amyloid 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, proposed mechanism of action, and potential administration of PRX012; and the Phase 1 SAD study of PRX012. 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 those 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, 2022, and 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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