



NEWS RELEASE

Prothena Announces Novo Nordisk Obtains Fast Track Designation from the U.S. FDA for Coramitug (PRX004) in ATTR Amyloidosis with Cardiomyopathy

2026-04-27

- Coramitug is a potential best-in-class amyloid depleter antibody for the treatment of ATTR amyloidosis with cardiomyopathy¹⁻³
- Coramitug is being evaluated by Novo Nordisk in the ongoing Phase 3 CLEOPATTRA clinical trial in ~1280 participants with ATTR-CM; primary completion expected in 2029
- The Fast Track Designation underscores the unmet need within ATTR-CM and could expedite the review of coramitug

DUBLIN--(BUSINESS WIRE)-- Prothena Corporation plc (NASDAQ:PRTA) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to coramitug, a potential best-in-class amyloid depleter antibody currently in Phase 3 development for the treatment of ATTR amyloidosis with cardiomyopathy (ATTR-CM). Fast Track Designation is intended to facilitate the development and expedite the review of investigational drugs that treat serious conditions and fill an unmet medical need.

"We are encouraged by Novo Nordisk's receipt of Fast Track Designation for coramitug, which underscores their continued commitment to advancing coramitug for patients living with ATTR-CM," said Gene Kinney, Ph.D., President and Chief Executive Officer, Prothena.

"We are pleased that the FDA has granted Fast Track Designation for coramitug, a recognition that reflects both the seriousness of ATTR-CM and the significant unmet need that remains for people living with this life-threatening disease, despite standard of care," said Michelle Lim-Watson, Associate Portfolio Vice President, Cardiovascular Disease and Rare Diseases, U.S. R&D, Novo Nordisk. "Coramitug is currently being investigated in the ongoing



Phase 3 CLEOPATTRA trial, which we believe could mark a meaningful step forward in how we treat ATTR-CM in the future.”

ATTR-CM is a progressive disease caused by the deposition of transthyretin as amyloid in the myocardium. Current therapies may slow disease progression but do not clear existing deposits. Coramitug is a humanized monoclonal antibody that targets misfolded transthyretin, designed to promote clearance of transthyretin amyloid through antibody-mediated phagocytosis⁴.

Novo Nordisk is evaluating coramitug in the ongoing Phase 3 CLEOPATTRA clinical trial in approximately 1280 participants with ATTR-CM with primary completion expected in 2029 (**NCT07207811**).

Novo Nordisk gained full worldwide rights to the intellectual property and related rights of the ATTR amyloidosis business and pipeline it acquired from Prothena in July 2021. Under the terms of the acquisition agreement, Prothena is eligible to receive up to \$1.2 billion including an upfront payment and upon achievement of clinical development and sales milestones, with \$150 million earned to date.

About Coramitug (PRX004)

Coramitug is an investigational antibody designed to deplete amyloid associated with disease pathology in hereditary and wild type ATTR amyloidosis, without affecting the native, normal tetrameric form of the protein¹⁻³. Coramitug’s proposed mechanism of action is to deplete both the deposited amyloid to improve organ function and circulating non-native TTR to prevent further organ deposition¹⁻³. This differentiated depleter mechanism of action could be developed as a monotherapy approach to ATTR amyloidosis and might also complement existing therapeutic approaches which either stabilize or reduce production of the native TTR tetramer³.

In a Phase 2 clinical trial conducted by Novo Nordisk, coramitug 60 mg/kg significantly reduced and improved NT-proBNP from baseline, in a patient population in which the vast majority (>80%) were already receiving standard of care treatment for ATTR-CM. Furthermore, compared with placebo, coramitug was associated with improvements in multiple echocardiographic parameters of cardiac function, and was well-tolerated in participants with ATTR-CM. These findings support the potential of coramitug as an amyloid-clearing immunotherapy for ATTR-CM and provide a rationale for additional clinical investigation of coramitug for the treatment of patients with ATTR-CM⁴.

About Prothena

Prothena Corporation plc is a late-stage clinical biotechnology company with expertise in protein dysregulation 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 Parkinson's disease, ATTR amyloidosis with cardiomyopathy, Alzheimer's disease, Amyotrophic lateral sclerosis (ALS) and a number of other neurodegenerative diseases. Prothena is developing and applying CYTOPE®, a novel technology that incorporates a cell-internalizing domain to drive efficient cytosolic delivery with highly specific macromolecular effectors. For more information, please visit the Company's website at www.prothena.com and follow the Company on X (formerly 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 coramitug; plans for ongoing and future clinical trials of coramitug; and amounts we might receive under our agreement with Novo Nordisk. 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 27, 2026, 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.

References:

- 1 Preclinical studies of PRX004 (coramitug) – data on file
- 2 Higaki JN et al. Amyloid, 2016
- 3 Suhr OB et al. Amyloid, 2025
- 4 Fontana M et al. Circulation, 2025

Mark Johnson, CFA

Senior Vice President, Head of Investor Relations and Corporate Communications

650-837-8550

IR@prothena.com

Media@prothena.com

Source: Prothena Corporation plc