



Protego Announces FDA IND Clearance for Phase 2/3 Study of PROT-001 in AL Amyloidosis

- *Clearance enables initiation of SHIELD-AL, a pivotal study in newly diagnosed patients with lambda AL amyloidosis*
- *Investigational oral light chain stabilizer to be evaluated as an add-on to standard-of-care plasma cell-directed therapy*

SAN DIEGO, Calif., October 19, 2026 – Protego Biopharma, Inc., a clinical-stage biotechnology company developing small molecule therapies for protein misfolding diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for PROT-001, enabling the company to initiate SHIELD-AL, its global pivotal Phase 2/3 study, in newly diagnosed light chain (AL) amyloidosis patients. PROT-001 is an oral investigational first-in-class lambda light chain stabilizer for the treatment of AL amyloidosis.

“Improving organ outcomes, particularly cardiac, in AL amyloidosis remains an urgent need, and studies in newly diagnosed patients with cardiac involvement have demonstrated that rapid depletion of amyloidogenic light chains closely correlates to improvements in survival,” said Brent J. Warner, MBA, Chief Executive Officer of Protego Biopharma. “This highlights a therapeutic opportunity for PROT-001, which acts directly on amyloidogenic lambda light chains to stabilize and neutralize their toxicity, as a complement to plasma cell-directed therapies that reduce light chain production. SHIELD-AL will evaluate whether this complementary approach with PROT-001 can help patients achieve deeper and faster organ responses while reducing cardiovascular complications beyond standard of care alone.”

SHIELD-AL is a randomized, double-blind, placebo-controlled study of PROT-001 in newly diagnosed lambda AL amyloidosis patients, with Part A consisting of an initial safety and dose confirmation study and Part B a pivotal safety and efficacy study.

Protego will be sharing data from its completed Phase 1 study evaluating PROT-001 in healthy volunteers at a medical meeting later this year.

About Protego Biopharma

Protego Biopharma is a clinical-stage biotechnology company developing first-in-class small molecule therapies for AL amyloidosis and other protein misfolding diseases. Protego aims to translate advances in protein stabilization into medicines that address the misfolding and toxicity responsible for progressive organ damage. Its therapies are designed to intervene in this disease process, with the goal of preserving organ function and improving patients' lives. For more information, visit www.protegio.bio.com.

About PROT-001

PROT-001 is Protego Biopharma's lead investigational small molecule pharmacological chaperone, being developed for the treatment of immunoglobulin light chain (AL) amyloidosis. PROT-001 is designed to stabilize amyloidogenic lambda light chain proteins and prevent their misfolding and the formation of proteotoxic species. The goal of this therapy is limiting the toxic effects that contribute to organ injury, including direct damage to cardiomyocytes in AL patients. PROT-001 represents a complementary approach to plasma cell-directed therapies, which reduce light chain production. By targeting the amyloidogenic light chain protein itself before it can adopt a pathogenic conformation, PROT-001 has the potential to complement existing treatments and address an additional mechanism of disease.

About AL amyloidosis

Immunoglobulin light chain (AL) amyloidosis is a rare, life-threatening disease affecting over 5,100 newly diagnosed patients annually and 28,000 US adults in which abnormal plasma cells produce light chain proteins that can misfold and aggregate. The direct toxicity of disease-related light chains and their accumulation as amyloid deposits in tissues both result in injury to organs, including the heart and kidneys. Cardiac injury is particularly serious, as toxic light chains can directly impair cardiomyocyte function, while amyloid deposits disrupt the structure and function of the heart. Current treatments focus on reducing light chain production with plasma cell-directed therapies and managing organ complications, leaving patients with a substantial need for complementary approaches that directly address light chain toxicity and improve organ outcomes.

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