Prothena Corporation is investigating new treatments for amyloidosis. Its lead candidate, NEOD001, is a humanized monoclonal antibody, which preclinical studies suggest may bind and neutralize amyloid in amyloid light chain (AL) amyloidosis. Unlike existing therapies, NEOD001 is specifically designed to target this form of amyloid, which is believed to contribute to organ dysfunction in patients with this disease. NEOD001 has investigational orphan drug status in the United States and Europe.

**UNDERSTANDING AMYLOIDOSIS**

Systemic amyloidosis is a family of rare progressive diseases in which abnormally folded proteins clump together to form aggregates, known as amyloid, that can accumulate and cause damage in organs and tissues.

AL amyloidosis is the most common form of systemic amyloidosis. In AL amyloidosis, plasma cells, a part of the immune system, overproduce an antibody fragment called light chain protein in an abnormal form that misfolds. The resulting amyloid accumulates in one or more organs, where it can disrupt normal functioning. The heart and kidneys are often sites of amyloid deposition in this disease.

**NEOD001: ONGOING PHASE 1 CLINICAL TRIAL**

NEOD001 is currently in Phase 1 clinical testing in patients with AL amyloidosis (Clinicaltrials.gov Identifier NCT01707264). Participating patients receive intravenous NEOD001 once every 28 days; if the dose level is safe and well-tolerated, subsequent dose groups will receive a higher dosage at the start of the next 28-day period. The dose level is escalated until the maximum tolerated dose, or recommended dose for Phase 2/3, is identified.
The primary objective of this ongoing Phase 1 clinical trial is to evaluate the safety and tolerability of NEOD001 in patients with AL amyloidosis and to determine the appropriate dose levels for further testing in order to initiate a Phase 2/3 study. In Phase 2/3, additional patients will be eligible to participate, and the primary objectives will be to establish the safety and effectiveness of NEOD001 for the treatment of patients with AL amyloidosis.

Patients are being recruited and treated at the following centers in the United States:

**Boston University School of Medicine**
Boston, Massachusetts 02118
Principal Investigator: David C Seldin, MD, PhD
Contact: Anthony Shelton
617-638-5612
anthony.shelton@bmc.org
Contact: Stephen Lo
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**Hospital of the University of Pennsylvania**
Philadelphia, Pennsylvania 19104
Principal Investigator: Brendan Weiss, MD
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scott.weber@uphs.upenn.edu

**Karmanos Cancer Institute**
Detroit, Michigan 48201
Principal Investigator: Jeffrey A Zonder, MD
Contact: Christiane Houde, BS, CCRP
313-576-9381
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**Mayo Clinic**
Rochester, Minnesota 55905
Principal Investigator: Morris A Gertz, MD
Contact: Ann Birgin, CRA
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**Memorial Sloan-Kettering Cancer Center**
New York, New York 10065
Principal Investigator: Heather Landau, MD
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Contact: Hani Hassoun, MD
212-639-3228

**Stanford University Cancer Center**
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**Tufts Medical Center**
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**Study Director** Theresa Neumann, PhD
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For preliminary results from the Phase 1 trial, see poster #PB-48, ISA 2014 or [www.prothena.com](http://www.prothena.com)

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**ABOUT PROTHENA**

Prothena Corporation plc is a biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of diseases that involve protein misfolding or cell adhesion, including AL and AA amyloidosis. Onclade Therapeutics Limited, a wholly owned subsidiary of Prothena, is conducting the Phase 1 clinical trial of NEOD001.

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Talk with your doctor to determine if participating in a clinical trial could be right for you. For more information, please visit:

- [http://clinicaltrials.gov/show/NCT01707264](http://clinicaltrials.gov/show/NCT01707264)
- [http://www.amyloidosissupport.org/](http://www.amyloidosissupport.org/)

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