

Evergreen Therapeutics Receives FDA Fast Track Designation for EG-501 in Cognitive Impairment Associated with Neuropsychiatric SLE

BETHESDA, MD. – September 4, 2026 – Evergreen Therapeutics, Inc., a clinical-stage biotechnology company leveraging artificial intelligence to address unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its investigational drug candidate, EG-501, for the treatment of cognitive impairment in adult patients with neuropsychiatric systemic lupus erythematosus (NPSLE-CI).

The Fast Track designation is based on positive data from the Phase II ClearMEMory study, a multisite, randomized, placebo-controlled 12-week trial that showed clinically meaningful improvements in objective neuropsychological function among patients with NPSLE-CI.

“We are very pleased to receive Fast Track designation for our EG-501 program, which underscores the urgency of advancing new treatment options for the NPSLE-CI community,” said Tom Du, M.D., Ph.D., Chief Executive Officer of Evergreen Therapeutics. “We look forward to working closely with the FDA as we advance the clinical development of EG-501 and strive to bring this potential therapeutic option to patients sooner.”

Fast Track designation is granted to investigational therapies intended to treat serious or life-threatening conditions and have the potential to address significant unmet medical needs. The designation is intended to expedite the development and review of eligible therapies.

About NPSLE-CI

Systemic lupus erythematosus (SLE) is a chronic autoimmune condition that can affect multiple organ systems, with cognitive impairment representing a significant clinical manifestation. Current epidemiological estimates suggest a substantial portion of patients may experience cognitive deficits, which can include memory difficulties and concentration issues. There remains a lack of approved therapies specifically for this indication.

Forward-Looking Statements

This press release contains forward-looking statements regarding the future development of EG-501, planned clinical activities, and potential therapeutic uses. These statements are subject to risks and uncertainties, including clinical trial outcomes and regulatory feedback, which could cause actual results to differ materially.