Elion Therapeutics Announces Initiation of Turletricin (EL219) Phase 2 Study in Invasive Mould Infection

- Turletricin Granted Qualified Infectious Disease Product (QIDP) and Fast Track Designations by FDA -

- Elion to Present Turletricin Clinical Data at ESCMID Global -

BOSTON, MA – (April 15, 2026) -- Elion Therapeutics, a biotechnology company dedicated to transforming the treatment of life-threatening fungal infections, today announced the initiation of its Phase 2 clinical trial evaluating turletricin (study drug EL219) early antifungal therapy in study participants with suspected and confirmed invasive mould infection ("TREAT-1"). Invasive mould infection (IMI) can cause severe or life-threatening illness in study participants with weakened immune systems, and early treatment is critical for improved patient outcomes.

"The QIDP designation and initiation of the TREAT-1 study, with its novel design, represents a key milestone for turletricin and underscores its distinctive potential as a once-weekly, broad-spectrum, non-nephrotoxic polyene antifungal used early in people with suspected IMI," said Dr. Kieren Marr, CEO of Elion Therapeutics. "Because delayed antifungal therapy is associated with poor outcomes in those who lack adequate immune responses, we are eager to progress enrollment towards demonstrating the potential advantages of weekly turletricin compared to the current standard of care."

The Phase 2 global TREAT-1 clinical trial is a multicenter, randomized, double-blind study evaluating the safety and efficacy of turletricin versus standard of care for early antifungal therapy in study participants with suspected and confirmed IMI. The primary outcome measure is all-cause mortality at Day 21 in the Intent-to-Treat (ITT) analysis set. Additional details are available on ClinicalTrials.gov (NCT07215273).

Turletricin has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for early antifungal therapy and treatment of invasive aspergillosis by the U.S. Food and Drug Administration (FDA). These designations are intended to support the development of new therapies that address serious or life-threatening infections. QIDP designation provides incentives for the development of new infectious disease technologies, including priority review and eligibility for an additional five years of market exclusivity.

On Saturday, April 18th, the company will present data on turletricin at the 2026 Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID Global), one of the world's leading congresses in clinical microbiology and infectious diseases in Munich, Germany. The presentation will highlight the early clinical findings supporting turletricin's potential as a broad-spectrum, novel analog of amphotericin B (AmB) that has been rationally designed to mitigate systemic toxicities.

Title: Turletricin (EL219/SF001) a novel, once-weekly, non-nephrotoxic polyene antifungal takes a novel clinical trial approach

Date/Time: Saturday, April 18 at 3:00 p.m. CEST

Location: Innovation and Pipeline Theatre

ABOUT INVASIVE FUNGAL INFECTIONS (IFIs)
More than 150 million people suffer from serious fungal infections worldwide. Severe, life-threatening fungal infections result in approximately 2.5 million annual deaths globally. IFIs typically occur in individuals with compromised immune systems due to multiple conditions, including HIV/AIDS, cancer therapies or organ transplants, and severe lung disease.

Only four classes of antifungal drugs are currently available, and antifungal resistance, organ toxicities, and drug-drug interactions complicate IFI treatment. The only systemic polyene antifungal is amphotericin B (AmB), a highly efficacious natural product widely used since the 1950s. Various different lipid formulations of AmB have been used to mitigate the severe toxicities caused by AmB, which most commonly include renal toxicity, electrolyte wasting, anemia and inflammatory infusion reactions. These formulations still cause toxicities, and clinical use is further limited by daily intravenous infusion.

ABOUT TURLETRICIN (EL219)
Turletricin is a next-generation AmB derivative that is engineered to be less toxic to the kidneys. In contrast to AmB, which targets human cholesterol as well as fungal ergosterol, turletricin is selective to fungal ergosterol, mitigating renal toxicity while retaining broad spectrum antifungal activity. Phase 1 studies in healthy volunteers and in people with moderate and severe renal insufficiency have shown turletricin to be well-tolerated with no adverse findings related to renal toxicity. Phase 2 clinical trials of turletricin in adult participants with suspected fungal infections and cryptococcal meningitis are ongoing.

ABOUT ELION THERAPEUTICS
Elion Therapeutics is a cutting-edge biotechnology company dedicated to transforming the treatment of life-threatening fungal infections. Elion was founded on the belief that mechanistic insights enable targeted optimizations of natural products. In 2024, Elion closed an $82 million Series B funding round led by Deerfield Management and the AMR Action Fund. Additional investors include Illinois Ventures. For more information, please visit www.eliontx.com.

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