

## Xinnate receives FDA Fast Track Designation for TCP-25 for the Treatment of Epidermolysis Bullosa

**Xinnate AB, a Swedish clinical-stage biotechnology company developing novel therapies based on its groundbreaking peptide technology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to TCP-25 for the treatment of Epidermolysis Bullosa (EB).**

TCP-25 is an investigational peptide-based topical therapy designed to treat patients suffering from EB, a rare and serious genetic disease characterized by extremely fragile skin.

The FDA's Fast Track program is intended to facilitate the development and expedite the review of therapies that address serious conditions and unmet medical needs. Products granted Fast Track Designation may be eligible for several benefits, including more frequent interactions with the FDA and, eligibility for Accelerated Approval, Priority Review, and Rolling Review of a New Drug Application (NDA).

“Receiving Fast Track Designation from the FDA represents an important milestone for Xinnate AB and our TCP-25 development program, as this is an external validation of the program by the regulatory authority,” says Helene Hartman, Chief Executive Officer of Xinnate. “This designation highlights the urgent need for new treatment options for patients with EB. We believe TCP-25 has the potential to significantly improve outcomes and quality of life for individuals living with this devastating disease.”

In January 2026, Xinnate announced the initiation of its Phase 2/3 STEP study, with the first patient enrolled. The STEP study is a global, randomized, placebo-controlled clinical trial evaluating the safety and efficacy of TCP-25 gel in patients with EB.

The study has received regulatory approval in the European Union, where several clinical sites are active and enrolling patients. U.S. clinical sites are currently in the start-up phase. The study has IND approval in the US.

### For more information

Helene Hartman, CEO

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### About Xinnate AB

Xinnate is a Swedish clinical-stage drug development company developing novel therapies based on its unique, groundbreaking peptide technology. These therapies address dysfunctional healing by modulating the interaction between microbes and inflammatory processes. With an ambitious development program, Xinnate is dedicated to improving the lives of, primarily, patients with Epidermolysis Bullosa. Xinnate is a member of the SmiLe Venture Hub at Medicon

[www.xinnate.com](http://www.xinnate.com)

### **About TCP-25**

TCP-25 is a novel immunomodulatory peptide with demonstrated anti-inflammatory, antimicrobial, and wound-healing properties. Xinnate's lead drug candidate, TCP-25 gel, is a topical formulation developed for the treatment of Epidermolysis Bullosa (EB).

### **About the STEP study**

The STEP study, protocol number TCP25-002, is a double-blinded, randomized, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of topically applied TCP-25 gel in patients with confirmed dystrophic EB (DEB) or junctional EB (JEB). The study uses intra-individual randomization, meaning that a pair of matched index wounds are randomized to local treatment with either TCP-25 gel or placebo. Approximately 32 patients from 4 years of age will be included in the study. The study is conducted in France, Greece, Italy, Spain, Sweden, and the United States.

For more information about the study, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov), ID: NCT06594393.