

Xinnate announces that recruitment has started and the first patient has been included in the STEP study with TCP-25.

Lund, 30th January 2026

Xinnate AB, a Swedish clinical-stage drug development company developing novel therapies based on its groundbreaking peptide technology, today announces that the first patient first visit (FPFV) has been completed in the company's clinical Phase 2/3 study with TCP-25 for the treatment of Epidermolysis Bullosa (EB).

The STEP study is a global, randomized, placebo-controlled clinical trial evaluating the safety and efficacy of TCP-25 gel in patients with EB, a rare and severe genetic disease characterized by fragile skin, chronic wounds, severe pain, and an increased risk of infection. The study has been approved in the EU, and clinical sites in several European countries have been initiated. Clinical sites in the United States are also in the start-up phase.

“Including the first patient in the STEP study is an important milestone for Xinnate and for patients with EB, who currently lack satisfactory treatment options. We are very proud of the extensive scientific and clinical work that has made this possible, and we look forward to continuing the development of TCP-25 together with our clinical partners and patients,” says Helene Hartman, CEO of Xinnate.

The STEP study will include 32 patients with different EB subtypes, and the results have the potential to be registration-enabling.

For more information

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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 Village in Lund.

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, ID: NCT06594393.