Press Release
18 August 2026 11:30:00 CEST

PILA PHARMA AB
Norra Vallgatan 72, 211 22 Malmö, Sweden
www.pilapharma.com.com

PILA PHARMA: REGULATORY APPROVAL RECEIVED TO CONDUCT PP-CT04, A 12-WEEK TRIAL EXPLORING THE SAFETY AND EFFICACY OF XEN-D0501 IN PEOPLE LIVING WITH OBESITY

PILA PHARMA AB (publ) (FN STO: PILA), a clinical stage biotech company pioneering development of an oral TRPV1-antagonist as a potential first-in-class treatment for obesity and diabetes, announces it has received regulatory approval from the European Medicines Agency, to conduct PP-CT04, a two-part, randomised, double-blind, placebo-controlled, parallel-group, 12-week trial investigating the safety, tolerability, pharmacokinetics and efficacy of XEN-D0501 in obese participants.

Malmö, Sweden, 18 August 2026

The trial is designed to explore a within-subject dose titration approach to reach anticipated therapeutic plasma concentrations of XEN-D0501 not previously investigated.

Dose escalation will be carried out individually for each participant, beginning at 4 mg BID and increasing stepwise up to a maximum of 16 mg BID. Each dose level will be administered for 1 week, resulting in a maximum dose escalation period of 4 weeks. Once the highest tolerable dose has been reached and confirmed to be tolerable, the participant will continue treatment at that dose for an 8-week maintenance period.

The trial is divided into two parts:

Part 1 will function as a pilot safety cohort with 8 participants randomised 3:1 to XEN-D0501 (6 participants) or placebo (2 participants).

Part 2 will comprise the remaining 38 participants randomised 1:1 to XEN-D0501 (19 participants) or placebo (19 participants).

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Part 2 may start once all participants in Part 1 have been dosed for at least 5 weeks and once a favourable recommendation has been given by the internal safety review committee.

The overall design of both parts is the same, but Part 1 entails more intense safety monitoring.

Part 1 will be carried out without the need for additional capital. After the successful outcome of the clinical trial application, a follow-on agreement with **CTC Clinical Trial Consultants AB**, Sweden for the conduct of Part 1 of PP-CT04 has been entered into today.

Chief Executive Officer Gustav H. Gram comments:
"It's really exciting to now have regulatory approval to continue our clinical development. It's a grand achievement of Founder/CSO Dorte X. Gram with her large virtual R&D team. They've worked tremendously dedicated to achieve this important milestone. As we mentioned before, higher doses and longer treatment durations are considered necessary to achieve good efficacy. Determining tolerability levels over three months in obese individuals, will therefore be an important part of our drug candidate XEN-D0501 and its continued clinical development."

For more information:

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PILA PHARMA's share ticker PILA is subject to trade on Nasdaq First North Growth Market, Sweden with Aqurat Fondkommission AB as Certified Adviser. Contact: M: **ca@aqurat.se** - T: +46 (0)8 684 05 800

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About PILA PHARMA AB (Publ)

PILA PHARMA AB is a Swedish clinical stage biotech company based in Malmö, Sweden. The aim of the company is to develop TRPV1 antagonists as a novel treatment of obesity and diabetes. The Company owns a TRPV1 asset with data and chemical entities including the clinical development candidate XEN-D0501. In July 2022, the Company was moreover awarded orphan drug designation ("ODD") for XEN-D0501 as a treatment for the painful rare disease erythromelalgia.