PILA PHARMA AB

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PILA PHARMA PREPARES CLINICAL TRIAL APPLICATION IN RARE DISEASE ERYTHROMELALGIA

PILA PHARMA AB (publ) (FN STO: PILA) ("PILA PHARMA" or the "Company"), an innovative biotech company developing a novel oral, small molecule TRPV1 inhibitor, today announces that it has initiated preparations for a clinical trial application for a proof-of-concept study in the rare disease erythromelalgia.

The ambition is to develop PILA PHARMA's oral TRPV1 inhibitor as a potential new treatment of erythromelalgia.

PILA PHARMA was awarded orphan drug designation for erythromelalgia from the United States' Federal Drug Administration (FDA) in 2022. PILA PHARMA's development plan is to first conduct a smaller proof-of-concept to demonstrate XEN-D0501's potential efficacy on relieving perceived pain in erythromelalgia. Thereafter, the plan is to conduct a phase 2/3 registration trial. Drug development of treatments for rare diseases generally have shorter timelines and incentives such as expanded market exclusivity. For XEN-D0501 as a treatment for erythromelalgia, the expected time to market registration is estimated to be around 3 years given positive results and adequate funding. The drug will be protected by regulatory exclusivity of 7 years in the US after approval, regardless of IP.

Erythromelalgia is a rare disease where neurogenic inflammation plays a role in the development of symptoms. The disease can cause near-constant or episodic pain (ranging from mild tingling to severe burning sensations), and redness to extremities. It most commonly affects the feet but may also occur in the hands, face, or other parts of the body with both nerves and blood vessels involved. Symptoms are frequently managed through avoidance of pain triggers. The disorder can be extremely debilitating, with a significant negative impact on quality of life and with potential to impact mortality rates among young people and the suicide rates among adults.

PILA PHARMA's Founder & CSO Dorte X. Gram comments:
"I'm very pleased that we can now actively start preparing to study the effect of our lead candidate in erythromelalgia. Patients often contact me, as they have heard of PILA's ambitions to develop a good treatment, that could ease their daily sufferings. As I understand it from those I have talked to, they don't have meaningful treatment options. So if XEN-D0501 is effective on relieving pain, without too many safety issues, it would really be a game-changer for them, allowing them to resume living a normal life without the near-constant pain. In PILA we're driven by the motive to heal, and it would be very meaningful if we could help reduce the suffering of people living with erythromelalgia."

PILA PHARMA's scientific expert in pain management, Hans Quiding comments:
It's great to hopefully bring relief for people living with erythromelalgia, that currently lack approved treatment options. I've worked extensively with TRPV1 antagonists for pain management, and I'm very hopeful that this molecule, with its unique safety profile could be of great value for EM patients. A small tablet is highly preferable due to its fast and easy swallowing at attacks. Furthermore, the systemic absorption rapidly distributes the drug to the feet and also to any other affected body area. The tablet can potentially also be used for preventive treatment, so its not just once patients have attacks, but preventing them from occurring in the first place. That would be great"

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This information is such information that PILA PHARMA AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted for publication on 09 February 2026 at 15:00 CET.
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

About PILA PHARMA AB (Publ)

PILA PHARMA is a Swedish biotech company based in Malmö, Sweden. The aim of the company is to develop TRPV1 inhibitors as a novel treatment of obesity, type 2 diabetes and potentially of other diseases with an inflammatory background. The Company owns a TRPV1 asset with data and chemical entities including the development candidate XEN-D0501. Further, the Company owns use-patents covering the use of TRPV1-antagonists for treatment of obesity and diabetes and intends to submit further patents regarding the synthesis, formulation, or use of XEN-D0501 or back-up compounds. In July 2022, the Company was awarded orphan drug designation ("ODD") for XEN-D0501 as a treatment for a painful rare disease erythromelalgia. PILA PHARMA currently focuses on obesity and type-2 diabetes whilst also retaining a focus on licensing opportunities for development of the candidate for erythromelalgia and abdominal aorta aneurysm.

About XEN-D0501 and TRPV1 antagonists

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 inhibitor that was in-licensed in 2016. The drug candidate is a small molecule currently formulated in a simple and stable tablet formulation.
TRPV1 inhibitors that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes and potentially other metabolic disorders like obesity. PILA PHARMA's founder and current CSO Dorte X. Gram, is the inventor of the principle of treating diabetes and obesity with TRPV1 inhibitors – a discovery-by-surprise during her PhD studies at Novo Nordisk, Denmark. Here she discovered that TRPV1 inhibitors would prevent glucose intolerance and body weight gain in spontaneously obese pre-diabetic rats. These results pointed to a new and previously undiscovered role of TRPV1 in regulating both blood glucose and body weight. Prior to in-licensing, XEN-D0501 had been found to have a good safety profile in other (non-diabetic) patient groups.
PILA PHARMA has to date completed two phase 2a clinical trials (PP-CT01 and PP-CT02), that both demonstrated that XEN-D0501 is well tolerated by in people living with obesity and type 2 diabetes. Further, in PP-CT02, it was demonstrated that XEN-D0501 (administered as 4 mg bi-daily for 28 days) - with statistical significance versus placebo - enhanced the endogenous insulin response to oral glucose. ANP, a cardiovascular biomarker for heart failure, was also highly statistically significantly reduced.
During 2023 the Company could report very good tolerability of XEN-D0501 following 13 weeks administration of very high doses in 2 animal species, and XEN-D0501 can thus progress into longer clinical trials. The next step is now to submit a clinical trial application for a dose-finding study in people living with obesity. The clinical trial application should be submitted around the end of Q1 2026. The ambition is to create a comprehensive and meaningful data package that supports XEN-D0501 as an oral, potential first-in-class drug candidate.

About obesity and diabetes

Obesity (BMI >30) is pandemic in its essence with estimates of more than 1 billion people living with it in 2025. Overweight (BMI >27) is also at staggeringly high levels with estimates of 4 billion people globally.
It is most often preceding the development of type 2 diabetes and is a serious risk-factor for not only developing type 2 diabetes but also co-morbidities resulting in "*whole body dysfunction*" and subsequent development of several diseases. The accumulated effect is a year-long reduction in quality of life for obese people with or without diabetes. Obesity leads to an increased risk of developing cardiovascular disease that eventually results in premature death and shortening of life duration. Recent advances and the development of effective anti-obesity drugs has proven that pharmacological weight management is possible and leads to obvious quality-of-life and longevity benefits for people living with obesity. Even long-term, public health costs are expected to be reduced if the clinically negative effects of the obesity pandemic are limited. This has sparked a general interest in future potential oral treatments that can meet the accessibility criteria needed to stimulate enormous and growing demand.
Diabetes is a similar spanning pandemic with strong ties to obesity, and with a staggering estimated prevalence of more than 828 million people living with diabetes corresponding to approximately 8-10% of the global adult population. Among these, its estimated that more than approximately 90 % of all diabetics suffer from type-2 diabetes, whilst approximately less than 10% suffers from type-1 diabetes. Despite recent therapeutic advances,

large and growing unmet needs exist both from efficacy, safety, and accessibility standpoints.
Having previously completed two clinical trials in people living with overweight and diabetes, the Company is now, together with its clinical partner, preparing a clinical trial application with estimated submission around end of Q1 / start of Q2 2026.

About erythromelalgia

Erythromelalgia is a rare disease where neurogenic inflammation plays a role in the development of symptoms. The disease can cause near-constant or episodic pain (ranging from mild tingling to severe burning sensations), and redness to extremities. It most commonly affects the feet but may also occur in the hands, face, or other parts of the body with both nerves and blood vessels involved. Symptoms are frequently managed through avoidance of pain triggers. The disorder can be extremely debilitating, with a significant negative impact on quality of life and with potential to impact mortality rates among young people and the suicide rates among adults. There are no current treatments available to patients, but it is widely believed by doctors that an oral solution with systemic effects would be highly preferable.
PILA PHARMA has made a draft clinical development plan for this project and the project is available for out-licensing. The company is preparing and planning to submit a clinical trial application, with submission estimated start of H1, 2026.