



**PILA PHARMA AB**

Norra Vallgatan 72  
211 22 Malmö  
Sweden

[pilapharma.com](http://pilapharma.com)

Malmö, 30 April 2025

## **PILA PHARMA PROACTIVELY MOVES FORWARD WITH PP-CT03 CLINICAL TRIAL APPLICATION FOR STUDY IN PEOPLE LIVING WITH OBESITY AND DIABETES**

PILA PHARMA AB (publ) (FN STO: PILA) today informs the continuation of preparations for the clinical trial application for PP-CT03, a pivotal and pioneering 12-week Phase 2a study evaluating XEN-D0501, a TRPV1 antagonist, in people living with diabetes and obesity.

PP-CT03 is designed to assess the safety and tolerability of increasing doses of XEN-D0501 vs placebo, as well as the potential effect on body weight loss.

Following the previously communicated plan to seek scientific advice from UK regulatory authorities MHRA, that was announced on 14 November 2024, PILA PHARMA has now received a mid-August 2025 date for written feedback.

To expedite the clinical trial timeline and given the non-binding nature of the scientific advice, the Company has today made a strategic decision to forego this option, and accelerate the work with the clinical trial application with plans of imminent submission. By foregoing the proposed scientific advice date, PILA PHARMA anticipates to expedite the timelines by taking the active dialogue with the regulatory authorities during the application process.

**Founder and Chief Scientific Officer Dr. Dorte X. Gram, states:**

*"I'm pleased that we have collectively chosen to move on and push forward as time is essential in our business. Initially we saw value in engaging with regulatory authorities for their advice, but due to the wait we have decided to move forward with a study design that we firmly believe enables safe individualised dose escalation and we look forward to discussing it in the application process instead."*

For more information, please contact:

Gustav H. Gram, CEO  
[ghg@pilapharma.com](mailto:ghg@pilapharma.com)

*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 30 April 2025 at 08:30 CEST.*

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](mailto: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 antagonists as a novel treatment of 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 as 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 ("Orphan drug designation") for XEN-D0501 as a treatment for erythromelalgia. PILA PHARMA currently focuses on 3 projects within Obesity & Type-2 Diabetes, Erythromelalgia, and Abdominal Aorta Aneurysm.

### **About XEN-D0501 and TRPV1 antagonists**

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed in 2016. TRPV1 antagonists 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. TRPV1 antagonists have been shown to 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, PP-CT02, 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. Furthermore, ANP, a cardiovascular biomarker for heart failure, was 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. Currently, a scientific advice regarding the study design of the next clinical phase 2a trial, PP-CT03, is being prepared and will be followed by a clinical trial submission in the UK. The objective of the study is to identify the maximal tolerable dose of XEN-D0501 in people living with obesity and type 2 diabetes and to evaluate the safety profile following 3 months chronic treatment. In addition to the safety assessment, PP-CT03 will also include sufficient participants that should allow for efficacy readouts on reduction of body weight.

### **About Obesity and Diabetes**

Obesity is an even larger pandemic with estimates of more than 1 billion people suffering from it in 2025. 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 by "Big Pharma" in 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 growing demand, and several acquisitions have been done in the obesity segment recently.

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.

### **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. Pila Pharma aims to conduct a small proof of concept study in persons with erythromelalgia to demonstrate an effect of XEN-D0501 on reducing perceived pain during "flare ups". There are no current treatments available to patients. PILA PHARMA has made a development plan for this project.

#### **About Abdominal Aorta Aneurysm**

Abdominal aorta aneurysm is a cardiovascular disease with 'ballooning' of the lower part of the main artery of the body, aorta. The cause is unknown, but risk factors are atherosclerosis, high blood pressure, cardiovascular inflammation and infection as well as trauma. It affects millions of people globally and accounts for the death of 1% of men over the age of 65. It develops gradually over several years up to a dilatation of more than 3mm in diameter when surgery to insert a stent to prevent rupture is then the only treatment option, which is both expensive and with possibility for complications. Currently no preventive treatment is available. In November 2023 a research collaboration was entered with Uppsala University. In December 2024, PILA PHARMAs TRPV1 antagonist, XEN-D0501, was shown to significantly reduce abdominal aorta aneurysm growth in mice, establishing preclinical proof-of-concept. A validation process is now ongoing in anticipation of creating a development plan.