PILA PHARMA AB

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PILA PHARMA SIGNS WITH NEW CLINICAL CRO TO PREPARE FOR CLINICAL PHASE IN OBESITY AFTER PRECLINICAL OBESITY STUDIES

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 entered into agreement with a new clinical Contract Research Organisation (CRO), to prepare and submit a clinical trial application in obesity. In addition, the Company also announces the completion of recent preclinical studies in obesity, albeit with inconclusive results.

Today, an agreement has been entered into with a new clinical CRO on preparing and submitting a clinical trial application in obesity. The clinical trial application is intended to be submitted around the end of Q1 2026.

The Company also announces that the two studies in rat obesity have been completed according to protocol, however results are currently inconclusive. As of now at completion of the studies, many results are still pending, including various obesity and inflammation endpoints, but most importantly the exposure analyses. Preliminary results show that bodyweight or other reported endpoints were not affected in the rats intended to be treated with XEN-D0501. The results on individual XEN-D0501 exposure are due within the next months after which it can be concluded if there was "*lack of efficacy*" with regard to obesity or simply "*lack of exposure*".

As previously communicated, the formulation used for the rat obesity studies had never previously been used with XEN-D0501. As PILAs own formulation for preclinical oral delivery, which was well tolerated in 13-week tox studies, was not tolerated by obese rats. The only option to conduct the "*ready to go*" rat obesity studies, was therefore to choose another formulation "*known-to-be-tolerated*" by obese rats or cancel the studies. The risk of using the new formulation, however, could be that XEN-D0501 absorption and thus resulting blood levels /exposure would be compromised, i.e. lower than expected and needed for efficacy.

Founder and CSO Dorte X. Gram comments:
"I'm pleased that we're now moving back to clinical testing of XEN-D0501 where we know we have good exposure of XEN-D0501 with the current tablet formulation. It was quite frustrating that we, at the last minute before the studies' start, had to choose a sub-optimal formulation for the rat studies, or otherwise cancelling the studies. As we had already committed our time and funds, we concluded it was too far in the process to cancel. We amended the protocols to take blood samples to determine the actual blood concentration of XEN-D0501 in each rat. If the formulation resulted in low exposure, a "*false negative*" effect on bodyweight could be the result. The results so far don't show an effect on bodyweight, but we are now awaiting the data to see if the rats got exposed to XEN-D0501 or not. If the rats didn't get XEN-D0501 into the bloodstream, then no effects on body weight or any other endpoints would be expected. Whilst we await the conclusion of the rat obesity studies, we have decided to move on to the clinical dose-finding study in people living with obesity, in collaboration with the new dedicated clinical CRO and the work is already underway!"

CEO Gustav H. Gram comments:
We're delighted to now move into clinical preparations in obesity as promised. Our overwhelmingly successful fundraise this past summer, which was subscribed to 293,5%, provided us with more funds than projected. This now allows us to accelerate the dose-finding study in people living with obesity, and thus we expect the true value of our molecule can be unlocked"

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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 26 January 2026 at 11:00 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 focusing on licensing opportunities 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 preparing to submit clinical trial applications in people living with obesity alone as well as with type 2 diabetes.

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 outlicensing.