



**PILA PHARMA AB**

Norra Vallgatan 72  
211 22 Malmö  
Sweden

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

Malmö, 24 August 2023

## **PILA PHARMA announces capital infusion via convertible loans.**

**The board of Pila Pharma AB (publ) has decided to immediately secure additional funds via convertible loan agreements to sponsor the next clinical trial applications.**

With the recent news that our tablets manufactured in 2021 are cleared by the manufacturer for use in phase 1 or 2a studies, Pila Pharma is now ready to continue the clinical development of XEN-D0501.

The next step will be to submit 2 clinical trial applications for regulatory approval. The new capital infusion will fund this work that will be resumed asap.

In diabetes/ obesity, we plan to conduct a phase 2a dose finding trial of 3-month treatment duration in obese persons with diabetes to explore safety and efficacy of XEN-D0501 on diabetes, obesity and cardiovascular markers in a wider dose-span than previously tested before progressing to a subsequent pivotal confirmatory phase 2b trial.

In pain/ erythromelalgia, we plan to conduct a phase 2a “proof-of-concept” trial to demonstrate the safety and efficacy of XEN-D0501 on relieving pain during “flare ups” in persons with erythromelalgia before progressing to a subsequent pivotal phase 2/3 registration trial.

The loans with an annual interest rate of 10% p.a. are to be paid out shortly and will be converted to shares at the next new shares issue in Pila Pharma.

### **CEO comments**

I'm really pleased, that some of our long-term investors have decided to again support us by providing these convertible loans so we can progress our clinical plans immediately. This should allow us to submit the applications during the autumn and hopefully before Christmas get regulatory approval to conduct both trials. In that case, the trials can be initiated after New Year given further funding has been secured by then.

*“When in doubt just take the next small step”*  
(Paulo Coelho)

For more information:

Dorte X. Gram, CEO  
Text: +46 (0)73 903 6969  
M: [dxg@pilapharma.com](mailto:dxg@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 24 August 2023 at 08:00 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](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 novel treatments of e.g. type 2 diabetes or of the painful rare disease erythromelalgia. The company owns both use patents for treating diabetes and obesity with TRPV1 antagonists, and the intellectual property rights for the mid stage clinical development candidate XEN-D0501 as well as back-up candidates. The FDA in USA in July 2022 granted Orphan Drug Designation for XEN-D0501 as treatment of erythromelalgia. The company was listed at Nasdaq First North GM in Stockholm, Sweden in July 2021.

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

The discovery of TRPV1 and its role in pain and neurogenic inflammation was awarded the 2021 Nobel Prize in Medicine or Physiology.

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was inlicensed in 2016 and, previously, developed by Bayer Healthcare, Germany and Xention/Ario Pharma, UK. The TRPV1 target (also called the “chili-receptor”) and TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes as well. 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 PPCT02), that both demonstrated that XEN-D0501 is well tolerated by type 2 diabetic patients. Further, PP-CT02, demonstrated that XEN-D0501 (administered as 4 mg BID for 28 days) – with statistical significance versus placebo – enhance the endogenous insulin response to oral glucose. Final results from recently completed preclinical 13-week safety studies show that XEN-D0501 is well tolerated in both “rodents” and “non-rodents” and the molecule can thus advance to clinical studies of up to 3 months duration.

### **About Diabetes**

Diabetes is a world-wide pandemic with a staggering prevalence of 537 million people with diabetes corresponding to approximately 8-10% of the population. Approximately 90 % of all diabetics suffer from type 2 diabetes, whilst approximately 10% suffers from type 1 diabetes. The disease can lead to cardiovascular disease resulting in reduction of quality of life for the patient, increased risk of death and high health care expenses. Despite recent therapeutic advances, large and growing unmet needs exist both from an efficacy, safety, accessibility, and affordability perspective.

### **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.