PILA PHARMA AB

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Malmö, January 30, 2023

Pila Pharma completes 13-week safety studies in "non-rodents" with no adverse signals during the dosing phase

PILA PHARMA AB (publ) (FN STO: PILA) today publishes that a 13-week oral safety study with the development candidate XEN-D0501 in non-rodents has completed the *in-life* phase with no adverse signals during the dosing phase and biological samples have now been received for assay.

Outstanding investigations still to be completed include the pathology, and the bioanalysis and toxicokinetic analyses which are necessary to determine the safety margin for the coming 3-month clinical phase 2b study in diabetes. This follows our earlier report that a 13-week oral safety study in rodents had also completed its *in-life* phase without registration adverse signals. That rodent study has now completed its outstanding investigations and the histopathology did not either demonstrate any adverse findings, and the bioanalysis results show that the exposure of XEN-D0501 was as expected, and in the same range as earlier studies. Final result reports from both studies are due to be completed by early March 2023.

Pila Pharma is, as previously announced, preparing a clinical phase 2b study of the drug candidate XEN-D0501 for type 2 diabetes. The aim with the phase 2b study is to test XEN-D0501 at higher doses and for a longer duration than the previously completed Phase 2a trial to further evaluate its glucose lowering properties. XEN-D0501 has already been evaluated in both toxicological safety studies and in phase 1 and 2a clinical trials in humans with up to 4 weeks treatment duration with good safety results, indicating that the molecule is well tolerated. The 13-week preclinical toxicological studies aim at confirming the preclinical safety prior to the coming 3 months phase 2b clinical study.

CEO comments:
" I'm very pleased that XEN-D0501 did not cause any clinical side-effects in the 13-week non-rodent study, and it supports that we may have a lead candidate suitable for chronic treatments. We now look forward to completing the "13-week safety package" that is a prerequisite to progress to the 3 months phase 2b clinical studies in diabetes and possibly other indications."

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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 30 January 2023 at 16:30 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.
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About Pila Pharma AB (Publ)
Pila Pharma is a Swedish biotech company in the diabetes segment based in Malmö, Sweden. The aim of the company is to develop TRPV1 antagonists as novel treatments. The company currently develop XEN-D0501, as a new oral antidiabetic agent. 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. A use-patent application on the use of XEN-D0501 as treatment of diabetes was filed in October 2021. 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
XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed 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 PP-CT02), 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. The preclinical 13-week safety studies about to complete are needed to be able to take XEN-D0501 further into a 3-month phase 2b clinical study in patients with type 2 diabetes. Considerations for the best clinical development of XEN-D0501 as a treatment for erythromelalgia are also ongoing.

About Diabetes
Diabetes is a world-wide pandemic with a staggering prevalence of 537 million diabetics 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 erythema, 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.