



PILA PHARMA AB

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XEN-D0501 can progress to clinical trials up to 3-month duration after being found safe in 13-week preclinical oral safety studies

PILA PHARMA AB (publ) (FN STO: PILA) today publishes that 13-week preclinical oral safety studies with the development candidate XEN-D0501 have completed without adverse signals.

Previously, it has been communicated that the “rodent” part had completed without adverse signals and that the “non-rodent” also completed the in-life phase without adverse signals despite high exposure. The remaining histopathology investigations in “non-rodents” have now been completed also without adverse signals.

These last results complete the “13-week tox package” of XEN-D0501 that overall demonstrates that the TRPV1 antagonist was safe and well tolerated at high doses and exposures in two animal species.

These good safety results therefore will permit XEN-D0501 to progress to oral dosing clinical studies of up to 3 months duration.

Pila Pharma is, as previously announced, intending to progress XEN-D0501 into a clinical phase 2b study in type 2 diabetes but also plans to develop the molecule as treatment of the rare painful disease, erythromelalgia.

CEO comments:

”I’m very pleased that XEN-D0501 has come out “clean” after the completion of the “13-week safety package”. These results support our belief that XEN-D0501 is a unique TRPV1 antagonist given the very good safety profile that we have recorded until now. In previous clinical studies, the molecule has been exposed to 300 people for up to 1 month without significant safety concerns at the doses administered. In our last phase 2a trial in type 2 diabetics, XEN-D0501 also demonstrated a small but significant effect on insulin secretion. Altogether, it consolidates my belief that this particular molecule may be the TRPV1 antagonist suitable for oral chronic treatment”, says Dorte X. Gram, founder and CEO of Pila Pharma.

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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.

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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 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

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. 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 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 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.