



PILA PHARMA AB

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

PILA PHARMA AB (publ) (FN STO: PILA) today publishes that a 13-week oral safety study in rats has completed the *in-life* phase with no adverse signals during the dosing phase.

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. A pivotal 13-week study in “non-rodents” has now also been initiated. The *in-life* part of this 2nd part of the “13-week tox package” is due to be completed by the end of 2022 and all results of the “13-week safety package” are expected in early 2023.

Pila Pharma is, as previously announced, preparing a clinical phase 2b study of the drug candidate XEN-D0501 for type 2 diabetes. Previously, XEN-D0501 has 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:

” It’s really good news that XEN-D0501 did not cause any clinical side-effects in the 3-month rat study, and it indicates 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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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. The FDA in USA recently granted Orphan Drug Designation for XEN-D0501 as treatment of Erythromelalgia. The company was listed at Nasdaq First North GM in Stockholm, Sweden in 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. Preclinical 13-week safety studies are ongoing and are needed to be able to take XEN-D0501 further into a 13-week 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.