PILA PHARMA AB

Västergatan 1
211 21 Malmö
Sweden

pilapharma.com

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Pila Pharma AB initiates toxicological studies

Pila Pharma AB (publ) announces that the preclinical toxicological three-month studies of the active substance XEN-D0501 has begun.

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 one month doses with very good safety results, indicating that the molecule is very well tolerated.
The new preclinical toxicological studies aims to confirm the safety of the duration of the forthcoming phase 2b study, ie three months.

CEO Dorte X. Gram comments:
"I am very pleased that we have reached another milestone within the timetable for our development plan. This is the last important step before we can begin our phase 2b study in humans.

For more information:

Dorte X. Gram, CEO
M: +46 (0)73 903 6969
E: dxg@pilapharma.com

PilaPharma´s share, ticker PILA, is subject to trade on Nasdaq First North Growth Market with Aqurat Fondkommission AB as Certified Adviser. info@aqurat.se.
Tel. +46 (0)8 684 05 800

About Pila Pharma (Publ)
Pila Pharma is a Swedish biotech company in the diabetes segment based in Malmö. The aim of the company is to develop a novel and superior tablet-based treatment for type 2 diabetes. 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 company was listed at Nasdaq First North GM in Stockholm in July 2021 to finance the further development of XEN-D0501.

About XEN-D0501 and TRPV1 antagonists
XEN-D0501 is a highly selective and very potent small molecule TRPV1 antagonist, previously in development by Bayer Healthcare and Xention/Ario Pharma. The TRPV1 target (also called the “chili-receptor”) has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes as well. XEN-D0501 was acquired by PILA PHARMA in March 2016, due to its very good safety and tolerability profile as compared to other clinical TRPV1-antagonist development candidates. TRPV1 antagonists as a drug-class has previously been associated with severe adverse events as fever (hyperthermia) but this has not been the case for XEN-D0501 in 8 clinical trials conducted so far. The maximal tolerable dose in non-diabetic individuals has previously been determined to be 4 milligrams twice daily, a dose level with good safety but no effect in non-diabetic patients with either overactive bladder disease or chronic cough. In November 2018, Pila Pharma reported the completion of its first clinical trial (PP-CT01), demonstrating a good safety profile of XEN-D0501 at single doses up to 8 milligrams when administered to people with type 2 diabetes. The most recent study results were announced in September 2020. The study (PP-CT02) demonstrated that multiple doses of XEN-D0501 (4 milligrams twice daily for 28 days) were likewise well-tolerated by people with type 2 diabetes and – with statistical significance versus placebo - that XEN-D0501 enhances the endogenous insulin response to oral glucose, thus demonstrating proof of principle.

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.