PILA PHARMA AB

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Malmö, March 22, 2022

Pila Pharma AB's annual report for 2021 delayed

Pila Pharma AB (publ) announces that the annual report for 2021, which was to be published on March 22, 2022, is delayed and will instead be published on March 23, 2022.

The reason is that problems have arisen in the technical production of the annual report. The delay has nothing to do with Pila Pharma's operations.

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The Company's share, with the ticker PILA, is traded at Nasdaq First North Growth Market, Stockholm, Sweden, with Aqurat Fondkommission AB as Certified Adviser. info@aqurat.se. Tel. 08-684 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 is listed at Nasdaq First North GM in Stockholm in July 2021 to finance the further development of XEN-D0501. Currently, new API for further 3 months preclinical safety studies is being manufactured to permit the company to progress XEN-D0501 to a pivotal 3 month phase 2b trial in patients with diabetes, scheduled to start in first part of 2023.

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 also – 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.