PILA PHARMA AB

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**PILA PHARMA AB (publ) announces GMP-certification of a new batch of 4 mg XEN-D0501 tablets for clinical use**

“I am pleased to share the information that, today, we were informed by our trial supply subcontractor, that a new batch of 4 mg XEN-D0501 tablets has successfully been manufactured and have received an approved CoA in accordance with GMP”, says CEO Dorte X. Gram.

PILA PHARMA in 2016 purchased the TRPV1 asset package including the clinical development candidate XEN-D0501 together with a batch of GMP certified tablets for clinical use as well as a batch of active pharmaceutical ingredient (API). The acquired tablets were used in PILA PHARMAs first two phase 2 clinical trials, PP-CT01 and PP-CT02, but expired in April 2020.

“The new tablets manufacture is a success in at least 2 ways. Firstly, it provides us with the option to plan and conduct new clinical trials. Secondly, it substantiates how impressively stable XEN-D0501 is, since, the new tablets were manufactured with the remaining API that was still within specifications.
For us to progress to phase 2b clinical testing as planned, extended toxicology studies as well manufacture of new tablets are needed. Therefore, a significant risk has been reduced with todays GMP-certification and we are now in a position where we already have study medication available, which is actually ahead of schedule” says Lars B. Rasmussen, COO.

*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 June 17, 2021 at 17:00 CET.*

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**About PILA PHARMA**
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.

**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 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). 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 good safety 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 mg twice daily for 28 days) were likewise safe and 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 463 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, adherence, accessibility and affordability perspective.