PILA PHARMA AB

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PILA PHARMA recieves GMP certification of placebo tablets

PILA PHARMA AB (publ) ("PILA PHARMA" or "the Company") announces that the placebo tablets to be used in coming clinical studies have now been manufactured, and GMP (Good Manufacturing Practice) certified.

Placebo tablets are a key component of most clinical trials, in order to ensure a high degree of outcome reliability. Already in June 2021 the Company received GMP certification of the 4 mg tablets containing the active pharmaceutical ingredient XEN-D0501.

As a result, both the active and the placebo tablets are now ready for use in PILA PHARMA:s upcoming phase 2b clinical study in type 2 diabetes. A clinical trial application will be sumbitted as soon as the preclinical toxicology studies are completed. Currently, drug substance production for these toxicological studies are ongoing with Almac Scienes Limited.

"We're very pleased having received the GMP certification of the placebo tablets. This is another major step forward towards being able to initiate the clinical phase 2b studies in type 2 diabetes", says COO Lars B. Rasmussen and CEO Dorte X. Gram.

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 September 14, 2021 at 08:00 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 maximum 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.