PILA PHARMA AB

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Pila Pharma AB announces certification of API

Pila Pharma AB (PILA) today announces that the study material (non-GMP API) to be used in three-month preclinical studies has received a certificate of analysis and is thus ready to use.

As announced in August 2021, the production of a new XEN-D0501 API for the planned preclinical safety studies was outsourced to Almac Group. This production has now been completed as Almac has verified that the final product complies with the specifications and has issued a certificate of analysis.

This in turn means that Pila Pharma's development of a new diabetes drug is going according to plan, and that the company can now proceed towards the planned longer preclinical studies that are necessary to be able to carry out a clinical phase 2b study.

“I am very pleased to see that our activities at Almac have developed according to plan. At the same time, I am excited about the excellent API results we have achieved along the way, where we have been able to significantly increase our understanding of the synthesis process. The synthesis that has been completed now has gone much better than expected. First and foremost, our API has an incredibly high quality - more than I have ever seen before - in addition, the optimized synthesis has resulted in us getting 50 percent more new API than we ordered. Last but not least, everything has been completed in less time than planned. We can now say that we have managed to reach one of the most important milestones that we have communicated (production of more study material) on our way to clinical phase 2 results and I am of course extremely satisfied with and proud of this. ”, says Pila Pharma's CEO, Dorte X. Gram.

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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 April 25, 2022 at 15:15 CET.

The Company’s share, with the ticker PILA, is traded at Nasdaq First North Growth Market 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. API for further 3 months preclinical safety studies is completed, permitting 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.

About Almac Group
The Almac Group is a contract development and manufacturing organisation providing an extensive range of integrated services across the drug development lifecycle to the pharmaceutical and biotech sectors globally. Its innovative services range from R&D, biomarker discovery development and commercialisation, API manufacture, analytical services, formulation development, clinical trial supply, IRT (IVRS/IWRS) through to commercial-scale manufacture.The privately owned company has over 6,000 personnel across 19 facilities including Europe, the US and Asia. For more information, visit almacgroup.com