PILA PHARMA AB

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PILA PHARMA AB, announces API manufacturing milestone achieved and changes to organisation

PILA PHARMA AB (PILA) today announces their first API manufacturing milestone has been successfully achieved.

The manufacture of new XEN-D0501 API for the planned preclinical safety studies was, as announced 6 months ago, outsourced to Almac Group. The task to manufacture a critical API "starting material" was managed by Almac at a partner site, in parallel to, scale-up and development of the synthetic process to the API internally.

Both actions now allows to initiate the final steps of manufacture of the new API, marking the achievement of the first significant API manufacturing milestone.

"I am very pleased to see that our activities with Almac are progressing in accordance with plan. The availability of new final API before summer is key for conducting the planned three-month pre-clinical studies, that in turn are a prerequisite for initiating the clinical phase 2b study in type-2 diabetics", says Lars B. Rasmussen, COO.

CEO Dorte X. Gram completes, "I am excited about these excellent initial API manufacture results and that we have been able to not only meet overall timelines, but also significantly increase our understanding of the API synthesis process and control which will be important for future cost-effective API manufacture".

With these positive operational news PILA also announces new changes to the PILA organisation.

Scientific Advisor Henning Beck Nielsen, as well as COO Lars B. Rasmussen have both decided to step out of their current PILA roles to focus more on other projects outside the company.

I, sincerely, thank them both for their tremendous contribution in developing PILA to its current stage. Together with Henning Beck-Nielsen we laid out and executed a plan to take our new Mode of Action oral diabetes agent, XEN-D0501, into first clinical trials in patients with type 2 diabetes. Together with Lars B. Rasmussen, we have listed PILA on Nasdaq First North GM in Stockholm, Sweden which have permitted our further successful development towards phase 2b results." says Dorte X. Gram, CEO.

New to the PILA organization is Susanne Rugh, previously Novo Nordisk, who has offered her diabetes drug development expertise and is appointed Project Director for the Diabetes Clinical Development program for XEN-D0501, "XEN-DIA".

Susanne Rugh has contributed significantly to current diabetes treatment by leading no less than 3 Novo Nordisk development candidates through to registration and marketing (Levemir®, Tresiba® and Ryzodeg®).

CEO Dorte X. Gram concludes, "I'm truly grateful that so many past and present skilled individuals and organisations have chosen to dedicate some of their excellence to help PILA

onwards! The new collaboration with Susanne Rugh will ensure the coming clinical development of XEN-DIA in accordance to best practice in pharma."

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 04 February 2022 at 16:30 CET.

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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.

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 informations, visit almacgroup.com