PILA PHARMA AB

Västergatan 1
211 21 Malmö
Sweden

pilapharma.com

Malmö, Sweden, 05 August 2021

PILA PHARMA AB, announces API manufacturing agreement signed

PILA PHARMA AB (PILA) today announces signing of a manufacturing agreement with Almac Sciences Limited, UK, for the production of XEN-D0501 active pharmaceutical ingredient (API). The availability of new API is key for conducting the planned 3 month toxicology studies, that are in turn a prerequisite for initiating the clinical phase 2b study in type-2 diabetics.

“During the last couple of months we have been focused on getting ready to kickstart the crucial operational activities in PILA, and the recent successful completion of the IPO has financially enabled us to move ahead full speed. Today’s signing of the agreement with Almac marks the first major step in scaling up the operational activities of the company”, says Lars B. Rasmussen, COO in PILA.

CEO Dorte X. Gram completes, “I am excited that we managed to finalize this contract right after the IPO when finances were secured. The scaling up of the company starting now, implies that we must also put extra focus on developing our internal structure to support the growth. Therefore, I am very pleased to inform that we have been able to attract attorney Miguel Lecumberri as Head of Compliance to support the efforts in securing a strong but flexible structure of PILA going forward”.

Miguel Lecumberri is a corporate lawyer specialized in compliance for life-science sector, intellectual property rights and has previously served in international law firms and has been external legal counsel for pharmaceutical companies such as Pfizer, Astra-Zeneca, Astellas, UCB and Novo Nordisk.

“I am honored to join the fantastic PILA team on its coming journey. Moving across the Atlantic from Mexico City to Malmö is a major personal decision, but I believe greatly in the potential of PILA”, Miguel Lecumberri states.

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 August 5, 2021 at 20:30 CET.

For further information, please contact:
Dorte X. Gram, CEO
M: +46 (0)73 903 6969
E: dxg@pilapharma.com

About Almac Sciences
Almac Sciences is global provider of integrated drug development services (small molecules & peptides) with proven expertise in small and large molecule analytics, API supply, stable & 14C radiolabelling, formulation development & solid-state services. Its global biocatalysis team has vast experience and expertise in enzyme engineering, enzyme supply, enzyme screening, developing new routes and manufacturing at scale, both GMP and non-GMP. With facilities located in the UK, Europe and the US, Almac Sciences provides a full suite of analytical testing services across 3 FDA approved laboratories. Encompassing method development, validation, transfer and stability studies on small molecule, biologics, active ingredients and finished products (including controlled substances).
For more information, visit: almacgroup.com/api-chemical-development/

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 milligrams 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.