PILA PHARMA AB

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PILA PHARMA AB, announces ink of agreement with pre-clinical service provider ERBC

PILA PHARMA AB (publ) announces that an agreement has been signed with the company ERBC, regarding the conduct of PILA PHARMA´s upcoming preclinical safety assessment studies. ERBC is a certified pre-clinical service provider, based in France and Italy.

PILA PHARMA is, as previously announced, preparing a clinical phase 2b study of the anti-diabetic drug candidate XEN-D0501. Previously, XEN-D0501 has been evaluated in both preclinical safety assessment studies and in human clinical trials of up to 1 month chronic dosing with very good safety results, suggesting the molecule to be very well tolerated in several species.
The scheduled preclinical studies to be conducted at ERBC are planned to confirm the safety of XEN-D0501 prior to the initiation of planned 3-month duration phase 2b and is a regulatory requirement.

“After evaluating a set of potential pre-clinical service providers, we have decided on ERBC as our partner of choice”, says Lars B. Rasmussen, COO at PILA PHARMA.

CEO Dorte X. Gram further comments: “I am very pleased that we have achieved yet another milestone in our development plan, and I look forward to getting these important studies executed.”

The preclinical safety studies at ERBC are planned to start in 2022. The XEN-D0501 study material, (non-GMP API) to be used in these studies, is currently being manufactured by Almac Sciences Ltd, under a previously announced agreement.

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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 537 million diabetics. 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.

About ERBC
Based in Baugy (France) and Roma (Italy), ERBC provides all services from preclinical proof-of-concept to market of any type of drug candidate or chemical compound. Each project is managed by a study director, relying on a multi-disciplinary team of experts, notably in general pharmacology, cardiology, electrophysiology and pathophysiology, also benefiting from a world class academic and private network. ERBC is deeply engaged in animal ethics and welfare. ERBC supports the Basel Declaration, respects the 3Rs concept and continually improves its tools and procedures to maximize the balance between the benefit for health and the animal well-being. Read more about ERBC at www.erbc-group.com.