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PILA PHARMA INKS AGREEMENT WITH LINDUS HEALTH ABOUT NEXT CLINICAL TRIAL WITH SAFETY AND OBESITY READOUTS

PILA PHARMA AB (publ) (FN STO:PILA) today announces it has entered into agreement with a United Kingdom based clinical research organisation, Lindus Health, on supply of clinical research services to assist with the submission of an clinical trial application for approval for PP-CT03, a phase 2a study in obese people with type-2 diabetes.

Lindus Health are experts in metabolic health and proactively seek to reduce clinical trial timelines and increase quality through technology and digital centric approaches to all facets of trial execution. They, furthermore, offer a risk-shared, fixed-price and milestone-based payment model attractive to companies like Pila Pharma.

During the first half of the year, Pila Pharma's clinical team has prepared the documents needed for regulatory approval and Lindus Health will now compile and submit the clinical trial application.

PP-CT03 is designed to define the maximal tolerable dose of XEN-D0501 as well as assessing the safety and tolerability and to determine any bodyweight effect following 3 months treatment in obese people with type 2 diabetes. Pending approval of the application, the expectation is that recruitment of trial participants to this phase 2a dose-escalation trial can begin in early autumn this year. The trial results are anticipated to pave the way for a phase 2b trial with efficacy endpoints.

CEO comments:
"*We are very pleased to announce our new collaboration with Lindus Health, UK. They have an impressive and smart new model for clinical research work that will both ensure high quality and accelerated timelines. They will now assist us with submission of the clinical trial application in anticipation of our next clinical trial, a trial that could be pivotal for Pila Pharma to define the potential of our novel and potentially "First-in-Class" oral anti-diabetic treatment based on a TRPV1 antagonist with potential effects on cardiovascular disease and obesity"* says Gustav H. Gram, CEO of PILA PHARMA.

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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 24 July 2024 at 18:00 CEST.

Pila Pharma's share ticker PILA is subject to trade on Nasdaq First North Growth Market, Sweden with Aqurat Fondkommission AB as Certified Adviser. Contact: M: ca@aqurat.se, T: +46 (0)8 684 05 800

About PILA PHARMA AB (Publ)
Pila Pharma is a Swedish biotech company based in Malmö, Sweden. The aim of the company is to develop TRPV1 antagonists as a novel treatment of type 2 diabetes and potentially of other diseases with an inflammatory background.
The Company owns a TRPV1 asset with data and chemical entities including the development candidate XEN-D0501. Further, the Company owns use-patents covering the use of TRPV1-antagonists as treatment of obesity and diabetes and intends to submit further patents regarding the synthesis, formulation, or use of XEN-D0501 or back-up compounds. In July 2022, the Company was awarded orphan drug designation ("Orphan drug designation") for XEN-D0501 as a treatment for erythromelalgia.
Pila Pharma currently focuses on 3 projects within Type-2 Diabetes, Erythromelalgia, and Abdominal Aorta Aneurism.

About XEN-D0501 and TRPV1 antagonists
XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed in 2016. TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes and potentially other metabolic disorders like obesity. Prior to in-licensing, XEN-D0501 had been found to have a good safety profile in other (non-diabetic) patient groups. Pila Pharma has to date completed two phase 2a clinical trials (PP-CT01 and PP-CT02), that both demonstrated that XEN-D0501 is well tolerated by type 2 diabetic patients. Further, PP-CT02, demonstrated that XEN-D0501 (administered as 4 mg bi-daily for 28 days) - with statistical significance versus placebo - enhanced the endogenous insulin response to oral glucose.
Furthermore, ANP, a heart failure biomarker, was highly statistically significantly reduced. During 2023 we could report a very good tolerability of XEN-D0501 following 13 weeks administration of very high doses in 2 animal species, and XEN-D0501 can thus progress into longer clinical trials.
Currently, the next clinical phase 2a trial, PP-CT03, is being prepared. The objective is identifying the maximal tolerable dose of XEN-D0501 in overweight or obese people with type 2 diabetes and evaluate the safety profile following 3 months chronic treatment in a smaller subject population before progressing to the pivotal phase 2b trial. In addition to safety assessment, PP-CT03 may identify (trends for) a reduction of HbA_{1c}, body weight and ANP, a relevant marker of cardiovascular disease.

About Diabetes and Obesity
Diabetes is a globally spanning pandemic with a staggering estimated prevalence of more than 537 million people living with diabetes corresponding to approximately 8-10% of the global adult population. Among these, its estimated that more than approximately 90 % of all diabetics suffer from type-2 diabetes, whilst approximately less than 10% suffers from type-1 diabetes.
Despite recent therapeutic advances, large and growing unmet needs exist both from efficacy, safety, and accessibility standpoints.
Obesity is most often preceding the development of type 2 diabetes and a serious risk-factor for not only developing type 2 diabetes but also co-morbidities resulting in "whole body dysfunction" and subsequent development of several diseases. The accumulated effect is a year-long reduction in quality of life for obese people with or without diabetes. Obesity leads to an increased risk of developing cardiovascular disease that eventually results in premature death and shortening of life duration. Recent advances by "Big Pharma" in the development of effective anti-obesity drugs, has proven that pharmacological weight management is possible and leads to obvious quality-of-life and longevity benefits for people living with obesity. Even long-term, public health costs are expected to be reduced if the clinically negative effects of the obesity pandemic are limited. This has sparked a general interest in future potential oral treatments that can meet the accessibility criteria needed to stimulate growing demand and several acquisitions have been done in the obesity segment recently.

About Erythromelalgia
Erythromelalgia is a rare disease where neurogenic inflammation plays a role in the development of symptoms. The disease can cause near-constant or episodic pain (ranging from mild tingling to severe burning sensations), and redness to extremities. It most commonly affects the feet but may also occur in the hands, face, or other parts of the body with both nerves and blood vessels involved. Symptoms are frequently managed through avoidance of pain triggers. The disorder can be extremely debilitating, with a significant negative impact on quality of life and with potential to impact mortality rates among young people and the suicide rates among adults. Pila Pharma aims to conduct a small proof of

concept study in persons with erythromelalgia to demonstrate an effect of XEN-D0501 on reducing perceived pain during "flare ups".

About Abdominal Aorta Aneurism
Abdominal Aorta Aneurism is a cardiovascular disease with 'balooning' of the lower part of the main artery of the body, aorta. The cause is unknown, but risk factors are atherosclerosis, high blood pressure, cardiovascular inflammation and infection as well as trauma. It affects millions of people globally and accounts for the death of 1% of men over the age of 65. It develops gradually over several years up to a dilatation of more than 3mm in diameter when surgery to insert a stent to prevent rupture is then the only treatment option, which is both expensive and with possibility for complications. Currently no preventive treatment is available. In November 2023 a research collaboration was entered on investigating the effect of XEN-D0501 on Abdominal Aorta Aneurism growth in mice.

About Lindus Health (by Lindus Health)
Lindus Health is an anti-CRO running radically faster and more reliable trials for life science pioneers – bringing ground-breaking treatments to patients more quickly. This is achieved through a commercial model that aligns incentives (fixed-priced quotes per study, with milestone-based payments), a world-class clinical operations team with its unique software platform, and access to over 30 million Electronic Health Records.
Clinical trials are the biggest bottleneck to advances in healthcare. Lindus Health removes this constraint by handling the end-to-end execution of clinical studies, including design, patient recruitment, clinical data capture, monitoring and project management. To date, Lindus Health has delivered more than 90 trials across the US, UK and Europe to tackle a range of conditions, including diabetes, asthma, acne, social anxiety, major depressive disorder, hypertension, chronic fatigue syndrome and insomnia. The company has raised over $24M from investors including Peter Thiel, CREANDUM, Firstminute Capital, Presight Capital, Seedcamp, Hambro Perks, Amino Collective and Calm/Storm.