PILA PHARMA AB

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PILA PHARMA ANNOUNCES SELECTION OF CLINICAL TRIAL SITE AND DECISION TO SEEK SCIENTIFIC ADVICE FOR OPTIMIZED PP-CT03 STUDY DESIGN

PILA PHARMA AB (publ) (FN STO:PILA) today announces the selection of the principal investigator, Professor Mark Evans and Cambridge University Hospital as principal clinical trial site for the conduct of PP-CT03 as well as the as having decided to seek further scientific advice as first step.

On 17 October, PILA PHARMA informed of optimization changes to the trial plan for PP-CT03 plan, due mainly to internal safety concerns of running the trial at a non-hospital site, as well as the decision to conduct at least the initial part at a hospital site.

The Company has now selected the scientific advisor to PILA PHARMA, Professor Mark Evans, as principal investigator of the study and the Cambridge University Hospital, UK, as the principal trial site of PP-CT03. Furthermore, following discussions with Professor Evans, it has been decided to seek scientific advice with the UK MRHA prior to clinical trial application. The objective is to further strengthen the PP-CT03 study design and increase the opportunity for this study to provide input to a clear development and regulatory plan in diabetes and potentially obesity**.**

Professor Evans comments: *"I'm excited to be working with PILA PHARMA and colleagues on planning a study to help determine the optimal dosing strategy for XEN-D0501. As part of this planning, we will take advantage of the opportunity to take scientific advice from the UK MHRA about the best scientific design for our planned study."*

CSO, Dorte X. Gram comments: **"***I'm very glad that we could quickly adapt our plans to conduct PP-CT03 in a prime hospital setting with our long-term scientific advisor Professor Evans. Following discussions with him and his team, we agree on the benefit of first asking for regulatory scientific advice, despite the subsequent delay of study timelines. The benefit, as we see it, will be that we can "hit the nail the first time", meaning that we will increase our chances of straight regulatory approval of the trial application following submission. These decisions mean that we expect to receive scientific feedback from the MRHA within 30 workdays from the scientific advice meeting in Q1 2025. Hereafter, which we can resume the clinical trial application submission plans, aiming at straight acceptance of the trial application. The effect on our clinical trial budget depends on the regulatory feedback and the final study design approved.*

CEO, Gustav H. Gram comments: *"As we approach an increasingly pivotal time point in the company's lifetime, we are focused on risk minimizing and efficacy optimizing every parameter we can. Whilst it is unfortunate with a new timeline, I'm happy we are cautious but move forward steadily. We will use the opportunity to build a relation with the authorities regarding this new drug class, and also seek to explore potential extra tests and measurements which are available in the hospital setting. We anticipate these tests and measurements can provide more details and higher quality data regarding the mechanism*

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and its potentially "functional weight loss properties" meaning if the body weight loss is mostly fat-mass or muscle-mass. Our recent attendance at Obesity Week® in the United States confirmed to us, that there is a big and increasing interest in this particular area, and by not including such measurements, we could miss crucial data. We also experienced a focus on developing new modalities that can also be made in oral solutions to allow for mass-market accessibility to stimulate the burgeoning demand. All in all it all fits to our vision at PILA PHARMA and we will continue to work hard on further progressing our exciting lead molecule, a first-in-class TRPV1-receptor antagonist, XEN-D0501, into longer human trials for treatment of metabolic diseases such as diabetes & obesity.

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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 in people living with obesity and type 2 diabetes. 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 cardiovascular biomarker for heart failure, was highly statistically significantly reduced. During 2023 the Company could report 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, a scientific advice regarding the study design of the next clinical phase 2a trial, PP-CT03, is being prepared and will be followed by a clinial trial submission in the UK. The objective of the study is to identify the maximal tolerable dose of XEN-D0501 in people living with obesity and type 2 diabetes and to evaluate the safety profile following 3 months chronic treatment. In addition to the safety assessment, PP-CT03 will also include sufficient participants that should allow for efficacy readouts on reduction of body weight.

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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 an even larger pandemic with estimates of more than 1 billion people suffering from it in 2025. It is most often preceding the development of type 2 diabetes and is 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". There are no current treatments available to patients. PILA PHARMA has made a development plan for this project.

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 with Professor Dick Wågsäter from Uppsala University for investigating the effect of XEN-D0501 on Abdominal Aorta Aneurism growth in mice. In November 2024, PILA PHARMA decided to co-sponsor the mouse studies to ease the progression of the preclinical studies.