PILA PHARMA AB

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Malmö, 13 November 2024

PILA PHARMA ANNOUNCES PROGRESSION AND CO-SPONSORSHIP OF PRECLINICAL RESEARCH COLLABORATION IN CARDIOVASCULAR DISEASE

PILA PHARMA AB (publ) ("PILA PHARMA" or the "Company") today announces the co-sponsorship of the research collaboration with the Research Group of Professor Dick Wågsäter, Uppsala University, Sweden (the "Research Group") to complete initial investigations on the effect of PILA PHARMA's lead molecule, XEN-D0501, on Abdominal Aorta Aneurism growth in mice.

The hypothesis is that XEN-D0501 may reduce the chronic inflammation that leads to cardiovascular disease including aorta dilatation. Thus, XEN-D0501 could potentially prevent the lethal end-stage development of Abdominal Aorta Aneurism (AAA).

This co-sponsorship amounts to approximately SEK 150.000 and will contribute to a further study in mice that the Research Group will conduct.

PILA PHARMA will now take on the active co-sponsor role to allow for progression of this important work. As previously disclosed, the results of the studies will be split in the sense that the Research Group gets the publication right (after patenting) and Prof. Dick Wågsäter has agreed to transfer to PILA PHARMA the patent rights against that PILA PHARMA sponsors any resulting patents. .

The aim of the collaboration is to establish a pre-clinical proof-of-concept of an effect of XEN-D0501 on preventing progression of AAA in mice.

"*Since our collaboration with Professor Wågsäter started last year, some technical difficulties with the mouse model arose that thus first had to be solved. Luckily, this is now sorted and with this small but significant financial support from PILA PHARMA, I look forward to complete our initial investigations on XEN-D0501's potential to reduce aorta aneurism growth in mice. If the results of this mouse study are positive it could open up to assessing the effect of XEN-D0501 in humans with AAA", says CSO Dorte X. Gram.*

CEO Gustav H. Gram further comments:
It's great to share that we will now activily co-sponsor the AAA pre-clinical project to further support the important work of Professor Dick Wågsäter, University of Uppsala. The disease AAA annually kills about 1% of all men above the age of 65 years and is currently without adequate treatment options. Hence there is a real need for new treatments. Cardiovascular diseases are major causes of death globally, with strong traces to the global obesity pandemic. Thus, by investigating how XEN-D0501 can affect AAA development in mice, we want to understand the cardiometabolic properties of our molecule better. Having a strong positive cardiovascular profile, can be of real benefit when determining the potential value of our molecule. At a cost of SEK 150.000, we in the team view this as a very minor investment with possibility of adding strong value if we can showcase positive results in addition to the expansive nature that results in a new indication would provide.

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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 13 November 2024 at 08:00 CET.

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 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, the next clinical phase 2a trial, PP-CT03, is being prepared. The objective is identifying the maximal tolerable dose of XEN-D0501 in obese people with type 2 diabetes and evaluate the safety profile following 3 months chronic treatment. In addition to the safety assessment, PP-CT03 will also include sufficient participants to allow for efficacy readouts on reduction of body weight.

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 (AAA)
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.