

PILA PHARMA AB Norra Vallgatan 72 211 22 Malmö Sweden

pilapharma.com

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PILA PHARMA RECEIVES AWARD OF INNOVATION GRANT

Pila Pharma AB (publ) (FN STO: PILA) hereby informs that it has been awarded an innovation grant corresponding to a value of SEK 100.000 to sponsor a further developed IP strategy.

The innovation grant is sponsored by the Swedish Innovation Agency, <u>Vinnova</u>, and has been handled via the local <u>Incubator</u> at <u>Medeon Science Park</u> in Malmö, Sweden wherefrom Pila Pharma AB started it's journey.

Engaged IP partner to develop Pila Pharma AB's updated IP strategy is the Scandinavian IP boutique firm <u>HØIBERG</u> that has been working with Pila Pharma AB's founder Dorte X. Gram since 2010. Their first assignment was to help getting the first use-patents issued on using TRPV1 antagonists as treatment of obesity and obesity related diseases and disorders. The issued use-patents to treat obesity and diabetes with antagonists of TRPV1 were the basis for founding Pila Pharma AB in 2014 and still valid. In 2016, Pila Pharma in-licensed a TRPV1 antagonist asset including the clinical development candidate, XEN-D0501. Given that the original chemistry patents have expired, it is essential for Pila Pharma AB to file new patents to protect Pila Pharma AB's future business. Any new patents filed will be publicly available 18 months after filing.

Jens Viktor Nørgaard, European Patent Attorney, Partner at HØIBERG and member of Pila Pharma AB's Scientific Advisory Board, comments: "The specific work to be done now during the next maximum 6 months is divided into three segments: 1) Overview of Pila Pharma's own current IP, 2) Competitor- and freedom-to-operate analyses and 3) Development of updated IP strategy to support the business strategy. We've done this kind of work many times and we have a deep understanding of Pila's status and potential so we look forward to contribute to this important key strategic document".

Chairman & Chief Scientific Officer in Pila Pharma AB, Dorte X. Gram complements: "We're very happy to receive this support from Vinnova via Medeon and I'm looking forward to having some extra funds to double check and further develop our IP strategy in Pila Pharma AB. We will be dependent on smart IP for our future commercialization. In late 2023 we decided to move from late to earlier patenting strategy, and we're thus already in the process of mapping what we can and need to target to IP protect. The timing is spot-on and with the new development of the obesity market as well as our recently shared positive results on a biomarker for heart failure, ANP, we obviously need to update our strategy to cover these two important potential additional markets as well. The new updated IP strategy will hopefully be serving as a future red thread showing a clear and meaningful path forward in our continued development of XEN-D0501".



For more information:

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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: <u>ca@aqurat.se</u> - 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, such as the painful rare disease erythromelalgia. 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 has focus on 3 projects within Diabetes/Obesity (ongoing, next step 3 mo phase 2a trial to assess maximal tolerable dose), Erythromelalgia (on hold pending funding, next step phase 2a PoC on pain during flare ups) and Abdominal Aorta Aneurism (ongoing, preclinical research collaboration).

About XEN-D0501 and TRPV1 antagonists

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was inlicensed 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 obesity as well. 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 PPCT02), 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 BID for 28 days) - with statistical significance versus placebo - enhance the endogenous insulin response to oral glucose. Further, 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. Recently, finances to sponsor a phase 2a dose-escalation study was secured and the study is being prepared with the objective of identifying the maximal tolerable dose of XEN-D0501 in overweight or obese people with type 2 diabetes as well as to identify (trends for) a reduction of HbA_{1c}, body weight and ANP, a relevant marker of CVD.

About Diabetes and Obesity

Diabetes is a world-wide pandemic with a staggering prevalence of 537 million people with diabetes 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. Despite recent therapeutic advances, large and growing unmet needs exist both from an efficacy, safety, affordability, and accessibility exists for treatment of people with type 2 diabetes. 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 all the co-morbidities resulting in "whole body dysfunction" and subsequent development of several diseased. The accumulated effect is a year-long reduction in of quality of life for obese persons 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 with obesity. Even long-term public health costs are expected to be reduced if the clinical negative effects of the obesity pandemic can be limited. This has sparked a general interest in future potential oral treatments that can meet the accessibility/ affordability criteria and several deals have recently been done in the obesity segment.



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. Currently the project is on hold awaiting finances to sponsor 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, both expensive and with 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.