



PILA PHARMA AB

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Malmö, 20 March 2024

PILA PHARMA PUBLISHES THE ANNUAL REPORT 2023

PILA PHARMA AB (publ) (FN STO: PILA) announces that the annual report (in Swedish) is now available on the Company's homepage, <https://pilapharma.com/investors/finansiell-information/>, and as an attachment to this press release.

” The year 2023 was when the global interest in treatments of obesity became a megatrend! This is interesting for us, since I expect that XEN-D0501 will also show effect on body weight reduction and would then, if proven, open for additional partner opportunities. During 2023, we ourselves shared 2 important results that both supports how unique a molecule XEN-D0501 is. First, we showed very impressive results of the 13-week preclinical safety studies in 2 animal species, where no side-effects were observed even at very high circulating levels of XEN-D0501. Secondly, we shared new results from our latest clinical study in overweight people with type 2 diabetes (PP-CT02) that ANP, a biomarker for heart failure, was highly significantly reduced after just 4 weeks treatment with bidaily doses of 4 mg XEN-D0501. These ANP results could mean that XEN-D0501 may reduce the risk of heart failure in overweight people. Heart failure is one of the causes of premature death in people with diabetes so, if prevented, people could live longer! In the end of 2023, we raised more capital and we're now actively working on getting all documents ready for the regulatory approval of the next phase 2a trial in overweight persons with type 2 diabetes. says Dorte X. Gram, founder and CEO of Pila Pharma.

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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.
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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 diseases. 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 'ballooning' 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.