PILA PHARMA AB

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Pila Pharma AB publishes annual report for 2022

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

CEO comments:
” The year 2022 was a year marked by two major activities in Pila Pharma.
First, we completed the initial two steps of our three-step plan presented in our 2021 IPO and successfully manufactured more API of XEN-D0501 to then complete 13-week preclinical safety studies. Secondly, we applied for and received orphan drug designation in the USA for XEN-D0501 as a treatment for the rare disease erythromelalgia, thereby establishing the foundation for a second development project in the company.
We are now facing a very exciting period where we want to take XEN-D0501 forward to "*proof of concept*" in both erythromelalgia and diabetes. Both projects are well prepared and, with a bit of luck and obtaining sufficient funding, can in both cases lead to a partnership with a major pharma company", 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 novel treatments of e.g. type 2 diabetes or of the painful rare disease erythromelalgia. The company owns both use patents for treating diabetes and obesity with TRPV1 antagonists, and the intellectual property rights for the mid stage clinical development candidate XEN-D0501 as well as back-up candidates. The FDA in USA in July 2022 granted Orphan Drug Designation for XEN-D0501 as treatment of erythromelalgia. The company was listed at Nasdaq First North GM in Stockholm, Sweden in July 2021.

About XEN-D0501 and TRPV1 antagonists
XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed in 2016 and, previously, developed by Bayer Healthcare, Germany and Xention/Ario Pharma, UK. The TRPV1 target (also called the “chili-receptor”) and TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes 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 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 BID for 28 days) – with statistical significance versus placebo – enhance the endogenous insulin response to oral glucose. Final results from recently completed preclinical 13-week safety studies show that XEN-D0501 is well tolerated in both “*rodents*” and “*non-rodents*” and the molecule can thus advance to clinical studies of up to 3 months duration.

About Diabetes
Diabetes is a world-wide pandemic with a staggering prevalence of 537 million diabetics 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. The disease can lead to cardiovascular disease resulting in reduction of quality of life for the patient, increased risk of death and high health care expenses. Despite recent therapeutic advances, large and growing unmet needs exist both from an efficacy, safety, accessibility, and affordability perspective.

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.