PILA PHARMA AB

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**PILA PHARMA announces positive phase 2a results in people with type 2 diabetes and strengthening of the organization**

PILA PHARMA AB, a Swedish biopharma company, is pleased to announce that its phase 2a trial, PP-CT02, designed to investigate the efficacy and safety following 28 days dosing of XEN-D0501 4 milligrams twice daily as compared to placebo in patients with type 2 diabetes, has been successfully completed.

No serious adverse events were observed in PP-CT02, and only few and mild to moderate (expected) adverse events were recorded.
Further, the patients receiving XEN-D0501 with statistical significance demonstrated an enhanced insulin response to an oral glucose tolerance test conducted on day 28.

“I’m very pleased to see, that also after a prolonged dosing period, XEN-D0501 proved to be safe in people with type 2 diabetes” says Dorte X. Gram, Chairman of the Board. “Further, the profound effect on insulin is remarkable in at least two ways. Firstly, it is the first time that a positive effect has been recorded for XEN-D0501 in type 2 diabetes patients, demonstrating it to be a highly promising safe and effective drug candidate. Secondly, it proves that our working hypothesis is true - that TRPV1 antagonists, e.g. XEN-D0501, exerts part of its anti-diabetic action via stimulation of endogenous insulin release. As an inventor of this principle, these results of course, makes me truly proud”.

With these clinical trial outcomes, PILA PHARMA remains highly confident in continuing the development of XEN-D0501 as a potential novel anti-diabetic agent and strengthens the Scientific Advisory Board with Dr. Mark Evans, UK, a well reputed clinical researcher in diabetes with a special interest in the effects of insulin in diabetes.

Further, the strong pharma-capacity, Lars Bukhave Rasmussen, will join the management team in becoming the first Chief Financial Officer in PILA PHARMA.

Lars B. Rasmussen brings significant business experience within the full pharma value chain to PILA PHARMA obtained primarily through his previous positions at LEO Pharma A/S, a global mid-size biopharma company headquartered in Denmark.

“I am extremely proud and excited to join PILA PHARMA at this crucial point in time for XEN-D0501. Having prior hands-on research experience with the “un-drugable” TRPV1 receptor, I am very convinced by the clinical XEN-D0501 data I have seen. PILA Pharma could very well have found the key to truly unlock clinically effective and safe TRPV1 targeted treatments. In essence, the company now has the potential to effectively address the high and growing unmet needs of type 2 diabetes patients

through a novel mode of action, as well as address other diseases with high unmet needs where TRPV1 may also play a role“, says Lars B. Rasmussen.

Chairman of the Board, Dorte X. Gram, completes: “Fifteen years ago, Lars did his DVM master-thesis on TRPV1 in diabetes with me as supervisor. Since then, I have followed his impressive career with great interest. Needless to say, I am more than pleased with having Lars back and he will be instrumental in maximizing the value of PILA PHARMAs core assets both from a scientific, market and financial perspective going forward”.

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**About PILA PHARMA**
PILA PHARMA is a Swedish pharmaceutical company in the diabetes segment based in Malmö. The aim of the company is to develop a novel and superior tablet based treatment for type 2 diabetes. 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.

**About XEN-D0501 and TRPV1 antagonists**
XEN-D0501 is a highly selective and very potent small molecule TRPV1 antagonist, previously in development by Bayer Healthcare and Xention/ Ario Pharma. The TRPV1 target (also called the “chili-receptor”) has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes as well. XEN-D0501 was acquired by PILA PHARMA in March 2016, due to its very good safety and tolerability as compared to other clinical TRPV1-antagonist development candidates. TRPV1 antagonists as a drug-class has previously been associated with severe adverse events as fever (hyperthermia). XEN-D0501 has in healthy volunteers been shown to induce a modest temperature increase following the first dose, that fades out during the first 2 weeks of dosing. The maximal tolerable dose in non-diabetic individuals has previously been determined to be 4 milligrams twice daily, a dose level with good safety but no effect in non-diabetic patients with either overactive bladder disease or chronic cough. In November 2018, PILA PHARMA reported the completion of its first clinical trial, PP-CT01, demonstrating good safety of XEN-D0501 at single doses up to 8 milligrams when administered to people with type 2 diabetes.

**About diabetes**
Diabetes is a world-wide pandemic with a staggering prevalence of 463 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, adherence, accessibility and affordability perspective.