PILA PHARMA AB

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PILA PHARMA announces good safety of XEN-D0501 following single doses in patients with type 2 diabetes

PILA PHARMA AB, a pharmaceutical company based in Malmö, Sweden, is pleased to announce that on November 1st, 2018, the dosing of patients in its first trial PP-CT01, studying the safety and tolerability of XEN-D0501 in patients with type 2 diabetes, was completed.

XEN-D0501 is a highly selective and very potent 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 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 was previously been determined to be 4 mg BID.

In PP-CT01, the doses to be studied were 1, 2 and 4 mg but during the conduct of trial, regulatory approval was obtained to increase to a higher maximal level of 8 mg due to better than expected safety of the lower doses.

No serious adverse events were observed in PP-CT01, and only few and mild (expected) adverse events were recorded.
Importantly, no hypo-glycemic events nor episodes of hyperthermia were observed.

"I'm very pleased to see, that we did not see any hyperthermia or other severe problems in the diabetic patients" says CEO Dorte X. Gram.
The finding that no patients experienced hyperthermia and that XEN-D0501 appear to be safe following a single dose to type 2 diabetic patients is really good news".

The recruitment of patients for PP-CT01 took a lot longer than expected, so in order to not stand still, PILA PHARMA earlier this year applied for the approval to conduct the next pilot phase 2 trial, PP-CT02.

In August, PILA PHARMA received the great news of regulatory approval of PP-CT02 and now works intensively to initiate this pilot phase 2 trial to investigate the efficacy and safety following 28 days dosing of XEN-D0501 BID as compared to placebo in patients with type 2 diabetes.

“It is a tremendous leap forward and could potentially be the steps towards proof-of-concept study in man, that I have been aiming at since the establishment of PILA PHARMA”, says Dorte X. Gram, founder and CEO of PILA PHARMA.

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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 diabetes. The company owns use patents for treating diabetes and obesity with TRPV1 antagonists and a clinical ready and safe TRPV1 development candidate XEN-D0501.

About diabetes
Diabetes is a world-wide pandemic with a staggering prevalence of 422 m diabetics corresponding to approximately 8-10% of the population. 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. Approximately 90 % of all diabetics suffer from type 2 diabetes, whilst approximately 10% suffers from type 1 diabetes.