



**PILA PHARMA AB**

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### **PILA PHARMA receives regulatory approval of its first clinical trial application and appoints new Chairman of the Board**

PILA PHARMA AB, a Swedish pharmaceutical company based in Malmö, Sweden, is pleased to announce that it has received regulatory approval of its first clinical trial application thus permitting the company to move its clinical development candidate, XEN-DO501, into a safety trial in type 2 diabetic patients.

“I am very excited about finally being at the point where we can progress a TRPV1 antagonist into diabetic patients!”, says Dorte X. Gram, founder and CEO of PILA PHARMA and continues: “It is nearly 17 years since I formulated the hypothesis that inhibitors of the TRPV1 (a.k.a. the “chili-receptor”) could be novel pharmacologic tools for the treatment of obesity and obesity-related diseases and disorders. Today, PILA PHARMA has use-patents that give us the exclusive right to treat obesity and diabetes with TRPV1 receptor antagonists and we are now very close to test the first development candidate, XEN-DO501, in diabetic patients.”

The first step will be to assess the safety of the molecule following a single-dose in diabetic patients. If successful, it can progress to multiple-dose efficacy trials to test the effect in diabetics later this year.

In 2003, Dorte X. Gram defended the hypothesis in her PhD thesis “Capsaicin-Sensitive Nerves in Experimental Diabetes” to a dream-team of opponents: professors Henning Beck-Nielsen, Jens Juul Holst and Mads Krogsgaard Thomsen.

During the last year PILA PHARMA has been working closely together with professor Henning Beck-Nielsen’s clinical team at Odense University Hospital in Denmark, to prepare for the clinical trial.

“Henning was the first to suggest that we should test the concept in man, but no clinical-ready TRPV1 antagonists were available at that time. Henning is one of the academic “heavy-weights” in diabetes, so I am extremely grateful that Henning still supported the project, when I called to ask for his help more than 10 years later, when antagonists were potentially available”, says Dorte X. Gram.

With Henning Beck-Nielsen back in the project, the plan for moving rapidly towards clinical proof of concept with a clinical ready substance was created and a pilot phase 2 protocol was suggested by Henning Beck-Nielsen.

“We still follow that plan, but due to regulatory requirements, a single-dose safety study was inserted in the plan and is now being initiated. As soon as possible, thereafter, we will conduct the pilot phase 2 originally designed by Henning”, says Dorte X. Gram.



Given PILA PHARMA's rapid development and predicted future increase in capital need, PILA PHARMA has appointed attorney Erik Nerpin as new Chairman of the Board. He has 25 years of experience in corporate finance and M&A, including high profile transactions such as Pfizer's acquisition of Pharmacia, where he advised Pfizer. For many years, he has been advisor to the Lundin Group of companies, including Lundin Petroleum and Lundin Mining. He has also long experience of board work in pharmaceutical companies, being currently Chairman of Kancera and Diamyd Medical, both listed on Nasdaq First North in Stockholm, Sweden.

"Over the years, I have advised numerous early stage pharmaceutical companies. Many of them have, as expected in this business, failed but some of them have actually made it, such as Alligator Bioscience, CellaVision and Hansa Medical, today all successful companies listed on Nasdaq in Stockholm, Sweden. It is an honor for me to enter the board as new Chairman and I am convinced that PILA PHARMA will grow into something really big in the near future", comments Erik Nerpin.

"I am extremely impressed by Dorte X. Gram as founder and CEO", comments Erik Nerpin further. Being a football fan, he adds "I believe everybody who knows football will understand when I call Dorte X. Gram *"The Special One"*".

Dorte X. Gram adds: "Erik is super sharp and I believe that he will add real value to me, our Board and the company. I am very, very proud that he has accepted to work with me as Chairman and closest colleague in 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.

In 2014, the global diabetes market was assessed to be 37,5 bn € and is projected to rise to >100 bn € in 2018. Approximately half of this market attributes to oral anti-diabetic agents (tablets) whereas the other half of the market attributes to injectable treatments, like insulin and GLP-1.