



#### **PILA PHARMA AB**

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### **PILA PHARMA Acquires Ario Pharma's TRPV1 Assets**

**The clinical assessment of a novel diabetes treatment seems within reach for PILA PHARMA with the acquisition of XEN-D0501, a clinical ready and safe TRPV1 antagonist development candidate**

PILA PHARMA AB, the Malmö based "micro-pharma" aiming at developing innovative new approaches to treat diabetes, announced today it has acquired the TRPV1 antagonist asset previously owned by Ario Pharma Ltd (Cambridge, U.K.).

The acquired asset include a series of small molecule TRPV1 antagonists including the clinical ready and safe development candidate XEN-D0501, patents, know-how and data.

The TRPV1 target (also called the "chili-receptor") has been shown to have applications across pain and inflammatory diseases and is speculated to have a role in diabetes as well.

After oral delivery, "target-interaction" (blockade of the "chili-receptor") has been demonstrated in man and *in vivo* efficacy in regulating blood glucose has been demonstrated in diabetic mice, together suggesting that this compound could have the potential to be effective in human diabetes after oral delivery.

PILA PHARMA is planning to undertake a fast-track clinical development program, assessing the efficacy and safety of XEN-D0501 in treatment of type 2 diabetes.

There is a significant unmet need to provide an orally available therapeutic for diabetes, which not only offers the regulation of blood glucose but that also addresses the co-morbidities of diabetes – elevated blood lipids and increased bodyweight that are associated with an increased risk of cardiovascular disease. In preclinical models of diabetes, TRPV1 antagonists have been shown to correct both insulin secretion as well as insulin sensitivity and be effective regulators of blood glucose and blood lipids.

The target product profile of PILA PHARMA's anti-diabetic TRPV1 antagonists is to effectively reduce blood glucose to near-normal levels via a dual regulation of insulin secretion and insulin sensitivity as well as regulating blood lipids and bodyweight thereby eventually reducing the overall risk of cardio-vascular disease".

Dorte X. Gram, CEO of PILA PHARMA, commented: "I am very pleased to have reached an agreement with Ario Pharma regarding this valuable asset. The acquisition of especially XEN-D0501 permits us to move straight to clinical safety and efficacy trials in type 2 diabetic patients. I'm thrilled that we are so close to know if the hypothesis of regulating diabetes with blockers of the "chili-receptor", TRPV1, that I put forward almost 15 years ago will be valid.



John Ford, CEO of Ario Pharma commented “XEN-D0501 is a highly potent and selective, orally available inhibitor of TRPV1. XEN-D0501 has demonstrated good oral bioavailability and appropriate pharmacodynamics and pharmacokinetics in humans, and has been well tolerated in both healthy volunteers and patients<sup>1</sup>.

1. Round P, Priestley A, Robinson J. An investigation of the safety and pharmacokinetics of the novel TRPV1 antagonist XEN-D0501 in healthy subjects. Br J Clin Pharmacol. 2011;72(6):921-31.

### **Notes to Editors:**

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### **About PILA PHARMA**

PILA PHARMA is a “micro-pharma” in the diabetes segment established in Malmö, Sweden. 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 will combine these with a clinical ready TRPV1 asset and initiate a fast-track clinical development program to demonstrate significant efficacy and safety in type 2 diabetics followed by exit. PILA PHARMA currently seeks investments for its clinical program. For further information, please visit: [pilapharma.com](http://pilapharma.com)

### **About Ario Pharma**

Ario Pharma Ltd focusses on the development of drugs that modulate TRP channels initially focusing on the treatment of respiratory indications. Ario has recently evaluated the anti-tussive properties of XEN-D0501, a potential best-in-class TRPV1 inhibitor, in two Phase 2 clinical trials. The company is managed by a highly experienced development team and supported by world-renowned KOLs and will now focus on the development of their TRPA1 asset for multiple indications. For more information see <http://www.ariopharma.com>



### **About diabetes**

Diabetes is a world wide pandemic with a staggering prevalence of 415 m diabetics corresponding to approximately 8-10% of the population and it expected to rise to 642 in 2040, according to the International Diabetes Federation. 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, according to Reuters.

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.