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## **Nobel prize for the discovery of PILA PHARMA's leading principle**

On Monday, October 4, the Nobel Assembly at Karolinska Institutet announced that the 2021 Nobel prize in Physiology or Medicine goes to the scientists David Julius and Ardem Patapoutian, both active at universities in the USA.

The two scientists are jointly rewarded "for their discoveries of receptors for temperature and touch". One of the receptors that they have discovered is the TRPV1 receptor, which is thanks to David Julius research known to react to pain and painful heat and cause the heat sensation.

PILA PHARMA a Swedish Biotech company, listed on Nasdaq First North GM Sweden, is using the TRPV1 receptor as the leading principle for a novel treatment of diabetes. This is done by developing a TRPV1 antagonist, (XEN-D0501), and in that way get the body to regulate insulin secretion and get a better glucose tolerance.

Dr. Julius used capsaicin, the hot ingredient in chili, to identify the responsive DNA fragment or gene in sensory nerves. This gene was later cloned and first named the capsaicin receptor and later VR1 and then TRPV1. Popularly, we in PILA PHARMA call it the 'chili-receptor'.

By means of creating a TRPV1 knock out mouse (a normal mouse, but without the TRPV1), the research group of Dr. Julius showed that TRPV1 plays a significant role in the sensation of pain.

"It's fantastic news to learn that, yesterday, the Nobel prize went to to 'our' TRPV1 receptor. I'm a true fan of Dr. Julius, and I used his TRPV1 knock-out mice to first demonstrate TRPV1's specific role in diabetes via regulation of insulin secretion and glucose tolerance! Results that we recently replicated in subjects with type 2 diabetes! With the Nobel prize committees honourable validation of TRPV1 as an important molecular target we look even more forward to further progress our TRPV1 antagonist to phase 2b tests in diabetes", says founder and CEO, Dorte X. Gram.

Link to our patent application based on the TRPV1 knock out data: <https://worldwide.espacenet.com/patent/search/family/035134546/publication/WO2006007851A2?q=capsaicin%20gram>

Link to the resulting publication: <https://pubmed.ncbi.nlm.nih.gov/31344877/>

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### **About PILA PHARMA**

PILA PHARMA is a Swedish biotech 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). The maximum 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. The most recent study results were announced in September 2020. The study (PP-CT02) demonstrated that multiple doses of XEN-D0501 (4 mg twice daily for 28 days) were likewise safe and well-tolerated by people with type 2 diabetes and also – with statistical significance versus placebo – that XEN-D0501 enhances the endogenous insulin response to oral glucose, thus demonstrating proof of principle.

### **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.