PRESS RELEASE

November 7, 2016

Saniona plans to initiate Phase 2a study in Prader-Willi in 2017

Saniona, a leading biotech company in the field of ion channels, today announces that it has filed a clinical trial application in Czech Republic and Hungary for the performance of a Phase 2a study for Tesomet in patients with Prader-Willi Syndrome (PWS) during the first half of 2017. This new study will be executed independent of the current study in patients with type 2 diabetes and is expected to take approximately a year. The PWS study may potentially pave the way for initiating a Phase 3 study. PWS is an orphan disease and Saniona plans to apply for orphan disease designation to both the EMA and FDA in the near future.

"The investment in a Prader-Willi study is a new and decisive step for Saniona. We see great potential for Tesomet in this indication since it may solve serious problems for a group of patients that currently lack possibilities for treatment. The study can be carried out within the framework of present financing," says Jørgen Drejer, CEO at Saniona.

Prader-Willi Syndrome is a rare genetic disorder with among other things an extreme and insatiable appetite as one of its hallmarks. Patients affected by this condition start gaining weight in childhood and especially during puberty which leads to greatly accelerated development of obesity, type-2 diabetes, CV disease and ultimately premature death. There is no cure today.

Tesomet is a combination of tesofensine and metoprolol, which currently is being tested in a Phase 2a study for treatment of type 2 diabetes. The recruitment was finalised in August and top line data is expected to be available early 2017.

Administration of tesofensine, one of the active ingredients in Tesomet, was investigated in a Phase 2 study where it demonstrated a pronounced and highly statistically significant weight loss in obese patients. It is believed that this large magnitude of weight loss is driven by the triple mode of action including normalization of the appetite, reduction in the craving for food and an increase in fat utilization. Due to the mode of action of Tesomet, Saniona believes that it potentially may be used for treatment of a number of metabolic syndromes and eating disorders including PWS, binge eating, type 2 diabetes and fatty liver diseases including NASH.

For more information, please contact

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This information is information that Saniona (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on November 7, 2016.

About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The company has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The research is focused on ion channels, which makes up a unique protein class that enables and controls the passage of charged ions across cell membranes. Saniona has ongoing collaboration agreements with Boehringer Ingelheim GmbH, Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq First North Premier and has about 4,400 shareholders. Pareto Securities is Certified Advisor for Saniona. The company's share is traded under the ticker SANION. Read more at www.saniona.com.

About Prader-Willi Syndrome (PWS)

Prader-Willi Syndrome (PWS) is recognized as the most common genetic cause of life-threatening obesity. The disease results from a deletion or loss of function of a cluster of genes on chromosome 15, which leads to dysfunctional signaling in the brain's appetite/satiety center (hypothalamus). Patients suffer from a constant, extreme, ravenous insatiable appetite which persists no matter how much the patients eat. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Compulsive eating and obsession with food usually begin before age 6. The urge to eat is physiological, overwhelming and difficult to control. Caregivers need to strictly limit the patients' access to food, usually by installing locks on refrigerators and on all closets and cabinets where food is stored. Currently, there is no cure for this disease. Patients with PWS have a shortened life expectancy. Common causes of mortality in PWS include respiratory disease, cardiac disease, infection, choking, gastric rupture, and pulmonary embolism. However, if obesity is avoided and complications are well managed, life expectancy for individuals with PWS is normal or near normal and most individuals can lead healthy lives[1]. PWS occurs in approximately one out of every 15,000 births[2]. Males and females are affected equally. The condition is named after Andrea Prader, Heinrich Willi, and Alexis Labhart who described it in detail in 1956. The common characteristics defined in the initial report included small hands and feet, abnormal growth and body composition (small stature, very low lean body mass, and early-onset childhood obesity), hypotonia (weak muscles) at birth, insatiable hunger, extreme obesity, and intellectual disability.

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[1] Butler MG, Lee PDK, Whitman, BY. Management of Prader-Willi Syndrome. 3rd ed. New York, NY: Springer Verlag Inc.; 2006. 0387253971

[2] https://www.fpwr.org/about-prader-willi-syndrome/ Foundation for Prader-Willi Research retrieved October 2016