PRESS RELEASE

April 26, 2018

Saniona progress to second part of Phase 2a study for Tesomet in Prader-Willi Syndrome based on positive results in adult patients

Saniona, a leading biotech company in the field of ion channels, today announced that it has obtained approval to initiate the second part of its Phase 2a trial for Tesomet in adolescents with Prader-Willi syndrome (PWS). Tesomet has the potential to significantly reduce weight and hyperphagia, characterized by an extreme and insatiable appetite in PWS patients – a major, debilitating problem for these patients and their caregivers.

"We are excited to continue advancing Tesomet's clinical development for Prader-Willi syndrome following encouraging results from our exploratory Phase 2a study in adult patients and positive discussions with key opinion leaders in the field. By pursuing an orphan indication such as Prader-Willi syndrome, we may develop and commercialize our own product in the U.S. and Europe within a relative short time and at a limited investment in an indication where the commercial opportunities appear to be very large," commented Jørgen Drejer, CEO of Saniona. "We believe that low dose Tesomet could prove to be a compelling treatment for adolescents with this currently untreatable disease. Patients suffering from Prader Willi syndrome currently face debilitating hyperphagia, which has severe consequences that also affect their families and carry a very high cost to payors and the society."

This exploratory randomized, double-blind, placebo-controlled Phase 2a study in patients with PWS was initiated in April 2016 and divided into two parts. In 2017, Saniona completed the first part of the study which included nine adult patients. The results from this study revealed that Tesomet may provide clinically meaningful weight loss and a significant reduction in hyperphagia. The study also revealed that patients with PWS should be given lower doses of Tesomet compared to other patient groups**.** The second part of this study may potentially include up to 10 adolescents with PWS. Based on the results from the first part of study, patients will receive either Tesomet (tesofensine 0.125 mg + metoprolol 25 mg daily) or placebo at a 3:2 randomization with a primary endpoint examining the change in bodyweight over 12 weeks of treatment compared to placebo. Secondary objectives are to examine eating behaviour and food craving (hyperphagia), body composition, lipids and other metabolic parameters. The study also includes comprehensive assessments of tolerability, safety and pharmacokinetic parameters in this patient population.

Dr. Roman Dvorak, Saniona Chief Medical Officer, added, "The data supporting Tesomet for Prader Willi patients has been impressive. During the first 3-month study, patients not only experienced a significant weight loss but also a remarkable reduction in cravings, measured by the hyperphagia questionnaire. We are now continuing the study at a lower dose in adolescents with PWS."

Additional information about the trial can be found at ClinicalTrials.gov.

For more information, please contact

Thomas Feldthus, EVP and CFO, Saniona, Mobile: +45 2210 9957, E-mail: tf@saniona.com

This information is information that Saniona (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and Sweden's Securities Market Act. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on April 26, 2018.

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, BenevolentAI, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq Stockholm Small Cap and has about 5,300 shareholders. 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 death 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.

---

[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