PRESS RELEASE

October 4, 2018

Saniona Completes Planned Patient Recruitment for Second Part of Phase 2a Study for Tesomet in Prader-Willi Syndrome

Saniona, a leading biotech company within ion-channel research, today announced that it has completed the planned recruitment of adolescents for the second part of its Phase 2a study of Tesomet in patients with Prader Willi Syndrome (PWS). Saniona has decided to keep recruitment open for a few more weeks as the participating centres have identified a few more patients who are interested in participating in this trial. The trial is expected to be completed in early 2019 with topline results available in Q1 2019.

“We are very excited to have completed the planned recruitment of adolescents into this second part of our Tesomet Phase 2 PWS study. Based on the positive effects seen in the first part of the study in adult patients with PWS and encouraging discussions and feedback from key opinion leaders we look forward to evaluate a lower dose of Tesomet in the adolescent patient population,” commented Jørgen Drejer, CEO of Saniona. “We remain confident that Tesomet holds the potential to treat debilitating hyperphagia and significantly reduce weight in this severely underserved population.”

The study is an exploratory randomized, double-blind, placebo-controlled Phase 2a trial. In the study, patients will receive either Tesomet or placebo at a 3:2 randomization. The primary endpoint of the study will examine the change in bodyweight over 12 weeks of treatment with Tesomet compared to placebo. Secondary objectives include eating behaviour and food craving (hyperphagia), body composition, lipids and other metabolic parameters. The study will also comprehensively assess tolerability, safety and pharmacokinetic parameters in this patient population.

The first part of Saniona’s Phase 2a in PWS was initiated in April 2017 and enrolled nine adult patients. The results from the first part of the 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.

Saniona will today present the data from the first part of Saniona’s Phase 2a in PWS at the “2018 Foundation for Prader-Willi Research Symposium” in Las Vegas. The presentation entitles: “The efficacy and Safety of Tesofensine/Metoprolol Co-administration in Adult Patients with Prader-Willi Syndrome: An exploratory Phase 2a study” will be given by Roman Dvorak, Chief Medical Officer of Saniona.

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

For more information, please contact

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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 four programs in clinical development. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona’s research center is based in Copenhagen, Denmark, and the company’s shares are listed at Nasdaq Stockholm Small Cap (OMX: 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. PWS occurs in approximately one out of every 15,000 births. 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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