**PRESS RELEASE**

**January 7, 2019**

# Saniona completes treatment in Phase 2a Prader-Willi syndrome trial and initiates open label extension study

**Saniona (OMX: SANION), a biotech company focused on CNS and eating disorders, today announced that it has completed the 3-month treatment period in adolescent patients in the second part of its Phase 2a study of Tesomet to treat Prader Willi syndrome (PWS). The first part of the study included nine adult patients and was successfully concluded in 2018. The second part of the study included nine adolescent patients, who have now completed the treatment period. The treatment appeared to be well tolerated and Saniona expects to report data from this placebo-controlled Phase 2a trial in the first quarter of 2019. Eight of the nine adolescent patients have agreed to continue in a 24-week extension study, which was recently authorized.**

*"We know from the first part of the study that Tesomet is efficacious in adult patients at a dose of 0.50 mg tesofensine," says Jørgen Drejer, CEO of Saniona. "This important second part of the exploratory study in PWS enables us to evaluate Tesomet at a lower dose in adolescents, who comprise a very significant part of the patient population. The completion of the last treatment visit for all patients is an important milestone and we are looking forward to reporting the top-line data this quarter. Based on the positive effects seen in the first part of the study in adult patients with PWS, 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 second part of the study, adolescent patients received either Tesomet or placebo at a 3:2 randomization. The primary endpoint of the study is to examine the change in bodyweight over 12-weeks of treatment with Tesomet compared to placebo. Secondary objectives include eating behavior and food craving (hyperphagia), body composition, lipids and other metabolic parameters. The study remains blinded until the final data have been collected from the central laboratories. Top-line data is expected to be communicated during the current quarter.

The first part of Saniona's Phase 2a study in PWS included nine adult patients and was successfully concluded in 2018. The results from the first part of the study revealed that Tesomet may provide clinically meaningful weight loss and a significant reduction in hyperphagia in adult patients (0.50 mg tesofensine). In addition, the half-life of Tesomet was observed to be longer than expected in the PWS patient population. As a result, a lower dose was chosen for the second part of the study in the adolescent patients (0.125 mg tesofensine).

*"The blinded Phase 2 data suggests that Tesomet was well tolerated in the adolescent PWS patients. Based on support from the Primary Investigators, we will extend the study for an additional 24-weeks to obtain longer-term treatment data relevant for future regulatory interactions. We are very encouraged that all but one patient have chosen to continue in this extension study," said Jørgen Drejer, CEO of Saniona.*

**For more information, please contact**

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This information is such information as Saniona AB (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 a.m. CET on January 7, 2019.

**About Saniona**

*Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders. The company has four programs in clinical development. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity 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 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[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