PRESS RELEASE

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Saniona reports positive Tesomet Phase 2a clinical results in adolescent patients with Prader-Willi syndrome

- **Tesomet was safe and well tolerated in growing adolescent patients with PWS at both tested doses**
- **Reduction in body weight and improvement of BMI observed at the high dose with hyperphagia score reduced to low single digits**
- **Data provides additional guidance for the pivotal Ph2b/3 studies now in planning**

Saniona (OMX: SANION), a clinical stage biotech company focused on eating disorders and CNS, today announced that adolescent as well as adult patients with Prader-Willi syndrome (PWS) are expected to receive significant benefit on body weight, body mass index (BMI) and hyperphagia from once-daily oral Tesomet treatment. This conclusion is supported by data from the analyses of the open label extension portions of Saniona's Tesomet Phase 2a study in PWS, which was just completed.

"Weight gain, hyperphagia and obsession with food are the greatest burden on both patients with Prader-Willi syndrome and their families. This novel drug appears to help controlling weight and appetite and it decreases preoccupation with food. Therefore, patients are more available to other activities, and life as a whole becomes easier for the patients and their families," said Dóra Török MD, PhD, Paediatric Endocrinologist and Primary Investigator of the Tesomet Phase 2a study in patients with Prader-Willi syndrome.

"This study, which included a limited number of patients, indicates a positive effect of Tesomet in this serious rare genetic disease and the data provide strong de-risking and guidance for the pivotal Ph2b/3 studies that we are now planning in PWS and other rare eating disorders, including hypothalamic obesity. The open label extension of the PWS study data confirms analyses from a previous adult study that the predicted 0.25 mg daily dose would be safe and efficacious in this patient population. Importantly, we have now treated adolescent patients with PWS for 9 months with Tesomet and are encouraged by its safety and efficacy," said Jørgen Drejer, CEO of Saniona

The first part of this exploratory Phase 2a study in PWS had already demonstrated that Tesomet is highly efficacious in adult patients with PWS at a dose of 0.5 mg per day and suggested that patients would also benefit from a lower dose.

The recently completed nine-patient dose finding exploratory extension study in an adolescent population shows that Tesomet appear to be safe and well tolerated at lower doses (0.125 mg/day and 0.25 mg/day) and that it provides dose dependent effects on weight, BMI and hyperphagia consistent to what we observed in adult patients at the higher 0.5 mg/day dose. Saniona's conclusion is that a broad spectrum of patients with PWS are likely to receive significant benefits on body weight, BMI and hyperphagia at a dose of 0.25 mg/day.

"We are confident that Tesomet has the potential to significantly reduce weight, BMI and treat debilitating hyperphagia in severe, rare and highly underserved eating disorders including PWS and hypothalamic obesity. Our confidence is further supported by the previously reported successful Phase 3 trial of tesofensine - the active ingredient in Tesomet - in 372 obese adult subjects."

About the Phase 2a study

This was an exploratory, randomized, double-blind, placebo-controlled Phase 2a trial in 18 patients with PWS, which was divided into two parts; the first was performed in nine adult patients with PWS and the second in nine growing adolescent patients. The primary endpoint was to examine the change in body weight with Tesomet compared to placebo. Secondary objectives included eating behaviour and food craving (hyperphagia), body composition, lipids and other metabolic parameters.

The first part was successfully concluded and first reported in 2018. The results showed that Tesomet 0.5 mg/day for three months provided clinically meaningful weight loss and a significant reduction in hyperphagia in adult patients. The study results also suggested that the optimal dose of Tesomet in patients with PWS may be lower than in other indications such as hypothalamic obesity.

The second part, being reported for the first time today, consisted of a 3-month double blind phase with adolescent patients followed by two 3-month open label extension studies.

Tesomet was safe and well tolerated, and all nine patients completed the placebo-controlled portion of the study. Most patients (8 of 9) opted to continue in the first 3-month open label extension and half (4 of 8) in the second 3-month open label extension. One of the eight patients entering the first extension dropped out after two months for reasons unrelated to the study drug (fear of blood sampling). One patient out of the four patients entering the second extension study dropped out after two months due to a non-drug related infection.

During the placebo-controlled portion, four adolescent patients with PWS received placebo and five received 0.125 mg/day Tesomet (tesofensine 0.125 mg + metoprolol 25 mg daily, referred to as 0.125 mg/day Tesomet). During the first open-label extension eight patients received 0.125 mg/day Tesomet for three months. During the second open label extension, three patients received 0.25 mg/day Tesomet (tesofensine 0.25 mg + metoprolol 25 mg daily, referred to as 0.25 mg/day Tesomet) while one remained on 0.125 mg/day.

Safety and efficacy data were collected monthly for all patients during study.

The small number of patients in exploratory rare disease studies such as these pre-empts formal statistical evaluation. However, signals of efficacy were observed during the open label extension studies.

Tesomet reduces body weight and improves BMI

The three adolescent patients receiving 0.25 mg/day Tesomet had a positive effect on body weight and BMI compared to when they received placebo and/or 0.125 mg/day Tesomet.

The three adolescent patients had an average body weight of 86 kg and achieved an average weight loss of 2.6% over the 3-month period on 0.25 mg/day Tesomet in the second extension study compared to a weight gain of 2.3% during the 3-month period in the first extension study on 0.125 mg/day Tesomet and a weight gain of 2.2% in the 3-month double blind study, where two received placebo and one patient 0.125 mg/day Tesomet.

In addition, these three adolescent patients had an average BMI of 36.1 kg/m2 at baseline and all patients obtained an improvement in BMI during the 3-month period on 0.25 mg/day Tesomet. The patients obtained an average reduction in BMI of 4.0% during the 3-month period on 0.25 mg/day Tesomet compared to an average increase of 0.8% during the 3-month on 0.125 mg/day Tesomet and an average increase of 1.7% during the 3-month double blind study, where two received placebo and one patient 0.125 mg/day Tesomet.

In addition, during the first open label extension study 0.125 mg/day, Tesomet demonstrated a small positive effect on body weight and BMI, when patients taking placebo were shifted to this dose.

Hyperphagia is reduced to very low levels

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The hyperphagia score, based on a questionnaire given to the caregivers, was measured on monthly basis. The scoring goes from 0 to 36, where 0 means that the patient had no hyperphagia and 36 means that the patient had extreme hyperphagia.

The average baseline score in this study was 12, ranging from 2 to 22 among the nine patients.

As previously communicated, Tesomet appeared to induce a complete hyperphagia blunting to a score of 0 in the adult part of the study at a dose of 0.5 mg/day Tesomet. The hyperphagia was also reduced in adolescents, dropping to low single digit scores in the second extension study, when 0.25 mg/day Tesomet was introduced. The average hyperphagia score for the three patients was 2.7 at the end of the period on 0.25 mg/day Tesomet representing a reduction of 69% to baseline (score 8.7 for the three patients) and 33% at the end of the first extension study where the patients received 0.125 mg/day Tesomet (score 4.0 for the 3 patients). In general, the recorded hyperphagia scores were very low during the three months on 0.25 mg/day Tesomet. The average score for the three patients during this period was 3.4 and one patient was reported to have a score of 0 at one visit and another patient a score of 1 at one visit.

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 and eating disorders. The company has five 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 signalling 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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