PRESS RELEASE

November 23, 2020

Saniona Reports Positive Topline Results from Tesomet Phase 2 Open-Label Extension Study in Hypothalamic Obesity

- **Tesomet was well-tolerated in hypothalamic obesity patients throughout the duration of the 48-week trial (24 week double-blind [DB] followed by 24 week open label extension [OLE]), with no clinically meaningful differences in heart rate or blood pressure observed. All patients who entered the OLE study completed it.**
- **Patients receiving Tesomet for the full 48 weeks of the study demonstrated statistically significant and clinically meaningful reductions in body weight and waist circumference from baseline to Week 48, as well as improvements in glycemic control. Improvements observed in the DB period of the study were maintained over the duration of the OLE period.**
- **Patients who received placebo in the DB period of the study and were subsequently switched to Tesomet for the OLE period also achieved reductions in body weight and waist circumference after being switched to Tesomet.**
- **Saniona to host webcast with Dr. Ulla Feldt-Rasmussen on Tuesday, 24 November 2020, at 2:00pm ET / 20.00 CET.**

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced positive top-line results from the Phase 2 open-label extension study of Tesomet in patients with hypothalamic obesity (HO). Patients treated with Tesomet for nearly one year (24 week double-blind [DB] followed by 24 week open label extension [OLE]) demonstrated statistically significant and clinically meaningful reductions in body weight and waist circumference, as well as improvements in glycemic control. No clinically meaningful differences in heart rate or blood pressure were observed over the course of the trial.

“Hypothalamic obesity is a rare disorder characterized by severe and debilitating obesity that is often complicated by depression, impulse control issues, complicated symptoms from necessary replacement of pituitary hormones, and increased risk of cardiometabolic disorders. There are no treatments specifically approved for HO, and standard weight loss approaches such as surgery, medication and lifestyle counseling are mostly ineffective in this rare disease,” said Professor Ulla Feldt-Rasmussen, M.D., DMSc., Department of Medical Endocrinology and Metabolism, Rigshospitalet Copenhagen University Hospital and Principal Investigator on the Phase 2 study. “The data from this nearly year-long study demonstrate the potential of Tesomet to help manage multiple key symptoms of HO – not only weight gain but also the metabolic dysfunction that can lead to serious diabetic complications. I look forward to the evaluation of Tesomet in further clinical studies.”

“The results of the open-label extension study reinforce the promising profile of Tesomet observed in the placebo-controlled portion of the Phase 2 study in patients with hypothalamic obesity,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development of Saniona. “If approved, Tesomet could be the first treatment

designed to address this rare disease. We look forward to continuing our discussions with the FDA and clarifying the path to bring Tesomet to the HO patients who desperately need treatment options."

Highlights from top-line open-label extension study data include:

- **Safety:** The primary endpoint of the study was the overall safety and tolerability of Tesomet in patients with HO. Tesomet was shown to be well-tolerated. Side effects observed in the open-label extension (OLE) period of the study were generally mild and consistent with those observed in the double-blind (DB) period. The most common adverse events included dry mouth, joint pain, headache and dizziness. There were three events of palpitations in the placebo patients who were switched to Tesomet, and none in the group that received Tesomet for the full 48 weeks. There was one serious adverse event related to abdominal pain which spontaneously resolved. There were no clinically meaningful differences in heart rate or blood pressure observed over the nearly year-long study. All 18 patients who entered the OLE study completed it.
- **Bodyweight:** As previously reported, treatment with Tesomet led to a statistically significant 6.28% average reduction in bodyweight compared to placebo (p=0.0169) in the 24-week DB period of the study. This reduction was maintained through the 24-week OLE period, with these patients demonstrating a statistically significant 5.96% average reduction in bodyweight at Week 48 (p=0.008 vs baseline). Additionally, patients who received placebo during the DB period and were switched to Tesomet at Week 24 for the OLE period demonstrated a clinically meaningful 4.95% average reduction in bodyweight from baseline to Week 48.
- **Waist circumference:** As previously reported, treatment with Tesomet led to a 5.04% reduction in waist circumference compared to placebo (p=0.0519) in the DB period. This reduction was maintained during the OLE period, with these patients demonstrating a 5.07% reduction in waist circumference at Week 48 (p=0.003). Additionally, patients who received placebo during DB period and were switched to Tesomet at Week 24 for the OLE period demonstrated a 2.24% average reduction in waist circumference from baseline to Week 48.
- **Glycemic control:** As previously reported, there were two diabetic (T2D) patients who received Tesomet during the DB period, and they showed marked reduction of HbA1c levels (48.8% at Week 24), while no change was seen in normoglycemic patients. These two diabetic patients continued to receive Tesomet during the OLE period, and the reduction in HbA1c was maintained (46.17% at Week 48).

Saniona intends to present and/or publish additional data from this study in an appropriate future peer-reviewed, scientific forum. Additionally, Saniona intends to provide these data to the FDA as part of ongoing communications around plans to ensure that only appropriate patients would receive Tesomet, if approved. Pending this alignment with the FDA, Saniona intends to initiate a Phase 2b study in HO in the first half of 2021.

About the Phase 2 Study

This randomized, double-blind, placebo-controlled Phase 2 study evaluated Tesomet administered daily in patients with HO. The primary endpoint of the study was overall safety and tolerability measured by all safety data collected during the study including recorded adverse events, laboratory data, blood pressure, and heart rate. The secondary efficacy endpoints included bodyweight, waist circumference, glycemic control and other measures. In the double-blind (DB) period of the study, patients received either Tesomet or matching placebo (2:1 randomization) for 24 weeks. A total of 21 patients (13 Tesomet, 8 placebo) were included within the modified intent-to-treat analysis pertaining to the DB period. Top-line results from the DB period were announced in a press release in April 2020.

All 18 patients who completed the DB period of the study were provided the opportunity to receive Tesomet in an open-label extension (OLE) period of the study for an additional 24 weeks. All 18 patients chose to participate in the OLE period, and all patients completed the OLE period. Patients entering the OLE were 83.3% female and on

average 44.9 years old, weighing 110.4 kg (243 lbs) with a BMI of 37.2 kg/m^2. Further details about the trial can be found at ClinicalTrials.gov.

Webcast
Saniona will host a webcast in which Dr. Feldt-Rasmussen will review the data from this study on Tuesday, 24 November 2020, at 2:00pm ET / 20.00 CET. A live webcast of the presentation can be accessed via: https://edge.media-server.com/mmc/p/33xc2m4t. Subsequently, the event will be archived for approximately 90 days on the Saniona website in the Company Presentations section: https://saniona.com/investors/company-presentations/.

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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 17:00 CET on November 23, 2020.

About Saniona
Saniona is a rare disease biopharmaceutical company focused on research, development and commercialization of treatments for the central nervous system. The company has four programs in clinical development. Saniona intends to develop and commercialize treatments for rare disease indications such as hypothalamic obesity and Prader-Willi syndrome on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona also has out-licensing agreements with several companies. Saniona is based in Copenhagen, Denmark, and in Boston, Mass., U.S. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

About Tesomet
Tesomet is an investigational fixed-dose combination therapy of tesofensine (a triple monoamine reuptake inhibitor) and metoprolol (a beta-1 selective blocker). Saniona is advancing Tesomet for hypothalamic obesity and Prader-Willi syndrome, two severe rare disorders characterized by obesity and loss of appetite control. The programs are currently in clinical development. Saniona holds worldwide rights to Tesomet and is actively evaluating opportunities to advance this treatment globally.

About Hypothalamic Obesity (HO)
Hypothalamic obesity (HO) is a rare disorder characterized by intractable weight gain and uncontrollable hunger. Additional symptoms may include memory impairment, attention deficit, impulse control and depression as well as increased risk of cardiovascular and metabolic disorders. Currently, there is no cure for this condition. Treatments used for general weight management such as surgery, medication and lifestyle counseling are often tried in HO, but are mostly ineffective, and there are no medications specifically approved for HO. HO is caused by damage to the hypothalamus, most commonly sustained during surgery to remove a rare, noncancerous tumor called a craniopharyngioma. This tumor can occur at any age, but is most common in children and older adults, creating a burden for both patients and families. HO occurs in approximately one out of every 50,000 to 100,000 people.