PRESS RELEASE

November 11, 2019

Saniona completes patient recruitment in Phase 2a hypothalamic obesity study

- **First patients completed double-blind part of the hypothalamic obesity (HO) study and entered the open-label extension part**
- **Results expected in Q2 2020**
- **Study is complementary to development of Tesomet in Prader-Willi syndrome (PWS)**
- **PWS and HO are orphan indications and promising opportunities requiring limited investments**

Saniona (OMX: SANION), a clinical stage biotech company focused on eating disorders and CNS, today announces that it has recruited the last patient in the Phase 2a clinical study for Tesomet in hypothalamic obesity. Saniona expects to report top line results from the double-blind part of the study in Q2 2020.

The first patients, who were recruited in March, have elected to continue as part of the open-label extension part of the study. Saniona anticipates announcing the results in Q2 2020.

“Following the positive Phase 2a data recently reported in Prader-Willi syndrome, we are pleased with the Phase 2a progress in our second rare eating disorder, hypothalamic obesity. Our primary goal is to develop Tesomet in these orphan indications internally up to market approval in the U.S. and Europe. They represent substantial medical needs, promising commercial opportunities, while requiring limited investments,” said Jørgen Drejer, CEO of Saniona.

About the Phase 2a study

This is an exploratory, randomized, double-blind, placebo-controlled Phase 2a trial in patients with hypothalamic obesity, conducted at Rigshospitalet in Copenhagen, Denmark.

Patients will receive either Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) or matching placebo (2:1 randomization) for 24 weeks followed by an open-label extension study where all patients will receive Tesomet for 24 weeks resulting in a total treatment period of 48 weeks. Saniona expects to report the results from the double-blind part of the study in Q2 2020.

The primary endpoint is overall safety and tolerability, which will be judged from all safety data collected during the study including recorded adverse events, laboratory data, blood pressure and heart rate. The secondary endpoints relate to satiety and appetite; bodyweight; body composition; lipids and metabolic parameters; quality of life; and craving for sweet, salty and fatty foods.

Further details 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 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 November 11, 2019.

About Saniona

Saniona is a research and development company focused on drugs for treatment of eating disorders and diseases of the central nervous system. 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 Hypothalamic Obesity

The hypothalamus is a tiny part of the brain with a size being close to that of an almond. The hypothalamus controls important biological functions including body temperature, hunger and body weight.

Hypothalamic obesity is a rare disease that can occur from the growth or surgical removal of rare benign brain tumors and from other types of injury to the hypothalamus including stroke, brain trauma or radiation for cancer patients. The surgical removal of a rare brain tumor, craniopharyngioma, is the most common cause of hypothalamic obesity. Hypothalamic obesity is therefore sometimes also referred to as craniopharyngioma associated obesity.

A craniopharyngioma is a benign tumor, which most commonly affects children between 5-10 years old, though onset can sometimes occur during adulthood. Craniopharyngioma is also a rare disease with an estimated prevalence of 1:50,000 in the US. The treatment involves surgical removal of the tumor in almost all patients. The procedure can lead to complications, including damage to the hypothalamus resulting insatiable hunger and morbid obesity. A high frequency of hypothalamic obesity, between 30% and 77%, has been reported following treatment. Due to the Prader-Willi syndrome-like insatiable hunger, hypothalamic obesity is sometimes referred to as "acquired Prader-Willi syndrome". As in Prader-Willi syndrome, the condition reduces quality of life and there is no pharmacological treatment available today for these patients.