PRESS RELEASE

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Saniona Initiates Phase 2b Clinical Trial of Tesomet for Hypothalamic Obesity

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced the initiation of a Phase 2b clinical trial of Tesomet in patients with hypothalamic obesity (HO). Tesomet is an investigational fixed-dose combination therapy of tesofensine, a triple monoamine reuptake inhibitor, and metoprolol, a beta-1 selective blocker. Data from the trial are expected in the second half of 2023.

“The initiation of this Phase 2b clinical trial represents the culmination of the significant work and combined expertise of our clinical, regulatory, technical operations and quality teams,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. “We are also preparing to initiate a Phase 2b clinical trial of Tesomet in Prader-Willi syndrome before the end of the year, which, combined with our ongoing Phase 1 trial for SAN711, means our team will end the year with three rigorous clinical programs underway.”

The Phase 2b clinical trial includes a randomized, double-blind, placebo-controlled 36-week treatment period followed by a 36-week open-label extension period. The trial will seek to enroll approximately 110 participants 16 years of age and older with hypothalamic obesity – a rare disease caused by damage to the hypothalamus. During the 36-week double-blind period, participants will be randomized to receive daily dosing with Tesomet at one of three dose levels or placebo. During the 36-week open-label extension period, all participants, including those who originally received placebo, will receive the highest tolerated dose of Tesomet as established during the double-blind period. The primary endpoint of the study is the percentage change in body weight from baseline to week 36. Secondary endpoints include the proportion of participants who meet pre-specified thresholds for body weight loss at week 36, as well as change from baseline to week 36 in body weight, waist circumference, and body mass index.

The clinical trial is being conducted at multiple sites around the world including in the United States, New Zealand, Australia, and in multiple countries in Europe including the United Kingdom, Sweden, Italy, Spain and others. More information is available at www.hypothalamicstudy.com or www.clinicaltrials.gov.

Amy Wood, Executive Director of the Raymond A. Wood Foundation and parent of a child living with hypothalamic obesity, commented, “Hypothalamic obesity is a devastating condition that causes excessive weight gain even when food is limited – and there are currently no FDA-approved treatments. Earlier this year, the FDA awarded Tesomet the first-ever orphan drug designation for HO, which was a significant milestone for the HO community, and we are so excited to now see another milestone achieved with the initiation of the trial.”

“Management of hypothalamic obesity is extremely difficult because standard approaches to treating obesity such as lifestyle counseling, medications for general obesity, and even surgery are largely ineffective in this population,” said Ashley Shoemaker, Attending Physician, Assistant Professor of Pediatrics, Pediatric Endocrinology, Vanderbilt University Medical Center. “We desperately need treatment options for HO, and I am encouraged to see Saniona initiate this clinical trial.”

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Saniona previously evaluated Tesomet in a randomized, double-blind, placebo-controlled initial Phase 2 trial in adults with HO. In the study, Tesomet was generally well tolerated and led to a statistically significant reduction in body weight, as well as improvements in waist circumference and glycemic control. Tesomet received the first-ever orphan drug designation in HO from the FDA, and the FDA has confirmed that Tesomet may be advanced via the 505(b)(2) regulatory pathway. Saniona is partnering with the Raymond A. Wood Foundation to inform the clinical trial design and clinical development processes, and to raise awareness within the HO community.

Saniona is also evaluating Tesomet for the treatment of Prader-Willi syndrome (PWS) and plans to begin a Phase 2b trial in in this indication before the end of this year. The FDA granted Tesomet orphan drug designation in PWS in March 2021.

For more information, please contact

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About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for patients suffering from rare diseases for which there are a lack of available treatment options. The company's lead product candidate, Tesomet, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, serious rare disorders characterized by severe weight gain, disturbances of metabolic functions and uncontrollable hunger. Saniona has developed a proprietary ion channel drug discovery engine anchored by IONBASE™, a database of more than 130,000 compounds, of which more than 20,000 are Saniona's proprietary ion channel modulators. Through its ion channel expertise, Saniona is advancing two wholly-owned ion channel modulators, SAN711 and SAN903. SAN711 is in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders, and SAN903 is in preclinical development for rare inflammatory, fibrotic and hematological disorders. Led by an experienced scientific and operational team, Saniona has an established research organization in the Copenhagen area, Denmark, and a corporate office in the Boston, Massachusetts area, U.S. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at http://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 serious rare disorders characterized by severe weight gain, disturbances of metabolic functions and uncontrollable hunger. 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 caused by injury to a region of the brain known as the hypothalamus. This injury is most commonly sustained during surgery to remove a noncancerous tumor called a craniopharyngioma (CP). HO is characterized by rapid, excessive, and intractable weight gain that persists despite restricted food intake. Patients may have hyperphagia, an uncontrollable hunger, and may display abnormal food seeking behavior such as stealing food. Additional symptoms may include memory impairment, attention deficit, excessive daytime sleepiness and lethargy, issues with impulse control, and depression. HO patients are also at increased risk of developing obesity-related comorbid conditions such as Type 2 diabetes, non-alcoholic fatty liver disease, hypertension, stroke, and congestive heart failure. Ultimately, CP survivors with extensive hypothalamic injury report a 20-year mortality rate at least three times higher than CP survivors without extensive hypothalamic injury. There are no medications approved specifically for HO, and there is no cure for this disease. Many HO patients are treated with approaches used for general obesity such as surgery, medication and lifestyle counseling, but these are mostly ineffective. The number of patients with of HO is estimated to be between 10,000 and 25,000 in the U.S. and between 16,000 and 40,000 in Europe.