PRESS RELEASE

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Saniona Initiates Phase 2b Clinical Trial of Tesomet for Prader-Willi Syndrome

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 Prader-Willi syndrome (PWS). 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 first half of 2023.

“The initiation of this Phase 2b clinical trial of Tesomet in Prader-Willi syndrome follows our recent initiation of a Phase 2b clinical trial of Tesomet in hypothalamic obesity – two serious diseases with high unmet need,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. “In addition to these two trials, we are also conducting a Phase 1 clinical trial of SAN711, which means Saniona is ending 2021 with three clinical trials ongoing. This is a significant achievement and represents the hard work and expertise of our clinical, regulatory, technical operations and quality teams.”

The Phase 2b clinical trial in PWS includes a randomized, double-blind, placebo-controlled 16-week treatment period followed by a 36-week open-label extension period. The trial is expected to enroll approximately 120 patients with genetically-confirmed PWS. Initially, the trial will enroll adults (18 to 65 years of age) and then, following confirmation by the data monitoring committee and by the FDA, the trial is planned to expand into adolescents (13 to 17 years of age). During the 16-week double-blind period, participants will be randomized to receive daily dosing with Tesomet at one of three dose levels or a placebo. During the 36-week open-label extension period, participants who wish to continue treatment, including those who originally received placebo, will receive the highest tolerated dose of Tesomet as established during the double-blind period. The primary objective of the study will be change in hyperphagia at week 16 as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), a caregiver-reported survey that evaluates food-seeking behavior, such as frequency of sneaking food or time spent talking about food, and which has been used as the primary outcome measure for most PWS clinical trials. Secondary endpoints include change in body weight, change in caregiver impression of hyperphagia, change in clinician impression of overall disease severity, and change in clinician impression of overall clinical status.

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.praderwillisyndromestudy.com or www.clinicaltrials.gov.

“Currently, there are no approved treatments for hyperphagia, the uncontrollable hunger that is one of the most debilitating symptoms of PWS,” said Paige Rivard, CEO of Prader-Willi Syndrome Association USA. “We are encouraged to see Saniona addressing hyperphagia, and we look forward to working with them to support this clinical trial through education and outreach amongst our community.”

“As a physician scientist with over 40 years of clinical practice experience, I have researched PWS extensively and cared for many patients and families afflicted by this disorder,” said Merlin G. Butler, M.D., Ph.D., Professor of Psychiatry, Behavioral Sciences and Pediatrics, and Director of the Division of Research and Genetics and the KUMC Genetics Clinic

at the University of Kansas Medical Center. “The complex presentation of PWS has made it a difficult target for drug developers, but I am encouraged by the initial Tesomet data and look forward to the data from this clinical trial.”

Saniona previously evaluated Tesomet in a randomized, double-blind, placebo-controlled initial Phase 2 trial in adults and adolescents with PWS. Adult patients receiving Tesomet achieved a statistically significant reduction in hyperphagia, as well as a reduction in body weight. Adolescent patients demonstrated dose-dependent reductions in hyperphagia and body weight in open-label extensions of the study. Tesomet received orphan drug designation in PWS from the FDA, who also confirmed that Tesomet may be advanced via the 505(b)(2) regulatory pathway. Saniona is partnering with the Foundation for Prader-Willi Research (FPWR), the Prader-Willi Syndrome Association USA (PWSA-USA), and the International Prader-Willi Syndrome Organisation (IPSWO) to inform the clinical trial design and clinical development processes, and to raise awareness within the PWS community.

Saniona is also evaluating Tesomet in a Phase 2b clinical trial for hypothalamic obesity (HO). The FDA granted Tesomet orphan drug designation in HO in July 2021.

For more information, please contact

Trista Morrison, Chief Communications Officer, Saniona. Office: + 1 (781) 810-9227. Email: trista.morrison@saniona.com

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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 Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS) is a rare genetic condition that results in a variety of symptoms. Patients often experience hyperphagia, an uncontrollable hunger, and may display abnormal food seeking behavior such as stealing food. Additional symptoms include abnormal growth and body composition; low muscle tone or hypotonia; and social, emotional, or cognitive deficits. Hyperphagia is reported by caregivers to be among the most worrisome aspects of PWS, as this insatiable hunger persists no matter how much the patients eat and often requires caregivers to install locks on refrigerators and food storage areas. Many of those affected with PWS become obese and suffer shortened life expectancy and significant mortality. Common causes of mortality in PWS include respiratory and cardiac failure, infection, choking, gastric rupture, and pulmonary embolism. There are no medications approved specifically for the hyperphagia associated with PWS, and there is no cure for this disease. Current treatment depends on symptoms and often includes hormone replacement, including growth hormone. PWS is estimated to impact between 11,000 and 34,000 patients in the U.S. and between 17,000 and 50,000 patients in Europe.