**PRESS RELEASE**

**April 19, 2021**

# Saniona Announces Partnership with the Foundation for Prader-Willi Research (FPWR) to Support its Prader-Willi Syndrome (PWS) Clinical Trial with Tesomet

**Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced it has entered into a partnership with the Foundation for Prader-Willi Research (FPWR) to increase awareness within FPWR's community about Saniona's Phase 2b clinical trial of Tesomet for the treatment of Prader-Willi syndrome (PWS), which is expected to initiate in the first half of 2021.**

"There are currently no approved-treatment options to manage hyperphagia, the uncontrollable hunger that is one of the most difficult symptoms of PWS, making clinical trials a high priority for the PWS community," said John Walter, CEO of FPWR. "We are pleased to partner with Saniona on this program to empower patients to learn about the clinical trial process, ensure that the patient view is represented throughout the clinical trial continuum, and raise awareness of Saniona's clinical trial within the PWS community."

As part of the collaboration, Saniona and FPWR will conduct a webinar with the PWS community to provide information and answer questions about Saniona's PWS clinical trial. FPWR will also utilize its online, email and social media platforms to raise awareness of Saniona's clinical trial.

"We are grateful to partner with FPWR because one of our top priorities is to incorporate caregiver and patient feedback into our clinical trial actitvities to ensure we meet the needs of the PWS community," said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. "We look forward to working with FPWR to gather this feedback and to increase awareness of our clinical trial."

Saniona previously evaluated Tesomet in a randomized, double-blind, placebo-controlled Phase 2a trial in adults and adolescents with PWS. Adult patients receiving Tesomet achieved a statistically significant reduction in hyperphagia, as well as a clinically meaningful reduction in body weight at a dose of 0.5 mg per day. A smaller study extension in an adolescent population showed that Tesomet appeared to be well tolerated at lower doses (0.125 mg/day and 0.25 mg/day) and suggested dose-dependent effects on weight and hyperphagia.

Saniona is currently planning to initiate a Phase 2b study of Tesomet in PWS in the first half of 2021. Saniona is also evaluating Tesomet for the treatment of hypothalamic obesity (HO) and plans to begin a Phase 2b trial in this indication in the first half of this year.

## For more information, please contact

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## About Saniona

Saniona is a biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for rare disease patients around the world. The company's lead product candidate, Tesomet, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, severe rare disorders characterized by uncontrollable hunger and intractable weight gain. Saniona's robust drug discovery engine has generated a library now consisting of more than 20,000 proprietary modulators of ion channels, a significantly untapped drug class that is scientifically validated. Lead candidate SAN711 is entering Phase 1 for rare neuropathic disorders, with SAN903 for rare inflammatory and fibrotic disorders advancing through preclinical studies. Led by an experienced scientific and operational team, Saniona has an established research organization in Copenhagen, Denmark and is building its 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 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 Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS) is recognized as the most common genetic cause of life-threatening obesity, with an estimated number of patients between 11,000 and 34,000 in the U.S. and between 17,000 and 50,000 in Europe. The disease results from a deletion or loss of function of a cluster of genes on chromosome 15, which leads to dysfunctional signaling in the brain's appetite/satiety center (hypothalamus). Many of those affected with PWS suffer from insatiable appetite (hyperphagia); abnormal growth and body composition; low muscle tone (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 cabinets where food is stored. Many of those affected with PWS become morbidly obese and suffer shortened life expectancy and significant mortality. Common causes of mortality in PWS include respiratory disease, cardiac disease, 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. Treatment depends on symptoms and often includes hormone replacement. 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.