PRESS RELEASE

October 9, 2020

Saniona receives pre-IND feedback from FDA on regulatory path for Tesomet in Prader-Willi Syndrome (PWS) and Hypothalamic Obesity (HO)

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that it received written feedback from the U.S. Food and Drug Administration (FDA) regarding pre-Investigational New Drug (IND) submissions for Tesomet in Prader-Willi Syndrome (PWS) and Hypothalamic Obesity (HO).

Regarding PWS, the FDA's Division of Psychiatry within the Office of Neuroscience provided additional feedback on conducting a supportive Phase 2b study evaluating multiple doses of Tesomet in adult and adolescent PWS patients. Saniona expects to begin this Phase 2b study in the first half of 2021.

As part of its ongoing discussions with the FDA, Saniona inquired if the planned Phase 2b study could serve as a single pivotal trial supporting approval of Tesomet in PWS. The FDA considered this request and, as Tesomet is a new molecular entity, the agency recommended that Saniona conduct a supportive Phase 2b study prior to initiating a Phase 3 study to confirm the safety and efficacy of the doses intended for commercialization. In addition, in recognition of the significant unmet need within the PWS pediatric population, the FDA recommended that Saniona plan to evaluate Tesomet in children younger than age 12.

Regarding HO, the FDA's Division of Diabetes, Lipid Disorders and Obesity within the Office of Cardiology, Hematology, Endocrinology, and Nephrology agreed that the 505(b)(2) pathway is an appropriate development pathway for Tesomet. The agency recommended that the clinical development program for Tesomet in HO include a supportive Phase 2b study followed by a Phase 3 study. The agency expressed concerns about potential off-label use in the general obese population and suggested this needs to be evaluated, such as through a cardiovascular outcomes study, or that Saniona would need to clarify how it would restrict distribution of Tesomet exclusively to the rare HO population. Saniona is seeking additional guidance from the FDA in order to clarify the path forward for Tesomet in HO.

"Prader-Willi Syndrome and Hypothalamic Obesity are rare diseases that represent significant unmet needs with high caregiver burden, and there are currently no treatments specifically approved for either indication," said Rami Levin, President and CEO of Saniona. "We now have a clear path forward for the development of Tesomet as a novel treatment for PWS, and we look forward to further engaging with the FDA to clarify the best path for bringing Tesomet to patients suffering from the serious, rare condition HO while avoiding inappropriate use in generally obese patients."

For more information, please contact

Trista Morrison, Chief Communications Officer. Office + 1 (781) 810-9227. Email: Trista.morrison@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 October 9, 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 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 also has out-licensing agreements with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and in Boston, 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 a rare disease characterized by constant, extreme, ravenous, insatiable appetite (hyperphagia) which persists no matter how much the patients eat. The urge to eat is physiological, overwhelming, and difficult to control. Caregivers need to strictly limit the patients' access to food, usually by installing 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. However, 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. Currently, there is no cure for this disease. PWS 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). PWS occurs in approximately one out of every 15,000 births.

About Hypothalamic Obesity (HO)

Hypothalamic obesity (HO) is a rare disorder characterized by uncontrollable hunger leading to rapid and intractable weight gain. 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 obesity such as surgery, medication and counseling are often tried in HO, but are mostly ineffective, and there are no medications specifically approved for HO. HO is caused by injury 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.