PRESS RELEASE

March 8, 2021

Saniona Receives Feedback from U.S. FDA Providing a Regulatory Path Forward for Tesomet in Hypothalamic Obesity

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced it received feedback from the U.S. Food and Drug Administration (FDA) providing further clarity on a regulatory path for Tesomet in the treatment of hypothalamic obesity (HO). Based on this feedback, Saniona is proceeding with plans to initiate a Phase 2b study in HO in the first half of this year.

“There is currently no medicine approved for hypothalamic obesity, a rare disease secondary to hypothalamic injury, characterized by intractable weight gain and complicated by uncontrollable hunger,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. “We are encouraged by this feedback from the FDA and look forward to continuing a constructive dialogue with them as we prepare to initiate our Phase 2b clinical trial with Tesomet.”

Saniona previously announced that the FDA had highlighted the potential for off-label use of Tesomet in the general obese population. As a result, Saniona submitted a response proposing a Risk Evaluation and Mitigation Strategy (REMS), which is often used to restrict commercial distribution to the appropriate patients suffering from an unmet medical need. The FDA indicated overall agreement with this proposal and stated Saniona should demonstrate that HO fulfills the criteria for an unmet medical need. Saniona further proposed including 24-hour ambulatory blood pressure monitoring (ABPM) and Holter (electrocardiogram) monitoring as part of the HO program. The agency stated that robust data from these analyses could be useful in determining the level of cardiovascular assessment needed in Phase 3. The agency also acknowledged the challenge of conducting 24-hour monitoring in HO patients and said the analyses could be conducted in a separate study in general obese people.

Saniona expects to file an Investigational New Drug (IND) application and initiate its planned Phase 2b clinical trial in HO in the first half of this year. In a 24-week, double-blind, randomized, placebo-controlled Phase 2 trial in HO, Tesomet was well-tolerated, and treated patients demonstrated statistically significant reductions in body weight and clinically meaningful improvements in waist circumference and glycemic control. These improvements were maintained during an additional 24-week open-label extension, with no clinically meaningful differences in heart rate or blood pressure observed. Saniona is also evaluating Tesomet for the treatment of Prader-Willi syndrome (PWS) 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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The information was submitted for publication, through the agency of the contact person set out above, at 14:00 CET on 8 March 2021.

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 the rare diseases Prader-Willi syndrome and hypothalamic obesity. Saniona also has a broad pipeline derived from its proprietary ion channel discovery platform, with lead candidate SAN711 entering Phase 1 studies for rare neuropathic disorders. Saniona intends to develop and commercialize its rare disease products internally. The company has out-licensed other programs, which may provide future supplemental revenue. Saniona is based in Copenhagen, Denmark and Boston, Mass., 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 Hypothalamic Obesity (HO)

Hypothalamic obesity (HO) is a rare disorder caused by injury to the hypothalamus, most commonly sustained during surgery to remove a rare, noncancerous tumor called a craniopharyngioma (CP). HO is characterized by rapid, excessive and intractable weight gain that persists despite limited food intake. Patients may have hyperphagia, an uncontrollable hunger, and may display abnormal food seeking behaviors such as stealing food. Additional symptoms may include memory impairment, attention deficit, excessive daytime sleepiness and lethargy, issues with impulse control, depression, and suicide. 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 hypothalamic injury report at least three times higher 20-year mortality than CP survivors without 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 often ineffective. The prevalence 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. It occurs most often in children and older adults, creating a burden for both patients and families.