PRESS RELEASE

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Saniona Receives U.S. FDA Orphan Drug Designation for Tesomet in Hypothalamic Obesity

Tesomet is the first and only investigational treatment for hypothalamic obesity to receive orphan drug designation

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Tesomet for the treatment of hypothalamic obesity (HO). Tesomet is the first and only investigational treatment for HO to receive orphan drug designation. Saniona is preparing to initiate two Phase 2b studies of Tesomet in the second half of this year, one in HO and the other in Prader-Willi syndrome (PWS), for which Tesomet has already received orphan drug status.

“There are currently no FDA-approved medicines for hypothalamic obesity. Despite the devastating weight gain and hunger this rare disease can cause, there has been relatively little drug development specifically for HO. Saniona is proud to be pioneering a regulatory path forward for people living with HO, and we are thrilled to have received the first-ever FDA orphan drug designation in HO. We look forward to initiating our Phase 2b trial of Tesomet for HO in the second half of this year,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona.

Amy Wood, Executive Director of the Raymond A. Wood Foundation and parent of a child living with hypothalamic obesity, commented, “The recognition of the first orphan drug designation in hypothalamic obesity is a critical milestone for the HO community. HO places a tremendous burden on caregivers and families; it causes severe weight gain and constant hunger no matter how much a person eats, forcing us to lock up food and avoid social situations where food is served. We are incredibly grateful that both the FDA and Saniona recognize the seriousness of this disorder, and we hope this orphan drug designation is the first step towards having an innovative treatment.”

Orphan drug designation is a special status granted by the FDA to medicines and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. The number of people living with HO is estimated to be between 10,000 and 25,000 in the U.S. and between 16,000 and 40,000 in Europe. Receiving orphan designation qualifies Saniona for certain development benefits, including tax credits, elimination of certain FDA license application fees, and seven years of market exclusivity in the U.S. following approval.

Saniona previously evaluated Tesomet in a 24-week, double-blind, randomized, placebo-controlled initial Phase 2 trial in HO. Adults receiving Tesomet demonstrated statistically significant reductions in body weight and improvements in waist circumference and glycemic control. These improvements were maintained during an additional 24-week open-label extension. Tesomet was reported to be generally well-tolerated, and most adverse events were mild. The most common adverse events included sleep disorders, dizziness, dry mouth and headache. No clinically significant differences in heart rate or blood pressure were observed between the Tesomet-treated patients and the placebo-treated patients.

In preparation for the initiation of the Phase 2b study of Tesomet in HO in the second half of 2021, Saniona has selected the clinical research organization (CRO) that will support the clinical trial and is in the process of assessing and selecting clinical trial sites in the U.S. and globally. Saniona has also selected the contract manufacturer to produce Tesomet for Phase 2b and Phase 3 clinical trials. Additionally, Saniona has initiated multiple partnerships with the HO advocacy

community to incorporate caregiver and patient feedback into the clinical trial process and to provide the community with education on clinical trials.

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 second half of this year. The FDA granted orphan drug designation to Tesomet for the treatment of PWS in March 2021.

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 in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders, and SAN903 for rare inflammatory and fibrotic disorders is advancing through preclinical development. Led by an experienced scientific and operational team, Saniona has an established research organization in Copenhagen, 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 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 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.