PRESS RELEASE

March 3, 2021

Saniona Receives U.S. FDA Orphan Drug Designation for Tesomet in Prader-Willi Syndrome

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 Prader-Willi syndrome (PWS). Saniona is preparing to initiate a Phase 2b study of Tesomet in PWS in the first half of this year.

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 patients with PWS is estimated to be between 11,000 and 34,000 in the U.S. and between 17,000 and 50,000 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.

“There is currently no cure for Prader-Willi syndrome and no medicines approved to address the uncontrollable hunger, or hyperphagia, that characterizes this rare disease,” said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. “Receiving orphan drug designation will help us advance Tesomet as expeditiously and efficiently as possible.”

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. In preparation for this study, Saniona has opened an Investigational New Drug (IND) filing with the FDA, 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, and the contract manufacturer is actively working on clinical production. Additionally, Saniona has initiated multiple partnerships with the PWS advocacy community to ensure caregiver and patient feedback is incorporated into the clinical trial process and to provide the community with education on clinical trials.

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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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 13.00 CET on 3 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 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.