PRESS RELEASE

June 9, 2020

Saniona Receives Positive Feedback from FDA on Regulatory Path for Tesomet in Prader-Willi Syndrome (PWS)

Saniona (OMX: SANION), a clinical-stage biotech company focused on rare diseases, today announced it has completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA), Office of Neuroscience and Division of Psychiatry, for the development of Tesomet in Prader-Willi syndrome (PWS), a rare disease with a large medical unmet need.

The positive feedback regarding the proposed regulatory path for Tesomet in patients with PWS confirmed that Tesomet may be advanced via the 505(b)2 pathway, and the agency indicated agreement with Saniona on the design, the proposed doses, and duration of the potential Phase 2b clinical trial in PWS.

“The collaborative interaction with the FDA has given Saniona needed clarity to advance Tesomet development for Prader-Willi syndrome, a devastating rare disease that currently has no cure,” said Rudolf Baumgartner, Chief Medical Officer and Head of Clinical Development at Saniona. “We look forward to formally submitting the IND and continuing our discussions with the FDA, as we advance our program in PWS”.

Saniona expects to file an IND for Tesomet in the treatment of PWS and begin its Phase 2b clinical trial in the second half of 2020. The primary endpoint of the Phase 2b trial will be hyperphagia, or chronic overeating caused by an inability to feel full, which is the hallmark symptom of PWS. In a Phase 2a clinical trial, Tesomet significantly reduced hyperphagia in both adult and adolescent PWS patients.

Saniona is also evaluating Tesomet for the treatment of hypothalamic obesity (HO), a rare disorder characterized by rapid and severe weight-gain with increased risk of cardiovascular and metabolic disorders. The company reported positive data from a Phase 2 clinical trial in HO in April 2020 and is currently conducting an open-label extension of this study, with data expected in Q4 2020. Saniona intends to pursue a meeting with the FDA in Q4 2020 to help define a regulatory path forward for Tesomet in HO.

For more information, please contact

Rami Levin, President & CEO, Saniona, Mobile: +1 (781) 987 3144, Email: rami.levin@saniona.com

Rudolf Baumgartner, CMO & Head of Clinical Development, Email: rudolf.baumgartner@saniona.com

The information was submitted for publication, through the agency of the contact person set out above, at 08:00 a.m. CET on June 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, US. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

About Tesomet

Tesomet is a fixed-dose combination therapy of tesofensine (a triple monoamine reuptake inhibitor) and metoprolol (a β1-blocker). Tesofensine and Tesomet have demonstrated strong weight reduction in overweight patient populations driven primarily through appetite reduction and reduction of craving for food. Saniona is advancing Tesomet for Prader Willi syndrome and hypothalamic obesity, two severe rare eating disorders characterized by loss of appetite control. The clinical programs are currently in mid/late stage 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, occurring in approximately one out of every 15,000 births. 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). Patients suffer from a constant, extreme, ravenous insatiable appetite which persists no matter how much the patients eat. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Compulsive eating and obsession with food usually begin before age 6. 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 on all closets and cabinets where food is stored.

Patients with PWS have a shortened life expectancy. 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.