PRESS RELEASE

June 11, 2018

Saniona plans Phase 2a study for treatment of Hypothalamic Obesity

Saniona, a leading biotech company within ion-channel research, today announced that it plans to initiate a clinical Phase 2a study in the rare eating disorder hypothalamic obesity with its lead product Tesomet. The Phase 2a study in hypothalamic obesity will complement Saniona’s development plans in Prader-Willi syndrome. These two rare eating disorders have several things in common, including clinical symptoms, clinical trial design and potential orphan drug designation.

“We have recently reported positive results from preclinical studies for Tesomet and from a Phase 1 study with our new patented Tesomet tablet. These two important stepping-stones enable us to perform long term clinical studies with Tesomet. We are aiming at developing Tesomet for severe eating disorders including Prader-Willi syndrome and hypothalamic obesity in the US and Europe. Both Prader-Willi syndrome and hypothalamic obesity are rare diseases characterized by a constant craving for food with severe consequences for the patients. This will further strengthen Saniona’s ambitions to bring Tesomet to the market for rare eating disorders,” said Jørgen Drejer, CEO of Saniona.

Saniona is planning to engage in clinical studies in patients with hypothalamic obesity in collaboration with several leading academic centers in Denmark. Hypothalamic obesity is a rare disease which often is caused by the surgical removal of a brain tumor. The tumor and/or the surgical removal often lead to damage of the appetite center in the brain (hypothalamus). This results in insatiable hunger and morbid obesity. Patients with hypothalamic obesity are consequently experiencing many of the same symptoms as those seen in patients with Prader-Willi syndrome.

“We will obtain several advantages of pursuing the development of Tesomet in the two indications. Prader-Willi syndrome and hypothalamic obesity have many things in common including clinical symptoms, clinical trial design, regulatory advantages from potential orphan drug designation and premium pricing as well as fast time to market due to relative short and small clinical studies,” said Jørgen Drejer.

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 08:00 a.m. CEST on June 11, 2018.

About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. Saniona has four programs in clinical development including three late stage clinical programs focused on the development of treatments to effectively regulate obsessions, cravings and addictions related to food and drugs. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome on its own and engage in partnerships with larger entities for development programs aiming to treat large indications such as obesity. The company’s research is focused on ion channels, which makes up a unique protein class that enables and controls the passage of charged ions across cell membranes. Saniona has ongoing collaboration agreements.
About Hypothalamus Obesity

The hypothalamus is a tiny part of the brain with the size being close to that of an almond. The hypothalamus controls important biological functions including body temperature, hunger and body weight.

Hypothalamic obesity is a rare disease that can occur from the growth or surgical removal of rare brain tumors and from other types of injury to the hypothalamus including stroke, brain trauma or radiation for cancer patients. The surgical removal of a rare brain tumor, craniopharyngioma, is the most common cause of hypothalamic obesity. Hypothalamic obesity is therefore sometimes also referred to as craniopharyngioma associated obesity.

A craniopharyngioma is a benign tumor, which most commonly affects children between 5-10 years old, though onset can sometimes occur during adulthood. Craniopharyngioma is also a rare disease with an estimated prevalence of 1:50,000 in the US. The treatment involves surgical removal of the tumor in almost all patients. The procedure can lead to complications, including damage to the hypothalamus resulting intractable hunger and morbid obesity. A high frequency of hypothalamic obesity, between 30% and 77%, has been reported following treatment. Due to the Prader-Willi syndrome-like intractable hunger, hypothalamic obesity is sometimes referred to as "acquired Prader-Willi syndrome". As in Prader-Willi syndrome, the condition reduces quality of life and there is no pharmacological treatment available today for these patients.