PRESS RELEASE

March 20, 2017

Saniona expects to initiate the planed Phase 2a study for Tesomet in Prader-Willi syndrome in Q2 2017

Saniona, a leading biotech company in the field of ion channels, today provides an update on the planned Phase 2a study for Tesomet in Prader-Willi syndrome (PWS). The regulatory agencies in Czech Republic and Hungary have approved Saniona's clinical trial applications. Saniona has held a meeting with the European Medicines Agency (EMA) for Scientific Advice and now collaborates with an international consortium to advance clinical trials for Prader-Willi syndrome. Based on these interactions, Saniona has decided to include additional clinical endpoints in the planned Phase 2a study. The trial is expected to be initiated in the second quarter of 2017.

"We are very pleased about the regulatory approvals and are looking forward to starting our first study in patients with PWS – a severe hereditary disease for which there is no treatment today. Due to the mode of action, we believe that Tesomet could provide substantial benefits to these patients," says Jørgen Drejer, CEO of Saniona.

Saniona has received EMA's Scientific Advice on various issues and clinical aspects of development of Tesomet in patients with PWS. The EMA's Scientific Advice is given at a dialogue meeting conducted by EMA.

"The objectives of the Phase 2a study are to assess efficacy, tolerability, safety, and pharmacokinetics of Tesomet in patient with PWS. We found the EMA Scientific Advice very helpful and constructive and believe that many of the discussed issues and clinical aspects can be addressed either in the planned Phase 2a trial, or our future clinical studies in these patients."

Saniona collaborates with the Prader-Willi Syndrome Clinical Trial Consortium, which is coordinated by The Foundation for Prader-Willi Research. The consortium comprises stakeholders from pharmaceutical industries, academia and patient organizations and supports researchers and a variety of other activities in this area. This also includes the development of new and meaningful clinical trial endpoints to address unmet medical needs in PWS. As an example of this collaboration a novel tool, a questionnaire, was developed and validated for assessing changes in hyperphagic behavior in PWS patients, a critical issue in their daily lives. Saniona has been granted permission to use this questionnaire for clinical studies.

"We believe that the information obtained by including this questionnaire in our Phase 2a study will provide an important insight into the effects of Tesomet on eating behavior in patients with PWS. We have therefore filed a small amendment to our existing clinical trial applications in the Czech Republic and Hungary."

For more information, please contact

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This information is information that Saniona (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 CET on March 20, 2017.

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. The company has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The 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 with Boehringer Ingelheim GmbH, Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Luc Therapeutics. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq First North Premier and has about 4,400 shareholders. Pareto Securities is Certified Advisor for Saniona. The company's share is traded under the ticker SANION. Read more at www.saniona.com.

About Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS) is recognized as the most common genetic cause of life-threatening obesity. 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. Currently, there is no cure for this disease. Patients with PWS have a shortened life expectancy. Common causes of death 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[1]. PWS occurs in approximately one out of every 15,000 births[2]. Males and females are affected equally. The condition is named after Andrea Prader, Heinrich Willi, and Alexis Labhart who described it in detail in 1956. The common characteristics defined in the initial report included small hands and feet, abnormal growth and body composition (small stature, very low lean body mass, and early-onset childhood obesity), hypotonia (weak muscles) at birth, insatiable hunger, extreme obesity, and intellectual disability.

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[1] Butler MG, Lee PDK, Whitman, BY. Management of Prader-Willi Syndrome. 3rd ed. New York, NY: Springer Verlag Inc.; 2006. 0387253971

[2] https://www.fpwr.org/about-prader-willi-syndrome/ Foundation for Prader-Willi Research retrieved October 2016