



## PRESS RELEASE

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### Saniona forms PWS Scientific Advisory Board and provides update on ongoing study

- Scientific Advisory Board (SAB) established for Tesomet in Prader Willi Syndrome
- Tesomet 0.25 mg/day extension study ongoing in Czech Republic and Hungary

Saniona (OMX: SANION), a biotech company focused on the central nervous system and eating disorders, announced today that it has established a Scientific Advisory Board for the development of Tesomet in PWS. Saniona has also extended the ongoing open label study in both Czech Republic and Hungary and the dose has been adjusted to 0.25 mg. This last extension of the study will be completed in July 2019.

“Tesomet has demonstrated reductions in craving for food and weight in the rare genetic eating disorder Prader Willi Syndrome and we are now planning for the final clinical and regulatory program targeting a billion-dollar market. Saniona has established a highly esteemed advisory board to oversee the program and provide guidance for the design of the final Phase 2b and Phase 3 studies, which is expected to be conducted in the U.S. and Europe over the coming two years,” said Jørgen Drejer, CEO of Saniona.

The Scientific Advisory Board which recently met for the first meeting in Copenhagen comprises several highly regarded and influential experts from the U.S. and Europe with a profound experience in Prader Willi syndrome, including:

Tony Holland, MD, CBE – Emeritus Professor of Psychiatry, University of Cambridge; President of the International Prader-Willi Syndrome Organisation

Theresa Strong, PhD - Director of Research Programs, Foundation for Prader-Willi Research

Janice Forster, MD – Child and Adolescent Psychiatrist in private practice in Pittsburgh, PA, specializing in Developmental Neuropsychiatry and Prader-Willi syndrome

Susanne Blichfeldt, MD - Consultant (Paediatrics), Copenhagen; Vice-Chair, Clinical & Medical Advisory Board, International Prader-Willi Organization

“We had very productive meetings with the SAB and are looking forward to continued constructive interactions with this highly experienced group of people, whose first task is to review our clinical plans and provide advice when preparing for the Phase 2b and Phase 3 meetings with the FDA and EMA later this year following the completion of the ongoing Phase 2a study, said Jørgen Drejer, CEO of Saniona.

#### For more information, please contact

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## About Saniona

*Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders. The company has five programs in clinical development. Saniona intends to develop and commercialize treatments for orphan 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 has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and the company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION). Read more at [www.saniona.com](http://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 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<sup>1</sup>. PWS occurs in approximately one out of every 15,000 births<sup>2</sup>. 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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<sup>1</sup> Butler MG, Lee PDK, Whitman, BY. Management of Prader-Willi Syndrome. 3rd ed. New York, NY: Springer Verlag Inc.; 2006. 0387253971

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