



## PRESS RELEASE

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### Saniona completes its six months double blind Phase 2a trial of Tesomet in hypothalamic obesity

- Last patient completes last visit in the six-month, placebo-controlled part of study
- 18 patients have continued into open-label extension
- Top-line results from placebo-controlled part of study still expected in Q2 2020

**Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases of the central nervous system, today announces the last patient has completed the last visit in the six-month, placebo-controlled section of a Phase 2a study of Tesomet in hypothalamic obesity (HO).**

A total of 18 patients, of the original 21 who started the trial, have now continued into the open-label extension part of the study. The placebo-controlled part of the study remains on track to report top-line results in Q2 2020.

*“We are very pleased that this Phase 2a trial of Tesomet is proceeding according to plan, at a time of such uncertainty and disruption around the world,” said Rami Levin, CEO of Saniona. “This study is an important part of the clinical package that Saniona is compiling, as we are rapidly advancing Tesomet towards pivotal clinical trials in the rare eating disorder of Hypothalamic Obesity as part of our longer-term strategy to become a global, commercial-stage company.”*

#### **About the Phase 2a study**

This is an exploratory, randomized, double-blind, placebo-controlled Phase 2a trial in patients with HO, conducted at Rigshospitalet in Copenhagen, Denmark.

Patients have received either Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) or matching placebo (2:1 randomization) for 24 weeks. This is followed by an open-label extension study where all patients will receive Tesomet for 24 weeks resulting in a total treatment period of 48 weeks. Saniona expects to report the results from the double-blind part of the study in Q2 2020.

The primary endpoint is overall safety and tolerability, which will be judged from all safety data collected during the study including recorded adverse events, laboratory data, blood pressure and heart rate. The secondary endpoints relate to satiety and appetite; bodyweight; body composition; lipids and metabolic parameters; quality of life; and craving for sweet, salty and fatty foods.

Further details about the trial can be found at [ClinicalTrials.gov](https://ClinicalTrials.gov).

#### **For more information, please contact**

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## **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 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).*