

PRESS RELEASE

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Saniona Reports Positive Topline Results from Phase 2 Trial of Tesomet in Hypothalamic Obesity

- **Tesomet is safe and well-tolerated in hypothalamic obesity patients**
- **Tesomet led to statistically significant reductions in the key efficacy endpoints, including change in body weight, waist circumference and glycemic control compared to placebo**

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced top line results from its 24-week double blind, randomized, placebo-controlled Phase 2 trial evaluating the safety and efficacy of Tesomet in patients with hypothalamic obesity (HO). The study results showed that Tesomet was safe and well tolerated. Furthermore, robust efficacy data was also reported, with statistically significant improvements in body weight, waist circumference, and glycemic control observed with Tesomet treatment compared to placebo.

“We are highly encouraged by the promising safety and efficacy observed in our Phase 2 randomized controlled trial,” said Rami Levin, President and Chief Executive Officer of Saniona. “This is an important accomplishment that we believe is a step forward towards a possible first approved treatment for HO. We recognize the importance of discovering a treatment for this devastating rare disease and are committed to rapidly advancing Tesomet for HO patients. We are evaluating next steps for the development of Tesomet in Hypothalamic Obesity and intend to pursue an End of Phase 2 meeting with FDA to define a regulatory path forward.”

Highlights from top-line study data include:

- Tesomet was found to be safe and well tolerated. Side effects seen more frequently in treated patients include sleep problems, dry mouth, and headache, which are well known side effects associated with tesofensine and/or metoprolol. There was a single case of Tesomet related anxiety/paranoia reported as a Serious Adverse Event (SAE), which improved after discontinuation of treatment.
- There were no clinically meaningful differences in heart rate or blood pressure between treatment groups.
- 18 of the 21 study participants completed the placebo-controlled part of the study (2 dropouts in placebo group; 1 dropout in treatment group) and have entered the open-label extension for an additional 24-week period.
- Treatment with Tesomet led to a statistically significant 6.8% average reduction in bodyweight compared to placebo ($p < 0.001$).
- Average waist circumference of Tesomet treated patients was significantly reduced by 7.9% compared to placebo ($p < 0.001$).
- Tesomet treatment improved glycemic control as measured by a statistically significant 14.6% reduction in hemoglobin A1c (HbA1c) compared to placebo ($p = 0.015$).



Professor Ulla Feldt-Rasmussen, M.D., DMSc., Department of Medical Endocrinology and Metabolism, Rigshospitalet Copenhagen University Hospital and Principal Investigator on the Phase 2 study stated, “Patients with hypothalamic obesity are faced with severe and debilitating overweight for which there is no approved treatments. I am highly encouraged by the study results, and I believe that Tesomet may become a valuable treatment of this rare disease, including management of the key characteristics of the disease such as: persistent hunger, loss of appetite control, uncontrollable weight gain and metabolic dysfunction. Equally important is the favorable safety and tolerability profile of Tesomet, which is highlighted by the fact that only one patient on Tesomet did not continue to the open-label study extension. These promising results warrant further studies and I look forward to the continued development of Tesomet as a potential first treatment to improve outcomes for patients with hypothalamic obesity.”

About the Phase 2 study

This randomized, double-blind, placebo-controlled Phase 2 trial evaluated Tesomet (tesofensine 0.5 mg + metoprolol 50 mg) administered daily in patients with HO, conducted at Rigshospitalet in Copenhagen, Denmark. The primary endpoint of the study was overall safety and tolerability measured by all safety data collected during the study including recorded adverse events, laboratory data, blood pressure, and heart rate. The efficacy endpoints included bodyweight; body composition; waist circumference, satiety and appetite; lipids and glycemic control; quality of life; and craving for sweet, salty and fatty foods.

Patients received either Tesomet or matching placebo (2:1 randomization) for 24 weeks, followed by an open-label extension of another 24 weeks for a total of 48 weeks of treatment. 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 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.