PRESS RELEASE

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Saniona reports top line results from the Tesomet Phase 2a interim study in Prader-Willi syndrome

Saniona, a leading biotech company in the field of ion channels, today announced top line results from its exploratory Phase 2a clinical trial for Tesomet in patients with Prader-Willi syndrome. The small number of patients in the study (n=9) and the failure of one placebo and four treated patients to complete the study preempts statistical evaluation. We did, however, observe a clinically meaningful weight loss as well as a remarkable reduction in hyperphagia over the course of the 3-month study. Surprisingly, plasma concentrations of tesofensine were found to be two to four times higher in this study compared to previous studies in obese and diabetic patients with the same tesofensine dose. This may explain the high dropout rate in the study and some of the observed side effects.

"The positive and convincing efficacy data from this Phase 2a study is highly encouraging, as it indicates that Tesomet can provide a clinically meaningful reduction in weight and hyperphagia in patients with Prader-Willi syndrome. Side effects and dropout rates, however, were of concern. Now it turns out that plasma levels of tesofensine were dramatically and unexpectedly elevated in this population, which may explain the high incidence of side effects in the treatment group. Moving forward, we intend to carefully analyze the data and confer with key experts in the field to evaluate potential follow up studies using a lower dose of Tesomet for this complex patient group," stated Jørgen Drejer, CEO of Saniona.

The exploratory, double-blind, randomized, placebo-controlled Phase 2a trial enrolled a total of nine adult patients with Prader-Willi syndrome, of which six patients received Tesomet and three patients received placebo. A total of four patients completed the trial (two on treatment and two on placebo). A total of seven patients completed eight weeks of the study (five on treatment and two on placebo). Overall, the results must be interpreted with caution.

Based on the data, the following observations can be made:

- The clinical trial achieved a positive outcome on the primary endpoint with a clinically meaningful reduction in weight for patients treated with Tesomet compared to placebo. After 8 weeks the mean change in body weight was 5.00 % (n=5) for patients receiving Tesomet compared to 0.46 % (n=2) for patients receiving placebo. After 13 weeks the change in body weight was 6.76% (n=2) for patients receiving Tesomet compared to 0.75 % (n=2) for patients receiving placebo. The average weight reduction was 4.78 kg (n=5) after 8 weeks and 7.95 kg (n=2) after 13 weeks for patients receiving Tesomet. There was significant variance in weight loss between patients.
- The average waist circumference was reduced by 7.2 cm (n=5) after 8 weeks and 10 cm (n=2) after 13 weeks for patients treated with Tesomet and by 4 cm (n=2) and 6.5 cm (n=2) for the two timepoints respectively in the placebo group.
- There was a remarkable reduction in the observed numbers for craving for food in patients treated with Tesomet. The total score measured by the validated hyperphagia questionnaire for clinical trials, fell from 10.00 (n=6) at baseline to 1.00 (n=5) after 8 weeks and to 0.00 (n=2) after 13 weeks where a score of 0 is equivalent to no signs of hyperphagia as measured by the hyperphagia questionnaire. After one week of

treatment the total score fell from 10 at baseline to 5.67 (n=6), which is equivalent to a reduction of 43%. The observed hyperphagia score in the placebo group varied over time due to the low number of subjects. After 13 weeks the total score was 9.50 (n=2) compared to a baseline of 11.67 (n=3).

- The plasma concentration of tesofensine in patients treated with Tesomet was on average two to four times higher than anticipated when compared to the plasma concentration in other patient groups from previous clinical trials who were given the same dose. The observed plasma concentration may be explained in part by a lower metabolic rate and clearance of tesofensine in Prader-Willi patients and their high body fat percentage.
- The cardiovascular parameters such as heart rate and blood pressure did not vary significantly compared to placebo despite the high concentration of tesofensine in patients receiving Tesomet.
- There were no reports of serious adverse events in the trial. However, there were reports of adverse events in all patients participating in the trial, which is typical in clinical trials in this patient group. Of the reported adverse events, 67 % of the placebo group and 83 % of the treatment group were qualified as possible or probably treatment related. In the treatment group, the adverse events included an exacerbation of already occurring behavioral problems and CNS disorders, which were reversed after the completion of the study or in two cases where patients were offered a temporary reduction in dose during the study.

Jørgen Drejer concluded, "We are pleased with the observed reduction in weight loss and food craving in this very small and short exploratory study for a difficult patient population. We believe that by reducing the dose, it may be possible to reduce the plasma concentration to a level where tesofensine is better tolerated in this highly sensitive patient group, and at the same time remain efficacious, as demonstrated in other patient groups. The results of this exploratory Phase 2a study supports further study of Tesomet in Prader-Willi syndrome, and we will discuss with key experts in the field how to pursue this opportunity. In parallel, Tesomet studies in other indications continue as planned".

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, 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, Proximagen Ltd., Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq Stockholm Small Cap and has about 5,300 shareholders. The company's share is traded under the ticker SANION. Read more at www.saniona.com.