PRESS RELEASE

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Saniona reports positive top line results from the Tesomet Phase 2a study in type 2 diabetes

Saniona, a leading biotech company in the field of ion channels, today announces positive top line results from its Phase 2a clinical trial for Tesomet in patients with type 2 diabetes. The primary endpoint showed statistically significant reduction in heart rate for patients treated with Tesomet compared to placebo. Furthermore, the key secondary and exploratory endpoints regarding body weight and waist circumference also showed statistically significant reductions compared to placebo. Glycemic secondary endpoints were not statistically significantly different from placebo in this rather short study.

"The positive outcome of this Phase 2a study is highly encouraging. The new data together with data from previous clinical studies with tesofensine supports the use of Tesomet as a safe and effective weight loss drug in patients with metabolic disorders like diabetes and obesity. It may potentially also be used for patients with eating disorders like binge eating disorder and Prader-Willi syndrome. We are impressed that Tesomet provides such robust weight loss and at the same time reduce cardiovascular risk factors in a relatively small and short study in a difficult patient population," says Jørgen Drejer, CEO at Saniona.

The clinical trial achieved a positive outcome on the primary endpoint with a statistically significant reduction in heart rate for patients treated with Tesomet. The 24 hours mean heart rate was reduced by an average of 4.3 beats per minute (bpm) for patients treated with Tesomet compared to an average decrease of 0.2 bpm for patients dosed with placebo ($p=0.0038$)[1].

In addition, there was a numerical reduction related to the secondary endpoints on systolic and diastolic blood pressures. Systolic and diastolic blood pressures were, respectively, numerically reduced by an average of 3.1 and 2.2 mmHg for patients treated with Tesomet compared to an average decrease of 0.7 and 0.2 mmHg for patients dosed with placebo.

Tesomet also showed efficacy in relation to weight reduction endpoints as treatment with Tesomet resulted in statistically significant reduction in body weight and waist circumference. In the 12-week study period, treatment with Tesomet resulted in a reduction in body weight of 3.5 kg (3.5%) from a baseline of 99.0 kg to 95.5 kg compared to a reduction of 0.3 kg (0.3%) for patients receiving placebo ($p<0.0001$). The reduction in body weight correlated with a reduction in waist circumference of 2.29 cm in the Tesomet treatment group compared to a reduction of 0.03 cm for patients receiving placebo ($p<0.01$).

Also, preliminary data suggest a numerical reduction in liver fat content for patients treated with Tesomet, but a full analysis is not available in the top line report.

Glycemic secondary efficacy endpoints including HbA1c were not significantly reduced in this rather short study. Further sub-analysis of these data are ongoing.

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[1] The presented results for all endpoints are based on full analysis data set.

“Our initial take on the data is that Tesomet has the potential to become a highly effective weight loss product with a benign safety profile that may reduce long term cardiovascular risk factors. About 80% of patients with type 2 diabetes have cardiovascular risk factors including high blood pressure. Data clearly supports that Tesomet can be targeted for this large group. Furthermore, we remain optimistic about the possibility to address glycemic endpoints in long term studies due to the statistical significant reduction in weight loss seen already after 12 weeks and the numeric reduction in liver fat achieved in this study,” says Jørgen Drejer, CEO of Saniona.

The Phase 2a trial comprised a total of 60 patients of which 58 completed the trial. The two patients, who did not complete the trial, were both in the placebo group. There was only reported one serious adverse event, which occurred in a patient dosed with placebo. In general, Tesomet was very well tolerated with low incidence of adverse events. The most frequently reported adverse events in patients treated with Tesomet (incidence ≥10%, n≥3) were dry mouth, nausea, impaired gastric emptying, fatigue, sweating, muscle spasm, dizziness, headache, and restlessness. Apart from fatigue, muscle spasm and restlessness, the above adverts events were also reported in patients dosed with placebo.

“Even though it was expected that the study would demonstrate a very benign adverse event profile based on previous experience with tesofensine and metoprolol monotherapy, we are very pleased that we now have these data in hand from this Phase 2a study. These results will be very important for the further development and potential registration of Tesomet in metabolic diseases and eating disorders”, says Jørgen Drejer, CEO of Saniona.

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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, Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona’s Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Inc. 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 4,600 shareholders. Pareto Securities is Certified Advisor for Saniona. The company’s share is traded under the ticker SANION. Read more at www.saniona.com.