

PRESS RELEASE

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Saniona's tesofensine meets primary and secondary endpoints in Phase 3 obesity registration trial

Saniona (OMX: SANION), a biotech company focused on CNS and eating disorders, today announced statistically and clinically significant weight loss for both doses of tesofensine compared to placebo in its Phase 3 Viking study with oral tesofensine in obesity. By demonstrating significant and superior weight loss for both doses of tesofensine compared to placebo, the trial achieved its primary objective. In general, tesofensine was very well tolerated with low incidence of adverse events. The study was conducted by its partner Medix® in Mexico.

Highlights and implications of the study:

- Ten per cent average weight loss in 24 weeks
- More than half of patients lost more than ten per cent in weight
- Statistically significant reduction in key obesity-related risk factors
- Partner Medix, which owns commercial rights in Mexico and Argentina, will now prepare regulatory filings in those territories
- Results support the development of Saniona's wholly-owned Tesomet comprising tesofensine and currently in Phase 2 for rare eating disorders

The 24-week double-blinded, randomized, placebo-controlled trial investigated the efficacy and safety of once-daily 0.25 and 0.50 mg oral tesofensine compared to placebo in 372 obese patients. The study's primary endpoint was the average percentage and absolute change in body weight compared to placebo. Secondary endpoints included the percentage of patients achieving weight loss of at least five per cent and ten percent of baseline body weight.

Two populations were used for statistical analysis, the intent-to-treat population with the last observation carried forward (ITT-LOCF)ⁱ and the completers populationⁱⁱ. The trial achieved its primary objective by demonstrating significant and superior weight loss for both doses of tesofensine compared to placebo in both tested populations (ITT-LOCF: $p < 0.001$, Completers: $p < 0.001$).

This registration study confirmed the compelling efficacy and favourable safety profile of tesofensine in obesity previously observed in Phase 2. We believe that these data will provide us with a solid basis to prepare regulatory filings of tesofensine in Mexico and Argentina", said Carlos López Patán, Director General of Medix.

"These positive Phase 3 data can potentially also be used for filings in other geographies where obesity represents an increasing unmet medical need and an important commercial opportunity for Saniona. The strong weight loss is driven by tesofensine's ability to reduce appetite and craving for food. Together with the favorable safety profile, these data strongly support our fully-owned program with Tesomet in rare eating disorders such as Prader Willi syndrome and hypothalamic obesity, since tesofensine is the key active compound in our proprietary formulation of Tesomet", said Jørgen Drejer, CEO of Saniona.



At week 24, both treatment groups obtained highly statistically and clinically significant reductions on all major efficacy endpoints compared to placebo including average percentage and absolute change in body weight, reduction in BMI and the proportion of patients achieving weight loss of at least five per cent and ten per cent of baseline body weight.

Statistically and clinically significant reductions in obesity-related risk factors were also observed in tesofensine-treated participants compared with those receiving placebo including, waist circumference, hip circumference, body fat, visceral fat, very-low-density lipoprotein (“bad”) cholesterol, triglycerides and insulin.

Medix and Saniona will provide further details about the results from this registration trial after having secured potential intellectual property rights and data protection rights.

“The robust reduction of both abdominal/visceral and subcutaneous fat stores and strong reduction in blood cholesterol and triglycerides as well as marked reduction in insulin after treatment with tesofensine further support previous data suggesting a better regulation of glucose metabolism in obese patients after treatment with tesofensine and the potential of reversing early type 2 diabetes”, said Jørgen Drejer, CEO of Saniona.

In general, tesofensine was very well tolerated with low incidence of adverse events and very similar to placebo. A similar pattern was observed when measuring cardiovascular effects, with a low but statically significant increase in heart rate and no significant effect on blood pressure at any of the doses tested.

The combined clinical safety data base from more than 20 clinical trials with tesofensine now contains approximately 1,600 patients exposed to relevant therapeutic doses for up to a year, providing a robust safety data set to support filings in Mexico and Argentina and potentially in other geographies, as well as the further development of Tesomet in rare eating disorders.

For more information, please contact

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This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 01:00 p.m. CET on December 18, 2018.

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 four 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.



About Productos Medix, S.A de S.V (Medix)

Medix is a Mexican pharmaceutical company established in 1956. Medix is primarily focused on treatment of overweight and obesity. The company is the market leader for treatment of overweight and obesity in Mexico where it offers the most comprehensive product and service line. Medix's leading product for treatment of overweight and obesity is among the top ten pharmaceutical products in Mexico overall. Medix has earned several recognitions for its social responsibility through its participation in philanthropic programs for the benefit of the Mexican population and for its educational efforts involving thousands of doctors in Mexico. The company has subsidiaries in Argentina and certain other South American countries.

About the Phase 3 Viking study

The Phase 3 program was a 24-week, randomized, double-blinded, placebo-controlled, three-armed, parallel, longitudinal trial comparing the efficacy, safety and satisfaction of two dose levels of once-daily oral tesofensine vs placebo in people with obesity treated with diet and exercise only. 372 patients were enrolled in the Phase 3 study and randomized 1:1:1 to receive either a dose of oral tesofensine (0.25 and 0.50 mg) or placebo once daily. The primary endpoint was percent change in body weight from baseline at week 24. From the beginning of the lead-in period and until the end of the follow-up period, all patients in the study followed the same reduced-calorie diet and the same exercise programme.

About Tesofensine

Tesofensine is a triple monoamine re-uptake inhibitor, i.e. a compound that blocks the re-uptake of the neurotransmitters serotonin, dopamine and noradrenaline in the brain with no direct effect on the monoamine receptors. The mechanism of action behind this class of compounds is very well described. Serotonin, dopamine and noradrenaline are all involved in the brain's central regulation of food intake, metabolic control and in subsequent weight control. Tesofensine's relative impact on the three monoamine systems is believed to induce weight reduction through both a reduction in appetite, in craving for food and an effect in the metabolic center in the brain leading to increased thermogenesis.

Tesofensine has been evaluated in Phase 1 and Phase 2 human clinical studies with the aim of investigating treatment potential with regards to obesity, Alzheimer's disease and Parkinson's disease. Tesofensine demonstrated strong weight reducing effects in Phase 2 clinical studies in obese patients. In general, tesofensine has been administered to more than 1,600 patients and is well tolerated.

About Obesity - clinical condition

Obesity is characterized by severe excess weight in the form of fat and is defined on the basis of a measure referred to as Body Mass Index (BMI). A BMI of more than 30 is referred to as clinical obesity, while a BMI of between 25 and 30 expresses overweight. According to the World Health Organization (WHO), obesity has reached epidemic proportions globally, with up to 1.6 billion adults (over 15 years old) overweight and at least 400 million of them clinically obese.



According to the American Obesity Association (Obesity Fact Sheet), patients with obesity are at risk of developing one or more serious medical conditions, which can cause poor health and premature death. Obesity has been found to be the largest environmental influence on the prevalence of diabetes and it complicates the management of type 2 diabetes by increasing insulin resistance and glucose intolerance, which makes the medical treatment for type 2 diabetes less effective. Approximately 90 per cent of individuals with type 2 diabetes are reported to be overweight or obese. In addition, obesity increases the risk of cardiovascular disease, and is a major risk factor for heart attack. Over 75 per cent of hypertension cases are reported to be directly attributed to obesity. A weight loss of as little as 5 per cent can reduce high blood sugar and blood cholesterol.

About overweight and obesity in Mexico

Mexico ranks among the most obese country in the world. It is estimated that more than 70 per cent of the 128 million Mexicans are overweight and that more than 30 per cent are clinical obese. Since the 1990s, fat has become the principal source of energy in the Mexican diet and it is assumed that the consumption of highly processed food will continue increasing. Consequently, Mexico has seen the same kind of health issues that other countries with overweight populations have. Standardized mortality rates (SMR) for diabetes, acute myocardial infarction (AMI), and hypertension have increased dramatically. As of 2012, diabetes - associated with obesity - was the largest single killer in Mexico.

ⁱ The ITT-LOCF analysis is based on all randomized patients who receive at least one dose of study drug and have at least one post-baseline assessment of body weight. The analysis is based on the last observations made during the study (carried forward) if patients do not complete the study.

ⁱⁱ The completers analysis is based on all randomized patients who came in for the baseline visit and the 24-week visit. This means that patients who were missing any visits in the middle were still included.