PRESS RELEASE

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Saniona's partner, Medix, obtains approval to initiate Phase 3 study in obesity

Saniona, a leading biotech company in the field of ion channels, today announces that the Mexican regulatory authority, Cofepris, has approved Medix's Phase 3 clinical study for tesofensine in obese Mexican patients. This Phase 3 study will include 372 patients at two sites in Mexico under the management of Medix. Medix expects to initiate the study following importation and subsequent release of the drug product. The trial is expected to be completed within two years from initiation.

"We are very excited about the collaboration with Medix. Their professional team has demonstrated a strong commitment to develop and commercialise novel treatment paradigms for overweight and obesity in Mexico where they have been market leaders for several years. This is probably the most important milestone for Saniona since we became operational in 2012," says Jørgen Drejer, CEO of Saniona.

The primary objective of this Phase 3 study is to evaluate efficacy and safety of tesofensine in adult Mexican patients with obesity.

"The initiation of the Phase 3 study for tesofensine in obesity represents an important step towards market approval. Tesofensine has shown outstanding weight loss in a Phase 2 clinical study in obese persons. Tesofensine has been tested in more than 1,300 patients and was in general well tolerated. Therefore, tesofensine has the potential to become the preferred treatment option for an important health problem in Mexico," says Carlos López Patán, CEO of Medix.

This randomized, double-blind, placebo-controlled, parallel-arm, Phase 3 clinical trial will include up to 372 ambulatory adult patients with obesity. The patients are randomized into three arms with 124 patients in each arm receiving either 0.25 mg tesofensine, 0.5 mg tesofensine or placebo tablets once daily. The study starts with a 2-week run-in period followed by 24 weeks treatment period.

The primary endpoint is absolute and percent change in body weight over the treatment period. Secondary endpoints include proportions of patients achieving a weight loss of more than 5 and 10 percent respectively, metabolic including glycaemic endpoints, as well as quality of life, comprehensive tolerability and safety evaluation.

In February 2016, Saniona entered a collaboration with Medix about the development and commercialization of tesofensine and Tesomet in Mexico and Argentina. Medix has exclusive rights to develop and commercialize tesofensine and Tesomet in the two countries and will finance and be responsible for the clinical development and regulatory filings. Saniona retains all rights to tesofensine and Tesomet including the exclusive rights to use the clinical data developed by Medix in the rest of the world. Medix will pay Saniona regulatory milestone payments and double-digit royalties on product sales.

For more information, please contact

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This information is information that Saniona (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 08:00 CET on April 12, 2017.

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 and Luc Therapeutics, 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 4,500 shareholders. Pareto Securities is Certified Advisor for Saniona. The company's share is traded under the ticker 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 overweight and obesity in Mexico

Mexico ranks the most obese country in the world. It is estimated that more than 70% of the 128 million Mexicans are overweight and that more than 30% 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.

Obesity is characterised 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 25-30 expresses excess weight. Obesity is a serious clinical condition that involves a notably increased risk of cardiovascular diseases and the development of type 2 diabetes. According to the World Health Organization, obesity has reached epidemic proportions worldwide with more than one billion overweight adults of whom at least 300 million are clinically obese. Today, there is a strong medical need for more effective treatment options for obesity.

About tesofensine

Tesofensine, a monoamine uptake inhibitor, is focused on obesity. 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 1,200 patients and is well tolerated.

Mode of Action – Tesofensine potentiate dopamine

Pathological overeating and obesity can be caused by decreased dopamine function in the reward centre of the brain. Dopamine transporter proteins are inhibited by tesofensine, so the dopamine receptors are stimulated for a longer period after activation and the brain's reward system is amplified. With a similar mechanism of action tesofensine also increases levels of two other monoamines, serotonin and noradrenaline.

Each of these transmitters exert an important function on appetite and metabolism at different locations in the brain. Dopamine acts in the nucleus accumbens of the forebrain to modulate reward and the "pleasure"-feeling of food. The two other transmitters act in the hypothalamus to increase metabolism and reduce appetite.

The unique efficacy of tesofensine in obesity may be explained by reversal of blunted dopamine response in obese patients. In obese individuals, the brain centre (striatum) controlling consummatory food reward dopamine receptors are reduced relative to lean individuals. It has been found that in the relevant brain region more than 70% of obese individuals have a blunted dopamine response to food intake.

Clinical Programs - Tesofensine has produced superior weight loss data.

The clinical Phase 2b trial (TIPO-1) reported in The Lancet showed levels of weight loss over a six-month period that were of high clinical relevance and highly competitive to other approaches. Patients lost an average of 12.8 kg on a 1 mg dose, 11.3 kg on a 0.5 mg dose and 6.7 kg on a 0.25 mg dose compared with a 2.2 kg loss in the placebo group. All participants were instructed to follow a diet with a 300 kcal deficit and to increase their physical activity gradually to 30-60 minutes of exercise per day. Of the patients receiving 0.5 mg daily, considered the relevant therapeutic dose, 87% of the patients (58% versus placebo) achieved more than 5% weight loss and 53% of the patients (46% versus placebo) achieved a weight loss of more than 10% after 6 months follow up.

There has also been reported interim results from a 48-week, open-label extension trial (TIPO-4) in which 140 patients who completed the 24-week Phase 2b trial (TIPO-1) were re-enrolled after an average of three months' wash-out. All of them were then treated with 0.5 mg tesofensine once daily but up-titration to 1 mg once daily was allowed in the first 24 weeks of the extension study. The 24-week interim results for those who were previously treated with 0.5 mg tesofensine in TIPO-1 showed a total mean weight loss of between 13 kg and 14 kg over 48 weeks of treatment. Furthermore, TIPO-4 confirmed the TIPO-1 results since the patients who were previously treated with placebo lost approximately 9 kg in the first 24 weeks of the TIPO-4 study.