



PRESS RELEASE

February 1, 2018

Saniona's Partner, Medix, Completes Recruitment of Phase 3 Obesity Study of Tesofensine in Mexico

Saniona, a leading biotech company in the field of ion channels, today announced that its partner in Mexico, Medix, has completed recruitment for its Phase 3 clinical study of tesofensine in obesity. The trial is expected to be completed in 2018 and topline data is expected by early 2019.

"Our collaboration with Medix represents a key pillar of our strategy for the development of tesofensine and Tesomet in metabolic indications. Not only will the study increase the efficacy and safety database for tesofensine thereby supporting further development of Tesomet; we believe that the potential commercialization of tesofensine in Mexico may provide significant financing for Saniona through royalty income in the coming years. We are very pleased by our partner's rapid recruitment, which was completed within an impressive five months. We are optimistic about completing and reporting topline data by early 2019, almost one year earlier than originally announced," commented Jørgen Drejer, Chief Executive Officer of Saniona.

Carlos López Patán, Chief Executive Officer of Medix, added, "In previous studies, tesofensine has demonstrated highly statistically and clinically significant weight loss in obese patients and we are confident that this study will further validate tesofensine as a novel and effective obesity treatment. This pivotal Phase 3 clinical trial for tesofensine may pave the way towards the submission of an application dossier in 2019 and subsequent potential market approval in Mexico, where obesity represents a severe health problem."

The randomized, double-blind, placebo-controlled, parallel-arm, Phase 3 clinical trial includes 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 for 24 weeks. 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 into a collaboration with Medix for the development and commercialization of tesofensine and Tesomet in Mexico and Argentina. Medix has exclusive rights to develop and commercialize tesofensine and Tesomet in these two countries. Medix will finance the studies and be responsible for the clinical development and regulatory filings. Under the agreement, Medix will pay Saniona regulatory milestone payments and double-digit royalties on product sales in Mexico and Argentina. Saniona retains all rights to tesofensine and Tesomet in the rest of the world including the exclusive rights to use the clinical data generated by Medix.

For more information, please contact

Thomas Feldthus, EVP and CFO, Saniona, Mobile: +45 2210 9957, E-mail: tf@saniona.com

This information is information that Saniona (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and Sweden's Securities Market Act. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on February 1, 2018.



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.

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 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 WHO, 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.