PRESS RELEASE

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Saniona completes recruitment of patients in Phase 2a study for Tesomet in type 2 diabetes

Saniona, a leading biotech company in the field of ion channels, today announces that it has recruited the last patient in the Phase 2a clinical studies for Tesomet in type 2 diabetes. The trial comprises a total of 60 patients. Saniona expects to report top line results from the study early 2017.

"We announced the initiation of this study on April 20 this year. We have now completed the recruitment of the 60 patients for this important Phase 2a study, which means that the last patient has had the first visit. The last patient will be treated for 90 days and meet for a follow up visit after another 20 days. We will then be able to start the data lock procedure and have the data analysed by independent statisticians. We are therefore optimistic that we may be able to report the results early 2017," says Jørgen Drejer, CEO of Saniona.

The study is conducted by Profil Germany at two of their clinical sites in Germany. The primary objective of the Phase 2a study is to examine whether Tesomet is neutral on heart rate in patients with type 2 diabetes. The secondary objective is to investigate whether Tesomet provides a reduction in blood glucose level, body weight and liver fat in patients with type 2 diabetes. The double blind, placebo controlled study comprises a total of 60 patients, where 30 patients will receive Tesomet (tesofensine 0.5 mg + metoprolol 100 mg daily) and 30 patients will receive matching placebo for a total of 12 weeks.

Further details about the trial can be found at ClinicalTrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02737891?term=tm001&rank=1

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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 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 4,400 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 Tesomet and tesofensine

- Tesofensine has in a Phase 2 study in obese patients shown body weight and fat reducing efficacy, which is superior to any of the current weight loss agents on the market. Tesofensine has also shown a significant reduction of key glycaemic parameters in a pre-diabetic subgroup of obese patients.
- Tesofensine has been dosed to approximately 1,300 healthy volunteers and patients with no unexpected side effects.
- There is full toxicology package on tesofensine, which has been reviewed and accepted by regulatory authorities. In general the adverse effect profile at therapeutic doses is similar to placebo.
- The combination of tesofensine and Metoprolol showed no clinically relevant drug-drug interaction in a Phase 1 study and a single dose of Metoprolol mitigated the tesofensine-induced increase in heart rate.
- Tesomet, the combination of tesofensine and metoprolol, has shown a desired cardiovascular profile without any loss of tesofensine' s weight reducing efficacy in an animal study.
- Saniona has now received approvals for initiating a Phase 2a clinical proof of concept study with Tesomet in patients with type 2 diabetes in Germany.
- If successful, Tesomet should provide an attractive profile combining a clinically meaningful anti-diabetic effect with unmatched weight loss together with a benign side effect profile.
- New IP estate - Recently approved and filed patent applications on the Tesomet product should provide protection until 2033.

In 2014, Saniona acquired tesofensine, a triple monoamine uptake inhibitor, which blocks reuptake of dopamine, serotonin and noradrenaline regulating appetite. This triple mode of action leads to a reduction in hunger, a feeling of satiety ("food addiction") and an increase in the metabolic drive.

Saniona intends to position Tesomet as a fix-dosed combination of tesofensine and metoprolol for treatment of type 2 diabetes. In addition to providing substantial weight loss in obesity, tesofensine has also the potential to treat type 2 diabetes by reducing liver fat.

Saniona believes that tesofensine represents an interesting new treatment option for type 2 diabetes, which not only may be used in parallel with existing treatments, but also may offer additional long-term benefits through its disease modifying properties directly affecting the pathophysiology of the disease. In general, tesofensine has been well tolerated in human clinical studies. However, an increase in heart rate has been observed at therapeutic doses of tesofensine. Several patent applications have been filed to protect the combination tesofensine and Metoprolol. Saniona already has an issued patent in the U.S., which includes the combination of tesofensine and Metoprolol and which will provide protection in the United States until 2033. The combination product is also covered by other recent Saniona patent applications with broad geographic coverage. Saniona has recently published new results from datamining of previous clinical studies, which show that tesofensine improved glycaemic parameters in prediabetes individuals participating in a Phase 2 obesity study and that Metoprolol blunts the increase in heart rate caused by tesofensine in volunteers in a Phase 1 study.

About Type 2 diabetes and the current medical treatment

Type 2 diabetes is a progressive disease characterised by hyperglycaemia resulting from a combination of insulin resistance and insulin secretion defects. Despite the wide prevalence of type 2 diabetes, the

understanding of the disease remains incomplete – particularly with respect to disease progression. Cellular stress and inflammation e.g. induced initially by excess liver fat can result in the release of fatty acids that eventually will reduce the insulin producing ability of pancreatic β-cells and lead to build up of further liver fat. This results in an accelerating cycle where the body is increasingly unable to deal with glucose, which leads to even higher blood glucose levels. The increased glucose level is slowly causing damages to vital organs, renal and cardiovascular complications, blindness, amputation and death.

Type 2 diabetes accounts for about 90% of diabetes cases. According to the International Diabetes Federation, the estimated number of diabetes sufferers worldwide was more than 400 million in 2014, and the number of adults with diabetes is predicted to increase to 642 million by 2040. Although not all sufferers are diagnosed, the market is very large and will continue to grow. While all current anti-diabetic medications in general are temporarily effective at managing the symptoms of the disease, the disease inexorably aggravates with time with grave consequences. There is substantial unmet medical need and thus large market potential for a diabetes therapy with a new mechanism-of-action and a good safety profile, even in the absence of break-through efficacy. There are several recent examples demonstrating that secondary or third line treatments show robust uptake and worldwide sales nearing or exceeding $1B within a year from launch.

About the role of weight loss in treatment of type 2 diabetes

Severe overweight and obesity is a major health problem in the developed world with a substantial number of people becoming clinically obese resulting in serious health problems. Obesity often leads to accumulation of fat in the liver that has been shown to have multiple deleterious consequences.

It has become clear in recent years that the accumulation of fat in the liver has a direct effect on the development of type 2 diabetes and that lowering body fat level by bariatric surgery or severe dieting can lead to normalization of diabetic symptoms and long term remission in type 2 diabetes; and independent studies show that bariatric surgery, gastric banding and hypocaloric dieting lead to reversal of type 2 diabetes to normal metabolic control and insulin secretion. Observation of and insights into the underlying pathophysiologic mechanisms (including the behaviour of the liver and pancreas) during the reversal of type 2 diabetes led to formulation of the so-called twin cycle hypothesis of the etiology and pathogenesis of type 2 diabetes:

"*The accumulation of fat in liver and secondarily in the pancreas will lead to self-reinforcing cycles that interact to bring about type 2 diabetes. Fatty liver leads to impaired fasting glucose metabolism and increases export of very low density lipoprotein (VLDL) triacylglycerol, which increases fat delivery to all tissues, including the islets. The liver and pancreas cycles drive onward after diagnosis with steadily decreasing β-cell function. However, of note, observations of the reversal of type 2 diabetes confirm that if the primary influence of positive calorie balance is removed, then the processes are reversible"* (Roy Taylor, Diabetes Care, volume 36, 2013).

Bariatric surgery resulting in about 20 kg weight loss and severe diet has been shown to reduce and even reverse type 2 diabetes. Tesofensine has been shown to cause more than 15 kg reduction in body weight in many overweight patients, and Saniona believes that tesofensine in the combination with metoprolol (Tesomet) can cause a sufficient reduction in body weight and in particular liver fat to successfully manage type 2 diabetes and subsequently be approved by regulatory authorities for this indication.