



PRESS RELEASE

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Saniona initiates confirmative Phase 2a study with Tesomet in the first half of 2016

Saniona, a leading biotech company within ion-channel research, announces that it expects to initiate a confirmatory Phase 2a study with Tesomet in the first half of 2016. Tesomet is a combination of Tesofensine and Metoprolol for treatment of type 2 diabetes. The objective is to confirm the recently published analyses of clinical data that provides clear evidence of the use of Tesomet as a treatment for type 2 diabetes.

"This is an important step for us in Saniona. Just a year and a half ago, we listed the company at AktieTorget. Now, we can already see that we will become a Phase 2 company with a compound in the clinic, which addresses one of the largest pharmaceutical markets in the world," says Jørgen Drejer, CEO of Saniona.

"In addition, our product, NS2359, against cocaine addiction may quickly enter Phase 2 if we receive public funding in support of this study. University of Pennsylvania is currently pursuing such funding for NS2359 together with Saniona."

The management of Saniona has reviewed the opportunity for positioning Tesomet for type 2 diabetes. On September 21, Saniona published new results from datamining of previous clinical studies, which show that tesofensine improved glycemic 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.

The ultimate objective with Tesomet is to offer a treatment, which may help patients with newly developed type 2 diabetes to become normalised in this serious disease.

"The new results from our datamining are remarkably consistent and we have now given this study high priority. We have worked a long time on the positioning of Tesomet for type 2 diabetes and we are now confident that this is the right way forward."

Saniona provides the following reasons for positioning Tesomet for type 2 diabetes:

- **Market** – is huge and growing dramatically as obesity and welfare diseases are becoming an increasing problem. According to Datamonitor, weight-reducing therapy options will drastically increase the value of the type 2 diabetes market over the next 10 years. Datamonitor estimates the type 2 diabetes market to grow from \$ 23.3 billion in 2014 to \$ 43 billion in 2023.
- **Regulatory considerations** – most countries consider type 2 diabetes as a serious disease that requires treatment whereas many countries see obesity as a life style issue that may not require treatment today.
- **Medical reasons** – recent research shows that type 2 diabetes can be reversible and that large proportion of patients will undergo long-term remission if they achieve a substantial weight loss (Roy Taylor - Diabetes Care, 2013).

"Saniona will now conduct a Phase 2a study for Tesomet in type 2 diabetes patients in order to confirm that Tesomet will cause a clinically relevant reduction in HbA1c in type 2 diabetic patients and that metoprolol in Tesomet counteracts the heart rate increasing effect of tesofensine. The production of the clinical materials



for the Phase 2a study has been initiated and, we have identified the clinical site to perform the study. We expect to initiate the regulatory filing of the study protocol early next year.”

Saniona has engaged a number of experienced clinicians and regulatory experts to the company as consultants. In addition, Saniona is working together with key opinion leaders within the metabolic field.

For more information, please contact

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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 an ongoing collaboration agreement with Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Idec Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard and 18 employees. Saniona is listed at AktieTorget since April 2014 and has about 2,000 shareholders. The company's share is traded under the ticker SANION. Read more at www.saniona.com.