PRESS RELEASE

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Sania reports UPenn to continue cocaine addiction study with NS2359 at higher dose after blinded interim analysis

- University of Pennsylvania Treatment Research Center continues investigator-initiated study
- Decision based on interim analysis of blinded data for first 50 patients
- Good scientific rationale for NS2359 to combat cocaine addiction, alcohol abuse

Sania, a biotech company focused on CNS and eating disorders, announced today that the University of Pennsylvania Treatment Research Center (TRC) plans to continue the ongoing Phase 2a study for NS2359 in cocaine addiction at a higher dose. TRC’s decision is based on an interim analysis of the blinded data for the first 50 patients enrolled.

While the blinded interim analysis was not aimed at detecting statistically significant differences between the treatment groups (placebo versus NS2359), the investigators concluded that there was sufficient support to warrant continuation of the study at a higher dose. Since the study will be continued, the results and data remain blinded. In general, NS2359 appeared to be well tolerated and data from other studies supports the use of higher doses to exploit the full potential of the drug in this indication.

Jørgen Drejer, CEO of Saniona, said, “While our priority is the development of Tesomet to treat rare eating disorders, we have followed with interest TRC’s investigator-initiated study for NS2359 in cocaine addiction. Both Saniona and the TRC believe there is good scientific rationale, supported by preclinical and clinical evidence, for NS2359 to combat cocaine addiction and alcohol abuse, which are significant public health problems and potentially important commercial opportunities for Saniona. Therefore, we are pleased that TRC plans to continue this investigator-initiated study.”

The Phase 2a study is funded by non-dilutive grants and conducted by TRC at the University of Pennsylvania’s treatment facility at the PENN / VA Center for the Studies of Addiction (CSA). Saniona has provided NS2359 drug substance for the trial. The double blind, placebo-controlled study comprises a total of up to 80 patients, where half of the patients receives NS2359 and half of the patients receive matching placebo for a total of 8 weeks. TRC has performed an interim analysis following the completion of 50 patients. The study is supported by grants from the Dana Foundation and the Groff Foundation.

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 08:00 a.m. CET on January 23, 2019.
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.