

PRESS RELEASE

June 30, 2021

Saniona Initiates Phase 1 Clinical Trial of SAN711

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that it has dosed the first patient in a Phase 1 clinical trial of SAN711, a novel molecule derived from Saniona's proprietary ion channel drug discovery engine. SAN711 is a first-in-class positive allosteric modulator of GABA-A $\alpha 3$ receptors and may be applicable in the treatment of rare neuropathic disorders. Data from the trial are expected in the first half of 2022.

The Phase 1 clinical trial will be conducted in approximately 80 healthy volunteers. The primary objective of the study is to determine the tolerability and the maximum tolerated dose of SAN711, which will be evaluated through single ascending dose and multiple ascending dose phases of the study. The secondary objective is to measure binding to target receptors, which will be assessed during a positron emission tomography (PET) evaluation phase of the study. The clinical trial is being conducted in the United Kingdom (U.K.) under the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA). After completion of the Phase 1 clinical trial, Saniona intends to select a lead indication and file an Investigational New Drug (IND) application with the United States Food & Drug Administration (U.S. FDA) to support Phase 2 studies for SAN711 in the U.S.

"SAN711 has demonstrated efficacy in multiple preclinical models of neuropathic pain, and we look forward to assessing its potential in clinical trials," said Rudolf Baumgartner, M.D., Chief Medical Officer and Head of Clinical Development at Saniona. "Importantly, SAN711 is the first product candidate from Saniona's proprietary ion channel drug discovery engine that our team has internally advanced into clinical trials. We believe it will be the first of many, as we have multiple additional ion channel modulators in research and preclinical development."

For more information, please contact

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The information was submitted for publication, through the agency of the contact person set out above, at 12.45 CEST on 30 June 2021.

About Saniona

Saniona is a biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for rare disease patients around the world. The company's lead product candidate, Tesomet, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, severe rare disorders characterized by uncontrollable hunger and intractable weight gain. Saniona's robust drug discovery engine has generated a library now consisting of more than 20,000 proprietary modulators of ion channels, a significantly untapped drug class that is scientifically validated. Lead candidate SAN711 is in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders, with SAN903 for rare inflammatory and fibrotic disorders advancing through preclinical development. Led by an experienced scientific and operational team, Saniona has an established research organization in Copenhagen, Denmark and a corporate office in the Boston, Massachusetts area, U.S. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

About SAN711

SAN711 is a first-in-class positive allosteric modulator of GABA-A $\alpha 3$ receptors that may be applicable in the treatment of rare neuropathic disorders. SAN711 emerged from Saniona's proprietary ion channel drug discovery engine and was designed to selectively enhance the effects of GABA-A on $\alpha 3$ containing receptors. Preclinical studies have indicated that this selectivity may allow SAN711 to provide pain relief and other benefits in the central nervous system while avoiding the typical adverse effects associated with non-selective GABA-A activation such as sedation, motor instability, cognitive impairment, abuse liability and physical dependence. Saniona is currently evaluating SAN711 in a Phase 1 clinical trial.