PRESS RELEASE

June 30, 2022

Saniona reports positive top line results from the SAN711 Phase 1 Clinical Trial

Saniona (OMX: SANION), a clinical stage biopharmaceutical company, today announced that it has successfully completed its Phase 1 clinical trial of SAN711, which is positioned for the treatment of neuropathic pain disorders. Data from the trial demonstrated that SAN711 was safe and well tolerated across all dosing cohorts with a favorable absorption and distribution profile. There were no serious adverse events, and all subjects completed the study. Long term dosing with SAN711 at a well tolerated dose of 0.8 mg twice a day resulted in 24-hour receptor occupancy ranging between 50% and 72% assessed to lead to desired pharmacological effects. The results of this Phase 1 clinical trial open the path for continued clinical development of SAN711.

The Phase 1 clinical trial was conducted in 66 healthy volunteers. The primary objective of the study was to determine the safety and tolerability of SAN711, which was evaluated through single ascending dose and multiple ascending dose phases of the study. The secondary objective was to measure binding to target receptors, which was assessed during a positron emission tomography (PET) evaluation phase of the study. The clinical trial was conducted in the United Kingdom (U.K.) under the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA).

"We are highly encouraged to see that our predictions from preclinical studies are reproduced so nicely in human volunteers", said Karin Sandager Nielsen, CSO. "As expected SAN711 was very well absorbed, distributed, and tolerated in humans. SAN711 shows clear differentiation in its side effect profile compared to classical, non-selective GABA modulators of the benzodiazepine type such as valium which is dose limited by sedation. Importantly, we have in this study demonstrated that we can safely exceed human exposure levels of SAN711 beyond what is needed to show strong efficacy in our preclinical pain models".

SAN711 was safe and well tolerated across all dosing cohorts. There were no serious adverse events, and all subjects completed the study. Adverse events were mostly mild, and the few adverse events of moderate intensity were, apart from two, assessed to be non-related to drug administration. There were no safety laboratory concerns, cardiovascular concerns, and no abnormal neurological examinations, including Mini Mental State Examinations. SAN711 was absorbed rapidly following single oral doses of 0.1 to 2.25 mg/kg (mean T_{max} of 0.75 h - 2.08 h). Linear pharmacokinetics was observed and the mean half-life for elimination (T½) ranged between 7.4 and 12.3 h over all dose levels. Maximum plasma levels of SAN711 reached up to 1577 ng/ml corresponding to 84% occupancy of all target receptors. PET results confirmed the hypothesis that a pharmacologically active receptor occupancy may be achieved at well-tolerated doses of SAN711. In the multiple ascending dose phase, a well tolerated dose of 0.8 mg/kg twice daily led to plasma levels consistent with 24-hour receptor occupancy ranging from 50% to 72%. Based on pre-clinical data, this exposure level is predicted to result in desired therapeutic effects.

Thomas Feldthus, CEO said: "The Phase 1 data package that we have now generated for SAN711 is a major step forward not only for progressing SAN711 but for Saniona in general. The Phase 1 study confirms that SAN711 is well tolerated in humans and the PET result provides a clear guidance for the design of the Phase 2 studies with 0.8 mg twice daily as an effective and well tolerated dose. As the first company in the world, we will now have the ability - either on our own or with a partner - to evaluate the new and highly promising GABA-A α3 concept for effective and tolerable pain management in severely impacted patient populations".

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. This information was submitted for publication, through the agency of the contact person set out above, at 16.00 CEST on 30 June 2022.

About SAN711

SAN711 is an investigational, potential first-in-class positive allosteric modulator of GABA-A α3 receptors. GABA is a neurotransmitter, or chemical messenger, that inhibits nerve cell activity in the brain, which can result in sedation, pain relief, itch relief or seizure inhibition. By selectively activating α3 GABA-A receptors, SAN711 has the potential to restore spinal inhibitory tone and prevent abnormal pain signaling to the brain. Preclinical studies have indicated that because SAN711 only activates α3 GABA-A receptors, 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. SAN711 is now ready to be studied in Phase 2 studies in patients.

About Saniona

Saniona is a clinical-stage biopharmaceutical company with a mission to leverage its ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments. The company's most advanced product candidate, Tesomet™, has been progressed into mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, serious rare disorders characterized by severe weight gain, disturbances of metabolic functions and uncontrollable hunger. Saniona has developed a proprietary ion channel drug discovery engine anchored by IONBASE™, a database of more than 130,000 compounds, of which more than 20,000 are Saniona's proprietary ion channel modulators. Through its ion channel expertise, Saniona is advancing two wholly owned ion channel modulators, SAN711, SAN903. SAN711 has successfully completed a Phase 1 clinical trial and is positioned for the treatment of neuropathic pain conditions; SAN903 is in preclinical development for rare inflammatory, fibrotic, and hematological disorders. Saniona is based in the Copenhagen area, Denmark, and is listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at http://www.saniona.com.