PRESS RELEASE

18 October 2021

Saniona completes submission of manufacturing data for Tesomet capsules to U.S. FDA

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that it has completed the submission of all information previously requested by the U.S. Food and Drug Administration (FDA) regarding its chemistry, manufacturing and controls (CMC) program for Tesomet capsules. With this submission completed, Saniona expects to be able to initiate its Phase 2b clinical trials for Tesomet before the end of 2021, as planned.

There are multiple potential advantages to offering Tesomet as a capsule rather than a tablet to people living with Prader-Willi syndrome or hypothalamic obesity. Some of these individuals have a tendency to chew tablets, which could disrupt the effectiveness of the fixed-dose combination of Tesomet's active ingredients. The Tesomet capsules contain the two active ingredients as microspheres, which are expected to minimize the impact of chewing or biting. Additionally, capsules are generally easier to swallow than tablets and simplify the development of multiple doses. Saniona initiated the work to transition from Tesomet tablets to capsules in late 2020. In April of 2021, the company announced that the FDA had stated that it agreed with Saniona's CMC development plan for Tesomet capsules but had also requested additional information related to the manufacturing of the capsules prior to the initiation of the Phase 2b trials. The requested information has now been submitted.

"The work we have done to transition Tesomet from tablets to capsules, and to align with the FDA on the supporting CMC information for the Tesomet capsules, sets us up for success in these two serious rare disorders. We have ensured that our Tesomet capsules are ready for Phase 2b and Phase 3 clinical trials, which provides us with the ability to consider different options to potentially accelerate our clinical development timelines," said Kyle Haraldsen, Chief Technical Operations Officer for Saniona. "We want to be ready to move as quickly as possible through clinical development so that we may bring Tesomet to patients who are suffering from these conditions."

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 14.00 CEST on 18 October 2021.

About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for patients suffering from rare diseases for which there are a lack of available treatment options. The company's lead product candidate, Tesomet, is in 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 ion channel modulators, of which more than 20,000 are Saniona's proprietary compounds. Through its ion channel expertise, Saniona is advancing two wholly-owned ion channel modulators, SAN711

and SAN903. SAN711 is in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders, and SAN903 is in preclinical development for rare inflammatory, fibrotic and hematological disorders. Led by an experienced scientific and operational team, Saniona has an established research organization in the Copenhagen area, 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 http://www.saniona.com.