PRESS RELEASE

April 22, 2021

Saniona Updates Tesomet Clinical Development Timelines Based on Manufacturing Feedback from U.S. FDA

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that it received feedback from the U.S. Food and Drug Administration (FDA) regarding its proposed chemistry, manufacturing and controls (CMC) plans for Tesomet. In preparation for Phase 2b through Phase 3 clinical trials and eventual commercialization, Saniona has undertaken multiple steps to optimize Tesomet, including transitioning from tablets to capsules. The company requested FDA feedback, and the FDA agreed with the company's proposal but requested additional information regarding Tesomet manufacturing. Saniona anticipates that addressing these requests will delay the start of the Phase 2b trials of Tesomet for Prader-Willi syndrome (PWS) and hypothalamic obesity (HO) into the second half of 2021.

Tesomet is an investigational fixed-dose combination of tesofensine (a triple monoamine reuptake inhibitor) and metoprolol (a beta-1 selective blocker). In preparation for Phase 2b through Phase 3 clinical trials and eventual commercialization, Saniona has taken multiple steps to optimize the manufacturing of Tesomet, including transitioning from tablets to capsules. The company chose to utilize a capsule form because some individuals with PWS and HO have a tendency to chew tablets, which would disrupt the performance of the fixed-dose combination. 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 facilitate the development of multiple dosage strength options.

Saniona requested a meeting with the FDA to get feedback on its manufacturing plans prior to initiating its clinical program. The FDA stated that it agrees with Saniona's CMC development plan for Tesomet capsules as related to the proposed Phase 2b clinical trials. However, the agency requested additional information related to the manufacturing of the Tesomet capsules. No additional clinical trials will be required to obtain these data; however, gathering this information will delay the initiation of the Phase 2b clinical trials of Tesomet in PWS and HO into the second half of 2021.

"While we are disappointed to delay the initiation of our Phase 2b clinical trials of Tesomet in PWS and HO, we are encouraged that we have clear agreement from the FDA regarding our development plans as they relate to the manufacturing of these new Tesomet capsules," said Kyle Haraldsen, Chief Technical Operations Officer for Saniona. "We believe that the work we are doing to optimize Tesomet and align with the FDA on manufacturing will enable us to move more expeditiously through our clinical trials, so that we may bring Tesomet to patients as quickly as possible."

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 01:00 CEST on 22 April 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 entering Phase 1 for 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 is building its 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 Tesomet

Tesomet is an investigational fixed-dose combination therapy of tesofensine (a triple monoamine reuptake inhibitor) and metoprolol (a beta-1 selective blocker). Saniona is advancing Tesomet for hypothalamic obesity and Prader-Willi syndrome, two severe rare disorders characterized by obesity and loss of appetite control. The programs are currently in clinical development. Saniona holds worldwide rights to Tesomet and is actively evaluating opportunities to advance this treatment globally.