

PRESS RELEASE

June 25, 2021

Saniona provides update on ongoing review of tesofensine in Mexico

Saniona (OMX: SANION), a clinical stage biopharmaceutical company focused on rare diseases, today announced that its partner Productos Medix, S.A de S.V, (Medix) has provided Saniona with an update on the Mexican regulatory authority Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)'s ongoing review of tesofensine for the treatment of obesity.

According to Medix, as part of the ongoing review process, the tesofensine application was reviewed by a COFEPRIS technical committee on new molecules (EI Comité de Moléculas Nuevas). The committee was unable to provide a favorable opinion on tesofensine at this time and cited the need for additional information regarding certain topics, including weight loss maintenance. Medix informed Saniona that it will gather the requested information and continue discussions with the committee as soon as possible, and that it fully intends to continue to pursue the process of seeking approval for tesofensine. However, Medix advised that the continuing discussions with the committee may delay the anticipated final approval decision from COFEPRIS into 2022.

Medix licensed the rights to develop and commercialize tesofensine in Mexico and Argentina from Saniona in 2016. Saniona retains all rights to tesofensine in the rest of the world.

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 19.45 CEST on 25 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 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 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.

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