

## **PRESS RELEASE**

May 20, 2022

## 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 the Mexican regulatory authority Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) has published on Twitter that its technical committee on new molecules (El Comité de Moléculas Nuevas) was unable to provide a favorable opinion on tesofensine following a meeting held on May 18, 2022. The statement on Twitter does not provide any details or explanation for the position taken.

As part of the ongoing review process, the tesofensine application was reviewed by a COFEPRIS technical committee on new molecules on May 18, 2022. Saniona's partner Productos Medix, S.A de S.V, (Medix) has not received any official statement from COFEPRIS yet. Therefore, Medix is not able to comment on this statement and the possible implication for pursuing the process of seeking approval for tesofensine in Mexico.

## 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 9.45 CEST on May 20, 2022.

## **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. These clinical trials are voluntarily paused due to funding limitations and Saniona is actively exploring partnering opportunities. 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 and SAN903. SAN711 is in a Phase 1 clinical trial and is positioned for the treatment of neuropathic pain conditions, and 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.

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