

PRESS RELEASE

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Saniona's partner Medix receives favorable opinion for tesofensine for the treatment of obesity and weight management in Mexico

Saniona (OMX: SANION), a clinical stage biopharmaceutical company, 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) has provided a favorable opinion on tesofensine for treatment obesity.

"We congratulate Medix on the positive opinion for tesofensine for the treatment of obesity in Mexico. This represents an important step towards the approval of tesofensine in Mexico as a new treatment option for obesity, which poses one of the largest health challenges in Mexico. In addition to addressing a significant medical need in a major market, this also represents a potential new source of income for Saniona, which is entitled to royalties on product sales in Mexico," says Thomas Feldthus, CEO of Saniona.

COFEPRIS' technical committee has expressed a favorable opinion on tesofensine for treatment of obesity. This opinion does not represent a market authorization or rejection. The non-binding technical opinion is issued as one of the steps in the process of reviewing new molecules.

Medix licensed the rights to develop and commercialize tesofensine in Mexico and Argentina from Saniona in 2016, Medix has conducted a successful Phase 3 obesity study in Mexico. The top-line results were published in December 2018 and Medix filed for a market authorization in Mexico at the end of 2019.

A 2020 publication in *The Lancet* cited obesity as the leading public health concern in Mexico and found that only 23.5% of the adult population had a healthy weight. Several of the main causes of mortality in Mexico are associated with obesity, including cardiovascular diseases, type 2 diabetes and liver diseases. According to Medix, the current market for prescription medicine for obesity in Mexico is approximately USD \$200 million.

For more information, please contact

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About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. The company's most advanced product candidate, Tesomet[™], has been progressed to mid-stage clinical trials for rare eating disorders. Through its ion channel expertise, Saniona is advancing three product candidates, SAN711, SAN903 and SAN2219. SAN711 has successfully completed a Phase 1 clinical trial for the treatment of neuropathic pain conditions. SAN903 is ready for Phase 1 clinical studies for the treatment of inflammatory and fibrotic disorders. SAN2219 is in preclinical development for epilepsy. The company has research and development partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cephagenix ApS. Saniona is based in Copenhagen, Denmark, and listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

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Attachments

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