

PRESS RELEASE

10 February 2025 08:00:00 CET

Medix to submit final version of tesofensine application following interaction with COFEPRIS

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that its partner Medix sees a clear regulatory path forward for tesofensine following discussions with the Mexican regulatory agency COFEPRIS.

Since the message from COFEPRIS, communicated in Saniona's press releases of November 6 and November 12, 2024, Productos Medix S.A. de S.V. (Medix) has worked closely with COFEPRIS on the approval pathway for tesofensine in Mexico. Following these discussions, Medix now sees a clear path to regulatory approval and is revising its application based on COFEPRIS's feedback. Medix expects to resubmit the dossier in February.

For more information, please contact

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About Saniona

Saniona (OMX: SANION) is a clinical-stage biopharmaceutical company leading the way in ion channel modulation for the treatment of epilepsy and other neurological disorders. Saniona's epilepsy pipeline includes SAN2219, targeting acute repetitive seizures; and SAN2355, addressing refractory focal onset seizures. Beyond epilepsy, Saniona oversees four clinical programs poised for collaboration. Tesofensine for obesity is Saniona's most advanced candidate and is out licensed to Medix in Mexico and Argentina. Tesomet™ is ready for Phase 2b, targeting rare eating disorders, while SAN903 is ready for Phase 1 for inflammatory bowel disease and SAN2465 is set for preclinical development for major depressive disorder. Saniona partners include Acadia Pharmaceuticals, Boehringer Ingelheim GmbH, Productos Medix S.A de S.V, AstronauTx Limited, and Cephagenix ApS. Saniona is based in Copenhagen and listed on Nasdaq Stockholm Main Market. For more information, visit www.saniona.com.

This information is information that 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 persons set out above, at 2025-02-10 08:00 CET.

Attachments

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