

PRESS RELEASE

20 February 2025 18:45:00 CET

Medix has resubmitted tesofensine application to COFEPRIS

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that its partner Medix has resubmitted the tesofensine application dossier to COFEPRIS, as referenced in Saniona's press release dated February 10.

"I congratulate the Medix team on this significant achievement. Following feedback from COFEPRIS, they have updated and resubmitted the complete tesofensine dossier - approximately 20,000 pages - addressing all regulatory questions and requests," said Saniona's CEO, Thomas Feldthus.

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 2025-02-20 18:45 CET.

Attachments

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