PRESS RELEASE

06 November 2024 08:00:00 CET

Mexican Application for Tesofensine Not Yet Approved

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that its partner, Productos Medix S.A de S.V (Medix), has not received approval from the Mexican regulatory agency (Cofepris) for tesofensine for the treatment of obesity. Instead, Medix is entering a dialogue with the agency regarding the path forward as it appears that the decision by Cofepris has not been based on the full data package as submitted by Medix.

The application is based on a Phase 3 program involving 372 patients conducted by Medix. The study confirmed compelling efficacy, with patients achieving an average weight loss of about ten percent in 24 weeks, and more than half of the patients experiencing a weight loss of more than ten percent. In general, tesofensine was very well tolerated, and a clinical safety database containing approximately 1600 patients provided a robust safety dataset.

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 SAN711, a Phase 2-ready candidate for absence seizures; 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 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 2024-11-06 08:00 CET.

Attachments
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