

PRESS RELEASE

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Update on Tesofensine Application

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today comments on Medix's recent regulatory submission for tesofensine in obesity, following COFEPRIS's decision to withhold approval. Medix is engaging with the agency to clarify the situation and out of respect for that process, Saniona will refrain from further comments.

On November 6, Saniona announced that Productos Medix S.A. de S.V. (Medix) has not yet received approval from the Mexican regulatory agency, COFEPRIS, for tesofensine as a treatment for obesity. Medix has engaged with the agency to clarify the situation and the path forward, as it appears that COFEPRIS may not yet have reviewed the full data package.

Saniona's November 6 press release was based on a very brief update from Medix. Since then, and after a more thorough review of the communication between COFEPRIS and Medix, Saniona has come to understand that the agency may not yet have completed a comprehensive assessment of the data package submitted. Thus, Medix and Saniona believe that COFEPRIS may not yet have reviewed the entire application package submitted by Medix.

While Saniona recognizes the importance of transparency for the company's stakeholders, Medix is the primary applicant for the approval and manages the process in line with its knowledge of the Mexican market and regulatory landscape. The role of Saniona is restricted to support Medix in this effort.

Medix is conducting a collaborative dialogue with COFEPRIS, which COFEPRIS has indicated a willingness to continue. Out of respect for this process, Saniona must refrain from further comments.

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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.

Attachments
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