PRESS RELEASE

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Saniona Receives Regulatory Approval for SAN711 Biomarker Study

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that it has been granted approval to begin a Phase 1 multiple ascending dose (MAD)/biomarker study in adults for SAN711. This study is a key step towards launching a clinical proof-of-concept study in children with absence seizures, scheduled for 2025.

The Phase 1 MAD/biomarker study will assess the safety, tolerability, and pharmacokinetics of higher SAN711 doses in a multiple-dose setting. It will also gather data on food interactions and the drug's pharmacodynamic effects on EEG during both awake and sleep states in healthy volunteers. The biomarker data can provide evidence of SAN711's central pharmacological activity, aiding in defining the dosing strategy for future patient studies. This information, combined with receptor occupancy data from a prior PET study, will guide the next steps.

Saniona is conducting this study in collaboration with Evotec at the Clinical Research Centre (CRC) of the University Hospital in Verona, Italy. Evotec and CRC bring extensive experience in neurological and psychiatric clinical research, enhancing the study's execution.

“We are thrilled with our collaborations with Evotec and CRC. Despite the tight timelines, all three teams have worked efficiently to move this complex process forward quickly. We expect to begin dosing patients within the next few weeks,” said Janus S. Larsen, Chief Development Officer at Saniona.

Additionally, Saniona is conducting a preclinical juvenile toxicity study and physiologically based pharmacokinetic modeling to translate adult Phase 1 data into appropriate dosing for children.

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 features SAN711, a Phase 2-ready candidate drug targeting absence seizures, SAN2219 for acute repetitive seizures, and SAN2355, addressing refractory focal onset seizures. Beyond epilepsy, Saniona oversees four clinical programs poised for collaboration. Tesofensine, Saniona’s most advanced candidate, is progressing towards regulatory approval for obesity in Mexico through a partnership with Medix. 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 has esteemed partners, including 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, please visit **www.saniona.com**.

Attachments

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