

PRESS RELEASE

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Saniona Initiates SAN711 Biomarker Study

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that it has dosed the first subjects with SAN711 in a Phase 1 multiple ascending dose (MAD)/biomarker study. This marks a significant milestone that put the foundation for launching a clinical proof-of-concept study in children with absence seizures, scheduled for 2025. Topline data from the Phase 1 study is anticipated by the end of 2024.

This Phase 1 MAD/biomarker study will investigate three critical aspects to inform future clinical trials: the effect of food intake on SAN711 dosing, the safety and tolerability as well as the potential benefits of higher doses using clinically relevant pharmacodynamic biomarkers.

These insights will refine the dosing strategy for future patient studies as the Phase 1 MAD/biomarker study will assess the safety, tolerability, and pharmacokinetics of SAN711 in higher doses than those used in the previous Phase 1 study, while gathering data on food interactions and the drug's pharmacodynamic effects on EEG during both awake and sleep states in healthy volunteers.

Saniona's earlier Phase 1 study demonstrated excellent tolerability and indicated potential therapeutic benefit at relevant clinical plasma concentrations. The current study builds on these findings by exploring whether higher doses can offer even greater potential without compromising safety.

Additionally, preclinical data suggests that SAN711 selective pharmacology modulates certain brain circuits, which can be detected via EEG measurements during both awake and sleep states. This not only serves as a functional biomarker of SAN711's activity in the brain but may also indicate potential benefits for patients in future studies.

The study is being conducted in collaboration with Evotec at the Clinical Research Centre (CRC) of the University Hospital in Verona, Italy. Both Evotec and CRC bring extensive expertise in neurological and psychiatric clinical research, which will support the successful execution of the study.

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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