

PRESS RELEASE

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Saniona Provides Update on Major Progress for SAN2355

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces significant progress in the preclinical development of SAN2355, a new generation Kv7.2/Kv7.3 activator aimed at treating focal onset seizures. The company has identified a stable solid form of the compound and completed synthesis optimization, enabling a robust, scalable manufacturing process. As a result, Saniona has successfully produced 4 kg of SAN2355 for GLP toxicology studies.

“We are delighted to have completed the analytical development, synthesis optimization, and production of the GLP toxicology batch. We expect the remaining preclinical work to take about nine months, which means that SAN2355 could enter Phase 1 clinical trials by Q3 2025,” said Janus Schreiber Larsen, Chief Development Officer at Saniona.

“SAN2355 is a key asset in our epilepsy portfolio. Kv7 activators have previously been clinically and commercially validated for treating refractory focal onset epilepsy, but no products are currently available on the market. SAN2355 stands out due to its unique selectivity profile and has the potential to become best in class, addressing significant unmet needs in the epilepsy market,” added Thomas Feldthus, CEO of Saniona.

The GLP toxicology batch was produced with assistance from the Danish firm Niels Clauson-Kaas, and the project is now ready for preclinical toxicity and safety studies, in compliance with GLP standards.

About Kv7 Channels and Epilepsy

Epilepsy is a neurological disorder characterized by recurrent seizures, affecting millions globally. Around 30% of patients do not respond to existing treatments, highlighting a critical unmet need.

Kv7 channels are crucial for regulating potassium ion transport across neuronal membranes, helping to prevent uncontrolled nerve impulses. Kv7.2 and Kv7.3 subunits, primarily expressed in the brain, play a key role in dampening overactive neurons, thus preventing seizures. While the non-selective Kv7 activator retigabine demonstrated proof-of-concept for treating resistant focal onset seizures, it was withdrawn from the market due to side effects unrelated to its target.

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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