PRESS RELEASE

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Saniona initiates GMP manufacturing and toxicology studies for SAN2355

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces the initiation of GMP manufacturing, drug product development, and PK/GLP toxicology studies for SAN2355. The objective is to finalize the data package for a clinical trial application by year-end 2025.

“During 2024, we have successfully completed analytical development, synthesis optimization, and production of the GLP toxicology batch. We expect to complete the remaining preclinical work in 2025, enabling Saniona to file a clinical trial application around year-end 2025,” said Janus Schreiber Larsen, Chief Operating Officer at Saniona.

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

About Epilepsy, Kv7 Channels, and SAN2355

Epilepsy is a neurological disorder affecting millions worldwide, with approximately 30% of patients not responding to existing treatments, highlighting a critical unmet need.

Kv7 channels regulate potassium ion transport in neurons, preventing uncontrolled nerve impulses. Among the five subtypes (Kv7.1–Kv7.5), Kv7.2/Kv7.3 is the key target for anti-epileptic treatment, while activating other subtypes can cause severe side effects.

Kv7 activation has been clinically validated in epilepsy, as seen with retigabine, a non-selective Kv7.2–Kv7.5 activator that was effective in treating focal onset epilepsy but withdrawn in 2017 due to adverse effects. XEN1101, a more potent retigabine analogue in Phase 3, remains unselective, with Phase 2 data showing urinary retention and CNS-related dropouts.

Beyond focal seizures, Kv7 activation holds promise for severe pediatric epilepsies, where Kv7.2/Kv7.3 mutations are a major cause. Retigabine was repurposed for this indication but discontinued by Xenon Pharmaceuticals in 2023, likely due to side effects.

SAN2355 is specifically designed to overcome the limitations of retigabine and XEN1101. It selectively activates Kv7.2/Kv7.3 while blocking Kv7.5 and sparing Kv7.1/Kv7.4, reducing CNS side effects and urinary retention. This differentiation is expected to provide strong seizure control with improved tolerability for both focal and generalized epilepsy as well as severe pediatric epilepsies linked to Kv7.2 /Kv7.3 mutations

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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 neurological disorders. Saniona's internal pipeline includes SAN2219, targeting acute repetitive seizures; SAN2355, addressing refractory focal onset seizures; and SAN2465, positioned for major depressive disorders. Saniona has two strategic development collaborations. SAN711 is being prepared for Phase 2 for essential tremor in collaboration with Acadia Pharmaceuticals and tesofensine is out licensed for obesity to Medix, which has submitted a market authorization application (MAA) in Mexico. In addition, Saniona oversees two clinical programs poised for collaboration. Tesomet™ is ready for Phase 2b, targeting rare eating disorders, while SAN903 is ready for Phase 1 for inflammatory bowel disease. Saniona partners include Acadia Pharmaceuticals, 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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