

PRESS RELEASE

26 March 2025 08:00:00 CET

Saniona initiates scale-up and manufacturing of toxicology batches for SAN2219, a potential new therapy for epilepsy

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces the initiation of scale-up and manufacturing of toxicology batches for SAN2219, advancing the program toward clinical studies by the first half of 2026.

SAN2219 is a candidate from Saniona's GABA-A $\alpha 2/\alpha 3$ positive allosteric modulator (PAM) program and has demonstrated strong efficacy in multiple seizure models. Its differentiated pharmacological profile supports potential development for both common and rare forms of epilepsy.

Preclinical activities include synthesis optimization, scale-up, GMP manufacturing, and GLP toxicology studies. Saniona completed analytical development and synthesis optimization in 2024 and has now signed a contract to produce GLP toxicology batches in summer 2025.

"Epilepsy affects 50 million people globally, with 30% resistant to current treatments," said Karin Sandager Nielsen. "There is a significant need for better therapies across both idiopathic epilepsy and rare pediatric syndromes. SAN2219 could help address these unmet needs by improving seizure control without the side effects that often limit current treatments. Our preclinical data indicates that SAN2219 combines strong seizure control with high tolerability and low risk of tolerance development - a rare profile in epilepsy therapies. This program builds on Saniona's deep ion channel expertise that has repeatedly generated high-value programs, as exemplified by the recent collaboration on SAN711 with Acadia."

SAN2219 is a selective activator of GABA-A $\alpha 2/\alpha 3/\alpha 5$ receptors, designed to inhibit excessive neural excitability in epilepsy. By avoiding activation of the $\alpha 1$ subunit targeted by benzodiazepines, SAN2219 offers robust seizure control with an improved safety profile, supporting both acute and chronic use.

About Epilepsy

Epilepsy is a chronic neurological disorder characterized by recurrent seizures caused by abnormal electrical activity in the brain. It affects approximately 50 million people worldwide, making it one of the most common neurological conditions. While many patients achieve seizure control with existing treatments, about 30% remain resistant to available therapies. Epilepsy can range from mild to severe, impacting quality of life and increasing the risk of injury, cognitive impairment, and comorbid conditions. There is a significant need for new treatment options, particularly for drug-resistant epilepsy and rare pediatric syndromes.

Rare pediatric epilepsies are severe and often debilitating forms of epilepsy that typically emerge in early childhood. Many are linked to specific genetic mutations affecting ion channels, neurotransmitter systems, or brain development. These conditions, including Dravet syndrome, Lennox-Gastaut syndrome, and CDKL5 deficiency disorder, are often resistant to standard antiepileptic drugs and associated with developmental delays, cognitive impairment, and other neurological complications. Because of their severity and limited treatment options, there is an urgent need for novel, targeted therapies that can provide better seizure control and improve long-term outcomes for affected children and their families.

For more information, please contact

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About Saniona

Saniona (OMX: SANION) is a clinical-stage biopharmaceutical company focused on neurological and psychiatric diseases. Its internal pipeline includes SAN2219 and SAN2355 for epilepsy and SAN2465 for major depressive disorder. Saniona has two strategic collaborations: one with Acadia Pharmaceuticals, which has licensed worldwide rights to ACP-711 and is preparing it for Phase 2 in essential tremor, and one with Productos Medix, which holds the rights to tesofensine for obesity in Mexico and Argentina and has submitted a market authorization application in Mexico. Saniona also has two clinical programs available for partnership: Tesomet™, ready for Phase 2b in rare eating disorders, and SAN903, ready for Phase 1 in inflammatory bowel disease. Saniona's partners also include Boehringer Ingelheim, AstronauTx, and Cephagenix. Based in Copenhagen, Saniona is listed on Nasdaq Stockholm Main Market.

For more information, visit www.saniona.com.

Attachments

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