

PRESS RELEASE

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Saniona selects SAN2668 as first-in-class clinical candidate for paediatric epilepsy

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces the selection of SAN2668 as a first-in-class clinical candidate for epilepsy.

SAN2668 has demonstrated unique selective pharmacology, robust efficacy, and a differentiated profile in preclinical models, supporting its potential to address the significant unmet needs of children with difficult-to-treat epilepsy syndromes.

In preclinical epilepsy models, SAN2668 showed strong efficacy combined with improved tolerability and reduced tolerance-induction compared to benzodiazepines, which are frequently used as anti-seizure medications in paediatric epilepsies such as Developmental Epileptic Encephalopathies (DEEs). Backed by strong pharmacology and validated biomarkers, SAN2668 is positioned to advance efficiently toward early proof-of-concept.

"SAN2668 exemplifies our focus on translating deep ion channel expertise into transformative medicines for patients with devastating rare epilepsies. This program reflects Saniona's strategy to advance high-value, first-in-class assets with strong potential for patients," said Karin Sandager Nielsen, CSO of Saniona.

"With SAN2668, we have the potential to overcome key challenges such as sedation, cognitive impairment, and tolerance-induction, which limit the use of widely prescribed benzodiazepines like clobazam in DEEs," said Pierandrea Muglia, CMO of Saniona. "Our goal is to bring forward a treatment option that is both effective and better tolerated for children and their families. Together with SAN2219 for epilepsy and SAN2465 for major depressive disorder, we are now progressing three internal programs towards Phase 2 proof-of-concept studies."

Saniona has initiated pre-clinical development with the aim to initiate Phase 1 clinical studies towards the end of 2026.

More about pediatric epilepsy syndromes and DEEs

Epilepsy is diagnosed in about 1% of children, making it the most common chronic neurological condition in childhood. Approximately one-third of young epilepsy patients suffer from difficult-to-treat epileptic syndromes, many of which are classified as developmental epileptic encephalopathies (DEEs). In children with DEEs, seizures derail normal cognitive and developmental trajectories, and a broad range of symptoms impair quality of life for both patients and families. Most available therapies are used off-label and are not specifically designed to address the underlying pathophysiology of these disorders.

SAN2668 is designed to directly target disease mechanisms in specific paediatric epilepsy syndromes, with the potential to become a differentiated treatment that addresses this major unmet medical need.

For more information, please contact

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About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for neurological and psychiatric disorders. The company's internal pipeline includes SAN2668 for paediatric epilepsy syndromes, SAN2219 for epilepsy, and SAN2465 for major depressive disorder. Saniona has established strategic collaborations with leading pharmaceutical companies, including Jazz Pharmaceuticals, which holds global rights to SAN2355 for epilepsy, Acadia Pharmaceuticals, which holds worldwide rights to ACP-711 for essential tremor, and with Medix, which holds rights to tesofensine for obesity in Mexico and Argentina, where a market authorization application is currently under review. In addition, Saniona has two clinical-stage programs available for partnering: Tesomet™, ready to advance to Phase 2b trials in rare eating disorders, and SAN903, ready to enter Phase 1 trials in inflammatory bowel disease. Saniona's ion channel discovery platform is further validated through research collaborations with Boehringer Ingelheim, AstronauTx, and Cephagenix. Headquartered in Copenhagen, Saniona is listed on the Nasdaq Stockholm Main Market.

For more information, visit www.saniona.com.

This information is information that Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-09-04 08:00 CEST.

Attachments

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