PRESS RELEASE

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Saniona successfully completes Phase 1-enabling work for SAN2668

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company focused on neurological and psychiatric disorders, today announces the successful completion of the preclinical and CMC work required to support Phase 1 clinical development of SAN2668, its lead program for severe pediatric epilepsies. Saniona plans to submit a Clinical Trial Application (CTA) through the EU Clinical Trials Information System (CTIS) by the end of December 2026.

“Completing the preclinical and CMC work for SAN2668 represents the major de-risking step ahead of Phase 1 clinical development,” said Janus Schreiber Larsen, Chief Operating Officer of Saniona. “The results strengthen our confidence in SAN2668’s potential to combine strong anti-seizure efficacy with improved tolerability. We are now finalizing the documentation for the CTA submission and preparing for the first clinical studies.”

Preclinical results support SAN2668’s potential to combine the strong anti-seizure efficacy of benzodiazepines with improved tolerability and benefits beyond seizure control in developmental and epileptic encephalopathies (DEEs).

Saniona has completed the toxicology, pharmacology and chemistry, manufacturing and controls (CMC) work required to support Phase 1. The company is finalizing the supporting documentation and preparing the CTIS application for submission under the EU Clinical Trials Regulation.

The planned Phase 1 study will evaluate the safety, tolerability and pharmacokinetics of SAN2668 in healthy volunteers. PET and quantitative EEG (qEEG) assessments will characterize target engagement and pharmacodynamic effects, including whether SAN2668 can safely achieve receptor occupancy levels associated with anti-seizure efficacy in preclinical models. The early clinical program also includes a planned proof-of-mechanism study in patients with photosensitive epilepsy. Together, these studies will inform dose selection for Phase 2.

“With SAN2668 and SAN2465 both advancing toward Phase 1, we are delivering on our strategy to build a balanced pipeline, partly financed through our partnerships,” said Thomas Feldthus, Chief Executive Officer of Saniona. “SAN2668 is central to this strategy, with the potential for Saniona to advance the program through late-stage development and commercialization in rare pediatric epilepsies.”

More about Developmental and Epileptic Encephalopathies (DEEs)
DEEs are a group of severe childhood epilepsies characterized by frequent seizures and/or epileptiform EEG activity, alongside developmental slowing or regression not explained by seizures alone [1,2]. DEEs affect approximately 1 in 590 children before the age of 16 [2]. Spike-wave discharges are a feature of several DEEs, and pathological thalamocortical rhythms are implicated in absence and other generalized seizures [3]. More than three in five children with a DEE develop drug-resistant epilepsy, compared with fewer than one in three across childhood epilepsy overall [4].

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The burden extends far beyond seizures. Intellectual disability, language and behavioral difficulties, and motor and sleep impairment contribute substantially to reduced quality of life [2,5]. Benzodiazepines help control seizures, but sedation, cognitive impairment, tolerance and dependence can limit long-term treatment and dose escalation. Despite advances in treatments for specific DEE syndromes, there remains a substantial need for therapies that combine effective seizure control with improved tolerability and benefits beyond seizures.

More about SAN2668
SAN2668, Saniona's lead program, is a GABA-A α2/α3 positive allosteric modulator designed for severe pediatric epilepsies. It selectively potentiates GABA-A α3 and α2 receptors while maintaining balanced α1 modulation and modest α5 activity. This profile is designed to preserve benzodiazepine-class anti-seizure efficacy while minimizing adverse effects.

Strong α3 modulation targets thalamocortical circuits implicated in spike-wave EEG pathology, while robust α2 activity is intended to provide protection against focal and generalized convulsive seizures. SAN2668 is designed to offer a wider therapeutic window, allowing higher receptor occupancy than can be tolerated with non-selective benzodiazepines. Its preclinical profile supports its potential to become a best-in-class therapy for pediatric epilepsy.

[1] Scheffer IE et al. Epilepsia 2025;66(4):1014–1023
[2] Poke G et al. Neurology 2023;100(13):e1363–e1375
[3] Specchio N et al. Epilepsia 2026;67(8):3835–3851
[4] Ayoub D et al. Epilepsia 2024;65(10):2995–3009
[5] Specchio N et al. Epilepsia 2025;66(4):970–987

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 pediatric epilepsy syndromes 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. Saniona's ion channel discovery platform is further validated through research collaborations with Boehringer Ingelheim, Cephagenix and AstronauTx, which holds worldwide rights to ATX0926. Headquartered in Copenhagen, Saniona is listed on the Nasdaq Stockholm Main Market.
For more information, visit **www.saniona.com**.

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Attachments
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