PRESS RELEASE

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Saniona completes toxicology and CMC studies for SAN2465, enabling IND submission by October 2026

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company focused on neurological and psychiatric disorders, today announces the successful completion of the toxicology, chemistry, manufacturing and controls (CMC) activities required to support an Investigational New Drug (IND) application for SAN2465. Saniona is now finalizing the IND package and expects to submit the application to the U.S. Food and Drug Administration (FDA) by the end of October 2026.

“The successful completion of the toxicology and CMC activities for SAN2465 marks an important milestone as we execute on our strategy to advance our prioritized proprietary programs," said Janus Schreiber Larsen, Chief Operating Officer of Saniona. "Major depressive disorder remains one of the largest and most underserved segments in CNS, and we believe SAN2465 offers a differentiated treatment approach with potential for a rapid onset of antidepressant effect. We look forward to submitting the IND application and to start dosing the first human subjects.”

With the toxicology and CMC studies complete, Saniona has the non-clinical and manufacturing data required to support an IND application for SAN2465. Saniona is currently finalizing the IND dossier, expected to be submitted to the FDA by the end of October 2026.

The planned Phase 1 study will evaluate the safety, tolerability and pharmacokinetics of SAN2465 in healthy volunteers. The study is also designed to assess pharmacodynamic biomarkers that may support future clinical development and dose selection.

More about Major Depressive Disorder
Depression affects hundreds of millions of people worldwide [1]. Conventional antidepressants have a delayed onset of effect, low remission rates, and more than 30% of patients do not respond adequately, leading to treatment-resistant depression [2]. Esketamine (Spravato®), the first approved rapid-acting antidepressant, reached worldwide sales of USD 1.7 billion in 2025 [3], highlighting the demand for fast-acting treatment options. However, due to risks including sedation, dissociation and respiratory depression, esketamine is only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program requiring administration and monitoring in a certified healthcare setting [4].

More about SAN2465
SAN2465 is designed to deliver ketamine-like rapid onset without the limitations associated with ketamine and esketamine. In the chronic mild stress model, a well-established animal model of depression [5], a single oral dose of SAN2465 produced a rapid and sustained reversal of chronic stress-induced depressive-like symptoms, including anhedonia, anxiety and cognitive impairment. The onset and magnitude of the effects were comparable to ketamine. GABA-A α5 receptors are highly expressed in the hippocampus and related limbic regions, brain regions involved in mood and cognition [6,7]. Through selective modulation of these receptors, SAN2465 has the potential to provide rapid antidepressant efficacy without the dissociative and other adverse effects associated with NMDA receptor antagonists, potentially enabling convenient oral treatment without the need for in-clinic administration and monitoring.

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[1] World Health Organization. Depression fact sheet, September 2026. **https://www.who.int/news-room/fact-sheets/detail/depression**

[2] Zhdanava M et al. J Clin Psychiatry 2021;82(2):20m13699

[3] Johnson & Johnson. Q4 and full-year 2025 results, January 2026

[4] SPRAVATO® (esketamine) US Prescribing Information, revised January 2025

[5] Willner P. Neurobiol Stress 2017;6:78–93

[6] Sur C et al. Brain Res 1999;822:265–270

[7] Atack JR. Pharmacol Ther 2010;125(1):11–26

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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