PRESS RELEASE

16 November 2026 08:00:00 CET

Saniona receives FDA clearance to initiate Phase 1 of SAN2465

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company focused on neurological and psychiatric disorders, today announces that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for SAN2465, allowing Saniona to initiate a Phase 1 study in healthy volunteers. SAN2465 is being developed as a rapid-acting oral treatment for major depressive disorder (MDD), and the first participant is expected to be dosed before year-end.

"We are excited to initiate the clinical development of SAN2465 in MDD" **said Pierandrea Muglia, Chief Medical Officer of Saniona**. "The Phase 1 study will assess safety and pharmacokinetics while exploring effects on brain activity and cognition to help guide dose selection for studies in patients. Our ambition is to deliver rapid antidepressant efficacy comparable to ketamine and esketamine in an oral treatment that patients could take at home. We expect to dose the first participant before year-end."

The Phase 1 study will include single ascending dose (SAD) and multiple ascending dose (MAD) parts and evaluate the safety, tolerability and pharmacokinetics of SAN2465 in healthy volunteers. Cognitive testing and pharmacodynamic assessments, including quantitative EEG, will explore its effects on brain function across dose levels and support dose selection for future studies in patients.

More about Major Depressive Disorder
Depression affects hundreds of millions of people worldwide [1]. Conventional antidepressants have a delayed onset for several weeks. Many patients do not achieve adequate relief with existing treatments. Approximately one-third of adults receiving medication for MDD in the United States are estimated to have 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 significant demand for fast-acting treatment options. However, due to risks including dissociation, sedation, respiratory depression, and abuse and misuse, esketamine is available in the U.S. only 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 a selective GABA-A α5 negative allosteric modulator being developed as a rapid acting oral treatment for MDD, with the potential to overcome 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 these effects were comparable to ketamine. SAN2465 has also been shown to significantly enhance hippocampal synaptic plasticity, as measured by long-term potentiation (LTP).

GABA-A α5 receptors are highly expressed in the hippocampus and related limbic regions involved in emotional regulation, mood and cognition [6,7]. Through selective modulation of these receptors, SAN2465 has the potential to deliver rapid antidepressant efficacy while avoiding the dissociative and other adverse effects associated with NMDA receptor antagonists, potentially enabling oral treatment at home without the need for in-clinic administration and monitoring.

Saniona AB (publ)
Murervangen 42
DK-2600 Glostrup
Denmark

Email: saniona@saniona.com
Web: saniona.com

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

[2] Zhdanava M et al. The prevalence and national burden of treatment-resistant depression and major depressive disorder in the United States. 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 September 2026

[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**.

For more information, please contact
Johnny Stilou, CFO, +45 21227227; **johnny.stilou@saniona.com**

Attachments
Saniona receives FDA clearance to initiate Phase 1 of SAN2465