

PRESS RELEASE

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Positive data on Saniona's SAN711 in epilepsy presented at SfN

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, today announces that positive preclinical data on Saniona's lead ion-channel drug candidate and phase 2 ready asset, SAN711, will be presented at the annual meeting of the Society for Neuroscience (SfN) 11th-15th November 2023, Washington DC. The data shows strong suppression of absence seizures, which demonstrates that SAN711 represents a novel precision approach for treatment of non-convulsive generalized seizures.

Professor Vincenzo Crunelli, Cardiff University, U.K., has evaluated SAN711 in the highly predictive and translatable animal model for absence seizures, the GAERS rat model. SAN711 demonstrated robust dose-related suppression of Spike-Wave-Discharges (SWDs), which are the EEG manifestations of absence seizures supporting clinical efficacy in absence seizures. Saniona has replicated Professor Vincenzo Crunelli's exciting findings in the GAERS rat model at the contract research laboratory, Synapcell (France), where SAN711 was administered peroral and compared to valproate, which is used as first line therapy today.

"This data provides convincing evidence that SAN711 with its unique differentiated pharmacological profile can target the root cause of the disease pathophysiology without liability for attentional impairments and embryofetal risks. It is a truly precision approach, where SAN711 aborts the SWDs by modulating the GABA α 3 containing receptors in brain circuits where the seizures are initiated and maintained resulting in a potential new treatment for various epilepsy patients with non-convulsive seizures including patients with childhood absence seizures, juvenile absence seizures and various type of pediatric epileptic syndromes. As SAN711 is not activating other GABAA receptors, it is anticipated to be much better tolerated as compared to other antiepileptic medications. This was clearly supported by the outcome of the phase 1 study reported last year," said Karin Sandager Nielsen, CSO of Saniona.

SAN711 is a unique subtype selective activator of GABAA α 3 receptors. A Phase 1 study in 2022 demonstrated that SAN711 is safe and well tolerated in humans[1]. A parallel Positron Emission Tomography (PET) biomarker study confirmed that it is possible to reach relevant receptor occupancies at well tolerated doses opening for continued clinical development of the asset.

"This new data supports the development of SAN711 as a precision medicine in patient populations suffering from generalized seizures. Over the last year, we have made significant progress in our two other programs, SAN2219 and Kv7, positioned for epilepsy. We now have three active programs within epilepsy and our deep understanding of ion channel function is a cornerstone for our novel approaches in this field," said Thomas Feldthus, CEO of Saniona.

More about absence seizures

Absence epilepsy is very prevalent in younger children and adolescents, where it comprises up to 10% of all childhood epilepsies[2]. Even though the majority is well treated, >20% remains refractory[3] to treatment and 40% continue to have absence seizures into adulthood[4]. Additionally, 30% have inherent cognitive impairments[5], and as first line treatment is to adversely affect cognition[6], there is a significant medical significant need for improved treatment options devoid of the limitations associated with standard-of-care today.

- [1] Topline data <https://saniona.com/newsroom/single-press-release/?slug=saniona-reports-positive-top-line-results-from-the-san711-phase-1-clinical-trial-3148ba6f>
- [2] Albuja A and Khan G., Absence Seizure Stats Pearls Oct. 2022
- [3] Trinká E et al., J. Neurol. 2004
- [4] Trinká E et al., Acta Neurol. Scand. 2005
- [5] Masur D et al., Neurol. 2013
- [6] Glauser T.A et al., NEJM 2010

For more information, please contact

Thomas Feldthus, CEO, +45 22109957; thomas.feldthus@saniona.com

About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. Saniona's most advanced candidate, tesofensine, has progressed towards regulatory approval for obesity by Saniona's partner Medix. Saniona is advancing four product candidates including Tesomet™ and three ion channel modulators SAN711, SAN903 and SAN2219. Tesomet™ has progressed to mid-stage clinical trials for rare eating disorders. SAN711 has completed Phase 1 for epilepsy. SAN903 is ready for Phase 1 for inflammatory and fibrotic disorders. SAN2219 is in preclinical development for epilepsy. Saniona has research and development partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V, AstronauTx Limited and Cephagenix ApS. Saniona is based in Copenhagen, and listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

Attachments

[Positive data on Saniona's SAN711 in epilepsy presented at SfN](#)