PRESS RELEASE

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Saniona reports progress on pipeline and other activities

Saniona (OMX: SANION), a clinical-stage biopharmaceutical company, reports progress and plans on pipeline, and other activities:

- **Saniona is implementing a development plan for SAN711, which includes a Phase 1 /Biomarker study in adults, a juvenile tox study, and physiologically based pharmacokinetic (PBMK) modelling in 2024 prior to conducting a clinical proof of concept study for absence seizures in pediatric patients in spring 2025**
- **Saniona has started preclinical development of SAN2355 and made progress on CMC with the identification of a scalable process and suitable and stable drug substance for clinical and commercial use**
- **Saniona has provided additional information to Medix to support their documentation and efforts for obtaining regulatory approval in Mexico this year**
- **Saniona's objective is to enter a least one new collaboration this year and is currently focusing its partnering activities on three programs which could provide significant upfront payments**

SAN711
Saniona is planning to conduct a Phase 1 multiple ascending dose (MAD)/Biomarker study in adults and certain pre-clinical activities to pave the way for starting a clinical proof of concept study in children with absence seizures during spring 2025.

In addition to investigate the safety, tolerability, and pharmacokinetics of using higher doses of SAN711 in multiple dose settings, the Phase 1 MAD/Biomarker study will also provide food interaction data and relevant pharmacodynamic effect data of SAN711 on EEG in healthy volunteers during awake and sleep settings. The biomarker effect of SAN711 would provide evidence of relevant central pharmacological activity that together with the exposure – receptor occupancy previously provided by the PET study - will help define the dosing strategy for future studies in patients.

Saniona expects to conduct the Phase 1 MAD/Biomarker study in collaboration with Evotec at the Clinical Research Centre (CRC) at the university hospital in Verona, Italy. The CRC was founded in 2005 as spin-off of the GSK Verona Clinical Pharmacology and Experimental Medicine Unit. Through the collaboration with Evotec/CRC, Saniona will capitalize on decades of experience that both Evotec and the CRC have in conducting clinical and preclinical studies for neurological and psychiatric indications.

To enable pediatric studies, Saniona will also conduct a preclinical juvenile toxicity study and PBPK-modelling for translating the Phase 1 data in adults into corresponding doses for children.

Saniona has previously shown in a Phase 1 clinical trial that SAN711 has a benign safety profile. SAN711 was well tolerated in the single ascending dose (SAD) study in doses up to 2.25 mg/kg. The corresponding PET biomarker study showed that SAN711 reached a very high level of target engagement with the receptor occupancy of SAN711 exceeding 80% during the SAD part. In the MAD study SAN711 was well tolerated at a dose of 0.8 mg/kg twice daily, which led to plasma levels consistent with 24-hour receptor occupancy ranging from 50% to 72%. Additional cohorts exploring higher doses was originally planned. However, the Phase 1 study was ended in Q1 2022 because of lack of funding after the dosing of 0.8 mg/kg twice daily without reaching the maximum tolerated dose.

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As outlined in earlier presentations, Saniona planned to conduct a short extension to the Phase 1 study followed by a mechanistic and/or proof-of-concept study in adults in spring 2025. As the proceeds from the financing in February 2024 do not fully support the previously outlined plan, Saniona has implemented certain cost reductions and developed an alternative plan for obtaining safety, and pharmacokinetics in pediatric patients in spring 2025. Considering the high seizure frequency and the ability to rely on objective endpoint, this study may also provide proof-of-concept for SAN711 in controlling absence seizures.

SAN2355
Saniona has started the preclinical development of SAN2355, a best in class and completely new generation of Kv7.2/Kv7.3 activators for treatment of focal onset seizures. The preclinical development includes syntheses design and optimization, scale-up, manufacturing of material under GMP, as well as preclinical toxicity and safety studies under GLP. The standard timeline for this CTA/IND-enabling process is 18 months. During the last three months Saniona has made considerable progress in chemical optimization and manufacturing of SAN2355. Saniona believes that it both has a scalable process and a suitable and stable drug substance for clinical and commercial use. Therefore, Saniona expects to complete the manufacturing part this year, which means that the program will follow the timelines for a standard preclinical development program.

Tesofensine
Medix filed for regulatory approval of tesofensine in Mexico in May 2023 and has had an ongoing dialog with the regulatory agency about submission of more information and documentation. During the last couple of months, Saniona has provided additional information to Medix to support their documentation. Medix expects to submit the additional information and documentation to the regulatory agency in the coming weeks to continue the approval process with the aim of obtaining regulatory approval in Mexico this year. If successful, Saniona will be entitled to an upfront payment and mid-teens royalties on product sales. Tesofensine may be an important product for treatment of obesity in Mexico and a regulatory approval might also open new opportunities in other territories. Therefore, it could be a major source of income and news flow going forward.

Business Development update
Saniona's goal is to enter at least one new collaboration this year with a focus on three programs, which could provide significant upfront payments enabling Saniona to resolve the company's debt and finance the development of other assets.

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About Saniona
Saniona (OMX: SANION) is a clinical-stage biopharmaceutical company leading the way in ion channel modulation for the treatment of epilepsy and other neurological disorders. Saniona's epilepsy pipeline features SAN711, a Phase 2-ready candidate drug targeting absence seizures, SAN2219 for acute repetitive seizures, and SAN2355, addressing refractory focal onset seizures. Beyond epilepsy, Saniona oversees four clinical programs poised for collaboration. Tesofensine, Saniona's most advanced candidate, is progressing towards regulatory approval for obesity in Mexico through a partnership with Medix. Tesomet™ is ready for Phase 2b, targeting rare eating disorders, while SAN903 is ready for Phase 1 for inflammatory bowel disease and SAN2465 is set for preclinical development for major depressive disorder. Saniona has esteemed partners, including 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 Main Market.
For more information, please 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 2024-05-07 08:00 CEST.

Attachments

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