

PRESS RELEASE

July 22, 2019

Saniona selects highly promising preclinical candidate with broad potential in autoimmune disorders

- Preclinical candidate SAN903 to be developed to Phase 1 clinical study in 18 months
- First-in-class compound with a new mode-of-action and strong IP

Saniona AB (OMX: SANION) today announces that it has selected a new development candidate, SAN903, for preclinical development, which can enter clinical Phase 1 in only 18 months. Based on work done to date, Saniona has elected to focus SAN903 initially on the treatment of Crohn's disease and colitis.

"SAN903, which is generated from our advanced ion channel platform, is a first-in-class product and, we believe, has the potential to transform the treatment paradigm for severe autoimmune diseases, including Crohn's disease and colitis. We look forward to bringing this exciting asset to the stage of Phase 1 first-in-man clinical studies in early 2021," said Jørgen Drejer, CEO of Saniona.

With SAN903, Saniona has identified a novel proprietary IK channel inhibitor that effectively dampens gut inflammation and can be used for the treatment of inflammatory bowel diseases (IBD), like Crohn's disease and ulcerative colitis. The drug will likely be the first ion channel modulator for IBD.

The IK potassium channel is very important for controlling immune cell functions in both peripheral tissues and the brain. A precise pharmacological modulation of the IK channel can thus be used for treatment of multiple diseases which involve overactive or mistimed immunological reactions, such as autoimmune diseases like rheumatic arthritis and multiple sclerosis, the prevention of organ rejection after transplantation, and reducing brain damage after a stroke. Furthermore, SAN903 also has potential in certain rare blood diseases, where Saniona may obtain an orphan designation, and develop the product all the way to the market.

The preclinical development of SAN903 will encompass scale-up of the manufacturing process, GMP production and various toxicology studies, which will form the basis for a regulatory application to initiate first-in-man clinical trials. Saniona is concurrently working with its development partners to initiate Phase 1 clinical trials early 2021.

For more information, please contact

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This information is such information as 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 person set out above, at 08:00 a.m. CET on July 22, 2019.

About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders. The company has five programs in clinical development. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and



Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and the company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

About SAN903

SAN903 inhibits the IK potassium channel (also known as KCa3.1, encoded by the gene KCNN4), which is important for controlling immune cell functions. A precise pharmacological modulation of the IK channel can thus treat diseases, which involve overactive or mistimed immune reactions, such as inflammatory bowel diseases and potentially also rheumatic arthritis and multiple sclerosis. Saniona assesses that SAN903 is the first ion channel modulator developed for IBD and will thus become first-in-class. SAN903 may also have potential to treat a rare congenital blood disease called hereditary xerocytosis (HX), which is caused by mutations in the IK channel. SAN903 has excellent freedom-to-operate and composition-of-matter protection until 2039.

About Inflammatory Bowel Diseases, IBD

Inflammatory bowel disease (IBD) is a group of inflammatory conditions in the large - and small intestine. It is estimated that more than 3.5 million patients are diagnosed with IBD (colitis and Crohn's patients) in Europe and the U.S.¹ The prevalence and incidence of IBD is increasing worldwide, especially in countries with an established or newly adopted Western lifestyle.

The market for anti-inflammatory treatments in IBD is estimated to be more than USD 5.9 billion in 2014². IBD patients require maintenance treatment as well as frequent interventions with strongly immune suppressing medicines, which have numerous side-effects. Currently used anti-IBD drugs are anti-inflammatory (5-ASA's, steroids), generally immune dampening (azathioprine, 6-mercaptopurine), or biologics targeting specific cytokines/integrins (e.g. infliximab, ustekinumab, vedolizumab) as well as JAK inhibitors (e.g. tofacitinib). Despite the medication IBD patients often face a gradual worsening of their condition due to chronic fibrotic changes in the gut, which may lead to life-threatening obstructions that must be resolved by acute gut-shortening surgery. There is preclinical evidence that the SAN903 mechanism may both reduce ongoing intestinal inflammation and have an independent effect on the chronic complications of the disease without side effects observed with the traditional IBD medicines.

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¹ www.ncbi.nlm.nih.gov/pubmed/26323879.

² Major markets 2014, Datamonitor