PRESS RELEASE

November 3, 2022

Saniona's anti-inflammatory and anti-fibrotic candidate SAN903 is ready for clinical studies

- **SAN903 has finalized preclinical development and fulfilled other requirements for clinical development**
- **Potential first-in-class compound offers a new treatment paradigm for inflammatory and fibrotic diseases**

Saniona (OMX: SANION), a clinical stage biopharmaceutical company, today announced that SAN903 is ready to start the regulatory process for entering Phase 1 clinical trials either by Saniona alone or together with a partner following successful completion of preclinical development.

"Preclinical data for SAN903 are very compelling and we believe it has potential to become first-line treatment in patients suffering from inflammatory bowel disease, IBD, where it could be the first maintenance drug with independent actions on both acute inflammation and chronic fibrotic complications. Other potential indications include fibrotic disorders such as chronic kidney disease, CKD, and the fatal lung disease idiopathic pulmonary fibrosis, IPF. There is a significant unmet medical need and commercial opportunities in inflammatory bowel disease and rare fibrotic disorders," said Thomas Feldthus, Chief Executive Officer of Saniona.

SAN903 is a novel, potential first-in-class medicine based on inhibition of the calcium-activated potassium ion channel, $K_{Ca}3.1$. This ion channel is found on several types of immune cells, where it participates in the control of the cellular pathways that maintain pathogenic activation and inflammation in chronic diseases. The $K_{Ca}3.1$ channel is also expressed on fibroblasts, especially on myofibroblasts, where it supports the overproduction of connective tissue that can lead to fibrosis. Prevention of fibrotic complications is an aspect of the disease, which is poorly treated by current standard-of-care IBD medicines, and progressed fibrosis often requires surgical intervention to resolve potentially life-threatening gut obstructions. SAN903 dampens inflammation and fibrosis by preventing cell division and cell migration of activated immune cells and fibroblast and by impeding cytokine release and collagen secretion of the respective cell types.

Palle Christophersen, EVP Research, commented: I am incredibly happy that SAN903 – which is the result of a long and challenging drug discovery phase – has now successfully completed the preclinical development package and is ready for entering the clinical stages. Inflammatory bowel disease is a complex disease with a rather low initial responder rate and poorly controlled disease progression. Due to its new mode-of-action, I anticipate that the entry indication for SAN903 can be newly diagnosed, mild-to-moderate colitis patients that are failing first-line treatment with standard-of-care medicine. Due to the actions on both inflammatory and fibrotic processes, I hope that SAN903 can become the first maintenance drug, which effectively prevents development of intestinal fibrosis in patients suffering from inflammatory bowel disease.

For more information, please contact

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

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 08.00 CET on 3 November 2022.

About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. The company's most advanced product candidate, Tesomet™, has been progressed to mid-stage clinical trials for rare eating disorders. Through its ion channel expertise, Saniona is advancing two product candidates, SAN711and SAN903. SAN711 has successfully completed a Phase 1 clinical trial for the treatment of neuropathic pain conditions. SAN903 is ready for Phase 1 clinical studies for the treatment of inflammatory and fibrotic disorders. The company has research and development partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cephagenix ApS. Saniona is based in Copenhagen, Denmark, and listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at http://www.saniona.com.

About inflammatory bowel diseases

It is estimated that 2.5 million patients are diagnosed with IBD (1 million colitis and 1.5 million Crohn's patients) in the seven major markets (USA, Japan; 5 major EU countries). The incidences are increasing, especially in newly industrialized countries, presumably due to changes in lifestyle. Currently used anti-IBD drugs are anti-inflammatory (5-ASA´s, steroids, JAK inhibitors), generally immune dampening (azathioprine, 6-mercaptopurine), or biological single cytokine/integrin neutralizing agents (e.g. infliximab, ustekinomab, vedolizumab). Despite these options and carefully optimized clinical procedures, patients still face rounds of gut-shortening surgeries (many Crohn's patients experience at least one surgery in their lifetime), and colitis patients may develop proctitis after colectomy. Suboptimal medical disease control with respect to maintaining long-term remission, to fight flare ups, and especially avoiding development of irreversible structural changes due to irresolvable gut fibrosis, represents a serious unmet need for IBD patients.