PRESS RELEASE

February 18, 2019

Saniona's SAN711 selected for clinical studies in itching and pain

- **SAN711 has achieved preclinical validation and met other requirements for clinical study**
- **First in class compound offers a new treatment paradigm for itching and neuropathic pain**
- **Targeting rare itching disorders with significant unmet medical need**

Saniona (OMX:SANION), a biotech company focused on CNS and eating disorders, announced today the successful completion of preclinical development of SAN711, for the treatment of chronic itching and neuropathic pain. Preparations for Phase 1 clinical trials are underway and scheduled to start during summer 2019.

"Preclinical data for SAN711 are very compelling and we believe it has the potential to become a first-line treatment in patients suffering from severe untreatable itching conditions and neuropathic pain disorders. There is a significant unmet medical need and a significant commercial opportunity in rare itching disorders for which we may potentially pursue accelerated development, for example in Brachioradial pruritus," said Jørgen Drejer, CEO of Saniona.

SAN711 is a selective $GABA_A$ α3 modulator (PAM) which has demonstrated strong efficacy in rodent itching and pain models. The company has completed a comprehensive preclinical package, including full toxicology and GMP validation. The clinical candidate now is ready for filing for clinical testing. SAN711 comes from Saniona's advanced ion channel platform. Phase 1 clinical testing is scheduled to start over the summer 2019, either internally or together with a potential partner.

SAN711 has the potential to become a novel treatment of severe and untreatable itching conditions caused by renal failure and liver diseases as well as rare neuropathic itching diseases such as Brachioradial pruritus. Many chronic itching conditions are not related to skin reactions but are a result of chronic changes in sensory modulation in the spinal cord, mediated by $GABA_A$ α3 receptors, which SAN711 targets. SAN711 has proven to be effective in relevant itching models and recent peer-reviewed literature[i] in the field provides a strong scientific rationale for developing SAN711 for itching.

SAN711 also has the potential to become a novel and revolutionizing non-narcotic treatment concept for chronic pain conditions such as neuropathic pain, which has proven to be notoriously difficult to manage. It is estimated that 40-60% of patients do not respond to existing drugs and that the responders only achieve partial pain relief.

Narcotic analgesics such as morphine are effective for acute treatment of neuropathic pain, but patients need higher and higher doses to maintain pain relief due to tolerance development. In addition, the abuse potential of narcotic analgesics has proven to be a major problem for treatment of chronic neuropathic pain. As opposed to morphine, the effect of SAN711 is maintained after chronic treatment in neuropathic pain models. Moreover, SAN711 appears to be very well tolerated without abuse liability and other side effects such as drowsiness, dizziness and somnolence seen with strong analgesic.

For more information, please contact

Thomas Feldthus, EVP and CFO, Saniona, Mobile: +45 2210 9957, E-mail: tf@saniona.com

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 four 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 chronic itching/pruritus

Pruritus or itch is the most frequent symptom seen in dermatology including atopic dermatitis, urticaria and psoriasis. Pruritus is often defined as an unpleasant sensation associated with the desire to scratch and significantly reduces the quality of life of the affected individuals in a wide range of medical conditions. With a lifetime prevalence of up to 22% and a high rate of therapeutic failure due to suboptimal treatment options, chronic itch imposes a significant socio-economic burden. Antihistamines have traditionally been the first-line treatment option for most pruritic conditions despite low efficacy in the substantial number of pruritic diseases characterized by histamine-independent pruritus. Certain systemic diseases have long been known to cause pruritus that ranges in intensity from a mild annoyance to an intractable, disabling condition. Generalized pruritus may be classified into the following categories based on the underlying causative disease: renal pruritus, cholestatic pruritus, hematologic pruritus, endocrine pruritus, pruritus related to malignancy, and idiopathic generalized pruritus. The global combined market for treatment of atopic dermatitis and psoriasis amounts to approximately US$10 million and is expected to double over the next 10 years.

About neuropathic pain

Neuropathic pain is caused by a lesion or dysfunction of the central or peripheral nervous system following diseases such as diabetes, varicella zoster, cancer and HIV or mechanical lesion and trauma or the use of drugs such as chemotherapy. Neuropathic pain is often chronic, irreversible and notoriously difficult to manage. According to industry estimates, neuropathic pain is believed to affect about 40 million people in seven major markets. Major indications include chronic low-back pain, painful diabetic neuropathy, post herpetic neuralgia (following shingles), neuropathic cancer pain and HIV related neuropathic pain. Well-known painkillers, such as Aspirin®, Panodil®, and ibuprofen have no or little effect on neuropathic pain. Apart from narcotic analgesics (where tolerance development is a further complication), patients are typically treated with drugs developed for other indications including anti-epileptic drugs and antidepressants. The market for neuropathic pain is estimated to be approximately US$4 billion with an anti-epileptic drug being the current market leader. It is estimated that 40-60% of the treated patients do not respond to existing drugs and that those that do respond to existing drugs only achieve partial pain relief, creating a significant medical need for more effective treatments. Furthermore, the existing drugs typically have severe and dose limiting side effects such as drowsiness, dizziness and somnolence.

About SAN711

SAN711 is a first-in-class pain and itch-relieving compound, which has the potential of being a first-line treatment option for pain management in patients suffering from untreatable neuropathic pain or itching disorders, either as standalone treatment or as an add-on medication to existing suboptimal therapies. SAN711 acts on the receptors for GABA, the main inhibitory signaling mediator in the nervous system. SAN711 works selectively on receptors containing the $GABA_A$ α3 proteins without efficacy on the main $GABA_A$ receptors in the brain including the so-called α1 protein. This is important, since the sedative and hypnotic adverse effects of current marketed product acting on the receptors of GABA, such as Valium®, are due to its action on the α1 containing receptors, whereas the pain relief and anti-itch effects rely on its effects on α3 containing receptors. This means that SAN711 may regulate the body's own pain and itch regulating system in the spinal cord without

promoting unwanted side effects through activation of other GABA systems in the brain. The preclinical studies with the compound have confirmed efficacy in animal models of neuropathic pain and itching without the sedative effect.

[i] e.g. Ralvenius et al. Nature Comm. 2018, 9 (3230): 1-15