



## PRESS RELEASE

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### **Saniona Selects Preclinical Candidate in GABA $\alpha$ 2/ $\alpha$ 3 Program for Neuropathic Pain and Chronic Itching**

**Saniona, a leading biotech company in the field of ion channels, today announces the selection of a preclinical candidate, SAN711, for the treatment of neuropathic pain and chronic itching. The nomination is consistent with Saniona's strategy to progress innovative products from its internal research pipeline towards clinical development prior to partnering.**

"The selection of SAN711 is a significant milestone for Saniona that further demonstrates the robustness of our unique ion channel platform. SAN711 has the potential to become a first-line treatment for pain management in patients suffering from untreatable neuropathic pain disorders. We have also established in preclinical studies that SAN711 could be used to treat itching, a severely disabling consequence of certain skin disorders including atopic dermatitis and psoriasis," commented Jørgen Drejer, CEO of Saniona.

In May 2016 Saniona announced plans to initiate extended non GLP preclinical studies on backup compounds for its first generation GABA $\alpha$  2/  $\alpha$ 3 compound AN363. These preclinical studies led to the selection of the GABA $\alpha$  2/ $\alpha$ 3 selective compound SAN711, which has demonstrated desirable efficacy and devoid of undesirable effects observed with its predecessor AN363.

Preclinical development of SAN711 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 in the first half of 2019.

Dr Drejer concluded, "We are enthusiastic about the opportunity to use GABA $\alpha$   $\alpha$ 3 subtype specific compounds for chronic pain and itching and are eager to progress SAN711 towards the clinic. In animal models, SAN711 has shown efficacy for neuropathic pain and itching. These models have also shown that SAN711 is well tolerated with no signs of sedation or other undesirable characteristics associated with other non-selective GABA modulators."

#### **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 CET on December 4, 2017.

#### **About Saniona**

*Saniona is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The company has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The research is focused on ion channels, which makes up a unique protein class that enables and controls the passage of charged ions across cell membranes. Saniona has ongoing collaboration agreements with Boehringer Ingelheim GmbH, Proximagen Ltd., Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq Stockholm Small Cap and has about 5,300 shareholders. The company's share is traded under the ticker SANION. Read more at [www.saniona.com](http://www.saniona.com).*



### **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 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 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-alpha3 proteins without efficacy on the main GABA-A receptors in the brain including the so-called alpha1 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 alpha1 containing receptors, whereas the pain killing and anti-itch effects rely on its effects on alpha 3 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.