PRESS RELEASE

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Saniona progresses its Kv7 epilepsy program into Lead Optimization

Saniona (OMX: SANION), a clinical stage biopharmaceutical company, today announced that it has progressed its promising Kv7 epilepsy program into the Lead Optimization Phase, which is the last drug discovery phase before potential selection of a clinical candidate.

Thomas Feldthus, CEO: “We believe that we have cracked the main challenges for making the next generation drug candidates of this class and see significant potential for delivering new breakthrough epilepsy treatments. The financial upside could be substantial based on very significant pharma deals recently executed in the Kv7 field”.

Epilepsy, characterized by recurrent seizures, currently affects millions of people worldwide. There is a significant medical need as approximately 30% of patients are insensitive to treatment by conventional epilepsy medicines. Furthermore, anti-seizure therepy may cause disabling side effects and often require careful dose adjustment to minimize these.

Kv7 ion channels are voltage-activated potassium channels that play a critical role by dampening of repetitive firing of neurons, which potentially can lead to seizure activity. The special importance of the Kv7.2/Kv7.3 heteromeric channel within epilepsy is clearly illustrated by the increasing numbers of mutations in Kv7.2 and Kv7.3 that are found to be associated with severe inherited forms of epilepsy. Thus, small molecule drugs that facilitate the opening of Kv7.2/Kv7.3 ion channels have potential to treat epilepsy as well as other neuronal hyperexcitability disorders.

There is proof of concept for the use of Kv7 modulators for treatment of epilepsy as a relatively recently approved non-selective Kv7 anti-seizure drug, ezogabine (retigabine), has demonstrated strong anti-epileptic activity. Unfortunately, this drug had to be withdrawn from the market due to serious adverse effects including skin discoloration, retinal changes, and increased risk of urinary retention, a potentially life-threatening condition. The skin discoloration and retinal changes are caused by ezogabine’s chemical instability and not by the compound’s mode-of-action, whereas the increased risk of urinary retention is believed to be due to the non-selective profile of ezogabine leading to unintentional activation of Kv7 subtypes expressed in the bladder.

Several companies and academic groups have over the past decade worked on developing a next generation drug candidate avoiding the limitations and tolerability issues with ezogabine. Saniona scientists have been active in the Kv7 drug discovery field for more than a decade and have worked in previous Kv7 Pharma partnership programs. Saniona has now managed to progress into lead optimization stage with a new chemical series that circumvent limitations with first generation drug candidates. The main features of these new Kv7 activators are improved chemical stability as well as differentiation in selectivity and mechanism-of-action, which can eliminate relaxation of bladder tissue. The objective of the lead optimization program is thus to develop a second generation Kv7 medicine without the side effects that led to the withdrawal of exogabine from the market.

Palle Christophersen, EVP Research: “Kv7 activation has been clinically validated as an effective anti-epileptic concept, but a new medicine is highly warranted. I strongly believe that an optimized candidate from our new Kv7 program will address unmet medical needs in difficult-to-treat patients, such as treatment-resistant partiel onset epilepsies and pediatric epilepsies caused by Kv7 mutations. By preserving or even improving anti-seizure activity with a chemically stable compound and avoiding unintended bladder relaxation, we are in a strong position to help these patients.”

Saniona AB (publ)
Smedeland 26B
DK-2600 Glostrup
Denmark

EMAIL saniona@saniona.com
WEB saniona.com

For more information, please contact

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

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About Saniona

Saniona is a clinical-stage biopharmaceutical company with a mission to leverage its ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments. The company's most advanced product candidate, Tesomet™, has been progressed into mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, serious rare disorders characterized by severe weight gain, disturbances of metabolic functions and uncontrollable hunger. Saniona has developed a proprietary ion channel drug discovery engine anchored by IONBASE™, a database of more than 130,000 compounds, of which more than 20,000 are Saniona's proprietary ion channel modulators. Through its ion channel expertise, Saniona is advancing two wholly owned ion channel modulators, SAN711, SAN903. SAN711 has successfully completed a Phase 1 clinical trial and is positioned for the treatment of neuropathic pain conditions; SAN903 is in preclinical development for rare inflammatory, fibrotic, and hematological disorders. Saniona is based in the Copenhagen area, Denmark, and is listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at http://www.saniona.com.