



## PRESS RELEASE

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### **Saniona participates in formation of Initiator Pharma A/S and spins out three noncore Saniona programs**

**Saniona, a leading biotech company in the field of ion channels, today announces that Saniona has participated in the formation of Initiator Pharma A/S (Initiator Pharma), a company focused on developing drugs for treatment of erectile dysfunction. Saniona owns 60% of Initiator Pharma, which has subsequently acquired three noncore programs from Saniona A/S. The management of Initiator Pharma plans to apply for a public listing at AktieTorget in Sweden. The board of directors of Saniona intends to propose at an extra ordinary general meeting that Saniona's shareholding in Initiator Pharma shall be distributed to Saniona's shareholders as a specific dividend payment before the listing of Initiator Pharma. The potential distribution of Saniona's shares is subject to application of Lex ASEA under the Swedish income tax act.**

"The management team of Initiator Pharma has really impressed us. They have performed important preclinical studies around one of the compounds in the programs and have a profound knowledge of developing these assets, which Saniona does not intend to develop internally. By combining the knowledge of the Initiator Pharma Founders and the technology from Saniona, we can create a new interesting company to the benefit of patients and Saniona's shareholders," says Jørgen Drejer, CEO of Saniona.

"We are very enthusiastic about the possibility of developing compounds acquired from Saniona. Our lead compound is positioned for treatment of the large group of patients with erectile dysfunction that do not respond to current treatments like Viagra. We see a significant potential for this compound, which is based on a unique mode of action and which may address a significant medical need within this large market," says Claus Olesen, CEO of Initiator Pharma.

The three programs, which Initiator Pharma acquires from Saniona A/S, comprise three monoamine reuptake inhibitors. Saniona has not discussed these assets publicly previously since Saniona does not plan to develop these assets and the technology does not fit into Saniona's research platform within ion channels. The Founders of Initiator Pharma intend to develop these assets for various indications. The lead compound will be positioned for erectile dysfunction where the Founders have obtained promising results in preclinical animal studies. Initiator Pharma intends to raise capital with the aim of starting preclinical development in preparation of Phase 1 clinical trials.

Initiator Pharma intends to submit an application for trading of the company's shares at AktieTorget in Sweden. Saniona has forwarded a request to the Swedish tax authorities in order to obtain prior confirmation whether a potential distribution of all Saniona's shares in Initiator Pharma is covered by Lex ASEA in the Swedish income tax act. The Founders and Saniona may consider other alternatives for financing the company if Saniona is unable to distribute its shareholding in accordance to Lex ASEA.



Saniona cannot give taxation advice and cannot be held responsible for any taxation consequences. A preliminary evaluation of the taxation consequences indicate that the distributed shares will not be taxed until a gain is realised for shareholders in Sweden if distributed in accordance to Lex ASEA and that the distributed shares for shareholders in Denmark may cause a very modest immediate taxation and further tax after realising any gains.

Saniona commercializes its research efforts through three different business models including internal development through early phases of drug development, through early stage research collaborations, and through spin-outs. The formation of Initiator Pharma represents a variant of the third model.

For clarity, the Founders, management and the other shareholders of Initiator Pharma are independent of Saniona's board, management and major shareholders of Saniona.

**For more information, please contact**

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**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 Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at AktieTorget since April 2014 and has about 3,000 shareholders. The company's share is traded under the ticker SANION. Read more at [www.saniona.com](http://www.saniona.com).*



## **About Initiator Pharma**

Initiator Pharma is a newly established biotech company based in Aarhus, Denmark. The company's lead compound IPED2015 represents a novel treatment paradigm for the treatment of Erectile Dysfunction (ED) and may improve the quality of life for the growing number for patients (and their partners) that do not respond or cannot be treated with the current marketed medication.

Current guidelines recommend Viagra type drugs (PDE5 inhibitors) such as sildenafil, vardenafil and tadalafil as the first line treatment of ED, however approximately 30-40% of men with ED do not respond to drug therapy (Gupta et al, 2005). Patients suffering from neurologic damage, diabetes mellitus or severe vascular disease as well as patients treated with certain antidepressants, antipsychotics and anxiolytics may be resistant to PDE5 inhibitors (Jackson et al, 2006, Gratzke et al, 2010).

Erectile dysfunction affects more than 150 million men worldwide and that number is expected to increase to more than 322 million by 2025. The market was valued to more than USD 4.3 billion in 2012, but is expected to decrease to a value of USD 3.4 billion in 2019 because of patent expiration of especially PDE5i compounds. With 30-40% of the ED patients and with an estimated general increase of ED patients by 2025 the market size for new non-PDE5i treatments is expected to comprise more than 100 million patients. This major unmet medical need constitutes a unique opportunity for launching a new ED product targeting this specific group of patients, which do not respond to PDE5i drugs.

Initiator Pharma believes that IPED2015 may become first line of treatment for the PDE5i non-responders and non-users with its unique mechanism of action that do not interfere with the cardiovascular system and that very uniquely can initiate an erectile response in contrast to all other marketed drugs, which only boost a local erectile response.

IPED2015 is supported by a large preclinical package that Initiator Pharma have combined with a highly experienced ED research group and specific competencies within conducting preclinical, clinical development and regulatory approval. This combination represents a unique opportunity to attain a clinical Phase 2 Proof-of-Concept with 3-4 years' time frame.

## **Initiator Pharma Management**

### **Claus Olesen PhD, Founder and CEO**

Dr. Olesen has been involved in numerous drug development projects in both academic and industrial collaborations. He is the co-founder of Pcovery Aps (2009) an antifungal Biotech situated in Copenhagen and NMD Pharma (2015) a biotech company focused on the development of new treatments for various neuromuscular disorders. Dr. Olesen earned his PhD. in Physiology and Biophysics from Aarhus University. He is the author of a number of articles including two first authorship articles in Science and Nature.

### **Dan Peters, Ph.D., Founder and CTO.**

Dr. Peters joined NeuroSearch in 1991 and served as project manager for the monoamine reuptake program from 1999, where he developed a novel platform of compounds including the compounds of Initiator Pharma as well as NSD-644, NSD-761 and NSD-788 which were taken into the clinic. From 2000-2011 Dr. Peters served as Director of Medicinal Chemistry and was in 2007 appointed Vice President of Medicinal Chemistry. Dr. Peters has authored more than 70 peer-reviewed scientific articles and is inventor of more than 100



patent-families. Dr. Peters is the founder of DanPET AB and holds a Ph. D. in Chemistry from the University of Lund.

**Ulf Simonsen MD. PhD. Professor, Founder and CMO**

Prof. Ulf Simonsen became Professor of Pharmacology at Aarhus University in 2005 and head of Department of Pharmacology from 2006-2011. In collaboration with Dr. Inigo Saenz de Tejada, Ulf Simonsen was the first to investigate the function of the smallest arteries in the penis (the “helicine” arteries), and since then he has been an active member of the European Society of Sexual Medicine, and Committee of World Health Organisation’s consultations on erectile dysfunction. The research group of Prof. Ulf Simonsen has ample experience in preclinical models for erectile dysfunction and cardiovascular disease from cell to man and participates in clinical studies. Prof. Ulf Simonsen is a medical doctor from Aarhus University and earned his PhD in physiology from Complutense University, Spain. He is author or co-author of more than 155 peer reviewed papers in international journals, several book chapters, and a couple of patents.

**Mikael Thomsen, M. Sc., Ph.D., CSO.**

Dr. Thomsen has worked in the pharmaceutical industry for 20 years in companies like Novartis Pharma and Novo Nordisk as well as at the U.S. Food and Drug Administration. He is co-founder of a number of biotech company including OSI Prosidion Ltd (UK), Sound Biotech (DK), Concit Pharma (DK) and Conrig Pharma (DK). He is an experienced Clinical Pharmacologist where he was responsible for planning and conduction of Preclinical, Phase 1 and Phase 2 activities. He has taken numerous compounds from research/pre-clinical into Phase 1/2. Dr. Thomsen has two M. Sc. degrees (Pharmacy and Human Biology) and has a PhD in Pharmacology and Toxicology (University of Copenhagen and FDA site, Arkansas, US) and a degree in Pharmaceutical Medicine (ECPM, Basel, Switzerland).