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## **Initiator Pharma - First patient dosed in Phase 2a trial with IP2018**

**PRESS RELEASE**  
**December 9, 2020**

**Initiator Pharma A/S, a clinical-stage biotech company, today announced that the first patient was dosed in its Phase 2a clinical trial with IP2018 to treat psychogenic sexual dysfunction. IP2018 is Initiator Pharma's second Phase 2 asset and is complementary to IPED2015 for which positive Phase 2a data on Organic Erectile dysfunction was reported earlier this year. Initiator Pharma has received a commitment from Innovation Fund Denmark to support the clinical development of IP2018.**

IP2018 is being developed for the treatment of sexual dysfunction in patients with major depressive disorder and patients with psychogenic Erectile Dysfunction (ED) of other causes. It is a unique drug candidate that targets a clear unmet medical need and IP2018 is differentiated from all existing anti-depressants and drugs for psychogenic ED. Up to 68 percent of patients with major depressive disorder suffer from sexual dysfunction, highlighting a significant unmet medical need.

The Phase 2a trial is a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of IP2018 in young, depressed patients with ED. The primary objective of the trial is to investigate the effects of IP2018 on penile rigidity and tumescence using a visual sexual stimulation test. The trial will be conducted on 24 patients at the MAC Phase I unit in Manchester, UK by MAC Clinical Research. Pending the Covid-19 situation the trial is planned to be executed within the next 9 months, and top-line data from the trial is expected end of H1 2021. The company has a commitment from Innovation Fund Denmark to fund the trial with up to 3.8 MDKK through the Innobooster grant.

*"We are very pleased to have been able to safely dose the first patient in this Proof of Concept clinical trial with IP2018, particularly under the difficult Covid-19 pandemic situation. We are also delighted about Innovation Fund Denmark's recent decision to fund the study with almost 4 MDKK, a clear validation of the drug candidate and our research", says CEO, Claus Elsborg Olesen. "With the initiation of this clinical trial, we have added a strong complementary asset to our clinical pipeline which supports our ambition to bring functional medication to patients in need and to create value for our shareholders".*

In connection with the company's latest rights issue of units and directed issue of units in June 2020, warrants of series TO 2 were issued. The exercise period for the warrants started on November 24 and runs until December 15, 2020. Upon full exercise of warrants, Initiator Pharma will receive approximately SEK 16.4 million before issue costs. The proceeds from the warrant exercise will primarily be used to develop IP2018 through the clinical phase 2a trial and generation of Proof-of-Concept. IP2018 strengthens the company's project portfolio. Obtaining Proof-of-Concept will position IP2018 as a new type of treatment for the large

number of depressive patients who, due to serious side effects, do not want or can use the medicines available on the market.

In addition to Innovation Fund Denmark's investment and the ongoing exercise of warrants, Initiator Pharma recently signed a financing agreement with UK's largest independent clinical development organization, MAC Clinical Research. The agreement, that is worth up to 23 MSEK, secures funding of the continued Phase 2 clinical development of the company's lead candidate drug IPED2015 in organic erectile dysfunction (ED).

**For more information about Initiator Pharma, please contact:**

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*This information is the type of information that Initiator Pharma (Ltd.) is obligated to publish pursuant to the EU Market Abuse Regulation. The information was provided by the contact person above, to be published on December 9, 2020, at 14:55 (CET).*

**About Initiator Pharma**

Initiator Pharma is a clinical-stage biotechnology company based in Aarhus, Denmark. The company's main clinical Phase assets are IPED2015, intended for patients with erectile dysfunction, and IP2018, for the treatment of psychogenic erectile dysfunction. The treatments both represent First in Class treatments for psychogenic and organic ED, respectively. These unique treatments are expected to improve the quality of life for a growing number of patients who are not responding to or cannot be treated with existing drugs on the market. Read more on [www.initiatorpharma.com](http://www.initiatorpharma.com).

**IP2018**

IP2018 is a monoamine reuptake inhibitor that has a unique profile inhibiting serotonin followed by dopamine reuptake, while it has markedly less effect on the noradrenaline reuptake. IP2018 has antidepressive effects in animal models for depression and a positive effect on erectile function. There is a solid preclinical data package, a phase I study, and a positive emission tomography (PET) study showing binding in patients to the serotonin reuptake and dopamine reuptake transporter.

**About Erectile dysfunction (ED)**

Erectile dysfunction is sexual dysfunction characterized by the inability to develop or maintain an erection of the penis during sexual activity. ED affects more than 150 million men worldwide, and that number is expected to increase to more than 320 million by 2025, fueled by aging demographics and increasing prevalence of lifestyle diseases such as diabetes, and performance anxiety. The number of ED patients is most likely grossly underestimated, particularly for patients with ED of psychogenic origin. ED patients have decreased quality of life due to various psychosocial factors such as low self-esteem, depression, sadness, anger, frustration, anxiety, medication, and relationship problems (1,2, 3). Erectile dysfunction can be divided into two main categories: Organic and Psychogenic ED that requires different

treatments, Initiator Pharma are developing IPED2015 and IP2018, respectively, for these similar but different groups of patients.

1. Shabsigh R, et al. (1998) Increased incidence of depressive symptoms in men with erectile dysfunction. *Urology* 52(5):848–852.
2. McCabe MP, Althof SE (2014) A systematic review of the psychosocial outcomes associated with erectile dysfunction: Does the impact of erectile dysfunction extend beyond a man's inability to have sex? *J Sex Med* 11(2):347–363.
3. Nguyen HMT, Gabrielson AT, Hellstrom WJG (2017) Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors. *Sex Med Rev* 5(4):508–520.