

## Initiator Pharma A/S secures bridge financing in preparation of a clinical phase 2a trial for the candidate drug IP2018

### PRESS RELEASE

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Initiator Pharma A/S (“Initiator Pharma”) is currently conducting a clinical phase 2a trial for the company’s main candidate IPED2015, which is intended to be completed later in the summer. Initiator Pharma is now able to announce that the company has secured bridge financing of SEK 5 million with the aim of preparing the company’s other candidate drug IP2018 for the start of a clinical phase 2a trial. With this bridge financing, the company is able to conduct activities for added value before seeking more long-term funding. The clinical phase 2a trial regarding IP2018 is expected to begin in early 2020.

### IP2018 – positioning in the market for depression and erectile dysfunction

Initiator Pharma has previously announced that the company, in addition to working intensively with its main candidate IPED2015, will continue to evaluate IP2018, a candidate drug that is ready for phase II testing and which the company has access to through an option agreement with Saniona. The option agreement gives Initiator Pharma the possibility to, free of charge, thoroughly evaluate the clinical and commercial potential of the candidate drug at no cost to the company. It also allows the company the possibility to expand and reinforce the pipeline with an additional clinical asset in order to match and supplement ongoing activities and its own development pipeline. In 2019, the company has generated a valuable data package that has increased the understanding of the candidate drug’s potential, and the company plans to utilise the option of proceeding with the clinical development of IP2018 and to position the candidate drug on the market for drugs to treat depression and erectile dysfunction.

*“In parallel with the intensive efforts we are putting into our main candidate IPED2015, for which we are planning to complete a clinical phase 2a trial later this summer, we have discovered the exciting possibilities of IP2018. In view of our findings, we have made the strategic decision to look further into IP2018 and to continue developing this candidate for a clinical phase 2a trial, with the aim of also potentially helping people suffering from depression in the future”* says **CEO Claus Elsborg Olesen**.

IP2018 raises the serotonin levels in the brain, and in its preclinical trials, Initiator Pharma has shown that IP2018 has an effect on both depression and erectile function, which is a clear differentiation from other antidepressants on the market today. In the planned clinical phase 2a trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the erectile function of patients and thereafter, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The company intends to position IP2018 as a daily treatment for patients suffering from depression and sexual dysfunction and/or as a supplement to treat erectile dysfunction in patients with medically induced sexual dysfunction.

Depression is a mood disorder that affects feelings, thoughts, and behaviour and leads to a variety of emotional and physical illnesses. If left untreated, depression significantly reduces quality of life and may ultimately result in premature death from medical conditions or suicide. The main treatments for depression are drugs that modulate the levels of serotonin, noradrenaline and dopamine by either inhibiting the reuptake of these signalling substances (“reuptake inhibitors”) or by influencing their degradation. A key side effect of the currently available antidepressants is their significant impact on male sexual function (desire-arousal-excitement-orgasm). In a survey, it was observed that 41.7 % of men discontinued psychiatric medications due to perceived sexual side effects (Rosenberg KP et al “A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance”, J. Sex Marital Ther. 2003;29(4):289-96). Between 14 and 35 % of young men experience ED. The causes of ED can be caused by psychological, neurological, or lifestyle issues. ED can also be the result of side effects of specific medications (including some antidepressants), performance anxiety, depression, schizophrenia, and other psychological disorders.

*This very high barrier to medication adherence demonstrates the clear unmet medical need, and a high clinical interest for a drug that can treat both sexual/erectile dysfunction in young and mildly depressed patients. With the promising efficacious and first in class profile IP2018 has the potential to win to significant market share and become a blockbuster drug selling for more €1 bn annually.*

– **Claus Olesen, CEO Initiator Pharma A/S**

Major depressive disorder is one of the main causes of disability worldwide due to its high prevalence and associated impairments. Lifetime prevalence is 14.3 % in high-income countries. The Global Burden of Disease study showed a 37.5 % burden increase due to major depressive disorder from 1990 to 2010, and major depressive disorder is the second leading cause of Disability Adjusted life years in 2020. About 13 % of all Americans take anti-depression medication summing up to more than 23 million prescriptions per year (National Center for Health Statistics). The global revenue for antidepressants is forecasted to reach \$18 bn in 2020. The biggest players, accounting for more than 60% of the antidepressant drugs sold, are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H. Lundbeck A/S - all facing a significant patent cliff over the next few years, with revenues projected to be hit hard by generics and biosimilars. All current marketed drugs have to varying degree been associated with erectile dysfunction emphasising the need to develop an attractive and superior alternative.

### **Bridge financing**

In order to finance Initiator Pharma's IP2018 programme until the start of 2020, when the company expects to have received approval for the start of a clinical phase 2a trial, the company has secured bridge financing of SEK 5 million from Formue Nord Markedsneutral A/S, Modelio Equity AB and Per Nilsson. The bridge financing is valid until February 2020 at an interest rate of 2 per cent per month, and is intended to be fully or partially repaid in cash.

### **Capital requirement**

In order to take the candidate drug IP2018 through a clinical phase 2a trial and carry out partner discussions in this regard, and to expand the company's pipeline with other candidates ready for clinical trials, the company has a further estimated capital requirement of approximately SEK 25 million, in addition to the secured bridge financing. However, the capital requirement may be smaller, depending on the outcome of the initiated partner discussions, if the company secures any soft funding, etc.

### **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 13 August 2019.*

### **About Initiator Pharma**

Initiator Pharma is a biotechnology company based in Aarhus, Denmark. The company's main asset, IPED2015, is a candidate drug intended for patients with erectile dysfunction. The treatment is 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).

### **About erectile dysfunction**

ED is a sexual dysfunction characterised by the inability to achieve or maintain an erection during sexual intercourse. More than 150 million men around the world suffer from ED; a number that is expected to increase to more than 320 million by 2025 due to an ageing population and an increased incidence of lifestyle illnesses such as diabetes. ED entails an impaired quality of life in patients due to various psychosocial factors, such as low self-esteem, depression, sadness, anger, frustration, anxiety and relationship problems (1, 2, 3).

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.