

## Initiator Pharma obtains approval to start Phase 2a trial for IP2018

Initiator Pharma A/S, a clinical-stage biotech company today announced that it has obtained approval from the Medicines and Healthcare products Regulatory Agency, MHRA, and the Ethical committee (EC) UK, for a Phase 2a clinical trial with its candidate drug IP2018. The Phase 2a clinical trial is planned to be initiated in Q3 2020.

IP2018 is a candidate drug being developed for the treatment of sexual dysfunction in patients with major depressive disorder. Up to 68% of patients with major depressive disorder suffer from sexual dysfunction, which for only 5% to 30% of these patients is resolved with antidepressant treatment. The clinical Phase 2a trial with IP2018 aims to obtain proof of concept for effect on erectile dysfunction in young patients with depression.

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, erectile dysfunction (ED) patients. The primary objective of this study is to investigate the effects of IP2018 on penile rigidity and tumescence using visual sexual stimulation test. The study will be conducted in 24 patients at the MAC Phase I unit in Manchester, UK. Pending the Covid-19 situation the trial is planned to start in Q3 2020 and top-line data is expected end of first half year of 2021.

“Once again, we have obtained a formal approval from MHRA and EC for a Proof-of-Concept study in this often overlooked patient group with a high need for better treatment”, says CEO, Claus Elsborg Olesen. “The approval means we are strengthening our pipeline with another promising candidate drug in clinical phase 2. We are now looking forward to initiate the study by dosing the first patients.”

### IP2018

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

### 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 June 29, 2020 at 10:25 CET.*

### 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.