

Initiator Pharma - Phase 2a study with IP2018 update

PRESS RELEASE

2 June 2021

Initiator Pharma A/S, a clinical-stage Life Science company today announced that it has received approval from the Medicines and Healthcare products Regulatory Agency, MHRA, UK and the Ethics Committee for optimizing the study execution of its Phase 2a study with IP2018.

As previously communicated the recruitment rate for the randomised, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of IP2018 in depressed, Erectile Dysfunction (ED) Patients has been slow due to the ongoing Covid-19 pandemic.

In order to mitigate the situation and ensure a successful completion of the trial Initiator Pharma has obtained approval from the regulatory authorities to modify certain inclusion criteria. Furthermore, thanks to the high vaccination ratio and the forthcoming reopening of the British society, the recruitment rate is expected to increase. The primary objective of the study is to investigate the effects of IP2018 on penile rigidity and tumescence using visual sexual stimulation test. The study is conducted in 24 patients at the MAC Phase I unit in Manchester, UK.

“We are excited with the granted amendments to the Phase2a a protocol, now we can cover an even broader portion of the Psychogenic ED patient segment and this will provide us a unique guidance for the future positioning of IP2018.” says CEO, Claus Elsborg Olesen. *“With the amendments, we hope to enroll and complete the study later this year – we will keep the market updated on the timing, but we do not foresee this pushing the overall ambition and timeline for a potential approval of IP2018“*

IP2018

IP2018 is a monoamine reuptake inhibitor and 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 in animal models for depression and effect on erectile function. There is 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.

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The information was provided by the contact person above, to be published on the 2nd of June 2021.

About Initiator Pharma

Initiator Pharma A/S is a Danish clinical stage life science company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of three clinical programs - the drug candidates IP2018 and IPED2015 for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug candidate IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition. Initiator Pharma is listed on Spotlight Stockmarket (ticker: INIT).