Initiator Pharma files CTA for IP2018 Phase 2a and exercises option agreement with Saniona

PRESS RELEASE
31 March, 2020

Initiator Pharma A/S, a clinical-stage biotech company today announced that it has filed a Phase 2a Clinical Trial Application (CTA) to the Medicines and Healthcare products Regulatory Agency, MHRA, UK, for its candidate drug IP2018. The company anticipates to obtain an approval and to initiate the Phase 2a clinical trial during the summer of 2020. Through the submission of the CTA, Initiator Pharma also exercises its option agreement with Saniona for IP2018.

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 resolves with antidepressant treatment for only 5% to 30% of patients. The planned 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 include 24 patients at the MAC Phase I unit in Manchester, UK.

"*It is very satisfying that we now have filed the CTA and soon will be able to initiate a Proof-of-Concept study in this often overlooked patient group with a high need of better treatment",* says CEO, Claus Elsborg Olesen. **"***The expansion of our pipeline with a promising Phase 2 asset is an important step in our efforts to establish Initiator Pharma as a cost-effective biotech that creates significant value by generating clinical Proof-of-Concept for drug candidates targeting indications with high unmet medical need and with attractive commercial attractive opportunities***".**

The submission allows Initiator Pharma to exercise its exclusive option agreement with Saniona for IP2018, entered in November 2018, and extended in October 2019. The deal involves no upfront and milestone payments. Saniona may receive up to 20 percent of future payments to Initiator Pharma in relation to IP2018 and single digit royalties on product sales.

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 an anti-depressive effect in animal models for depression and effect on erectile function. There is a robust 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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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 at 16:15 hour CET on 31st March 2020.

About Initiator Pharma
Initiator Pharma is a clinical-stage 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.

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 (2, 3, 4).

1. *Hellstrom WJ, et al., (2013) A phase II, single-blind, randomized, cross-over evaluation of the safety and efficacy of avanafil using visual sexual stimulation in patients with mild to moderate erectile dysfunction. BJU Int. 111:137-47.*
2. *Shabsigh R, et al. (1998) Increased incidence of depressive symptoms in men with erectile dysfunction. Urology52(5):848–852.*
3. *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 Med11(2):347–363.*
4. *Nguyen HMT, Gabrielson AT, Hellstrom WJG (2017) Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors. Sex Med Rev5(4):508–520.*