

Initiator Pharma completes dosing in Phase 2a trial with IP2018

Initiator Pharma A/S, a clinical-stage biotech company, today announced that it has completed dosing all 24 patients for its Phase 2a clinical trial with IP2018. Draft results are expected end of Q2 2023, as previously communicated.

The primary objective of this study is to investigate the effects of IP2018 on penile rigidity and tumescence using a visual sexual stimulation test. 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 study was conducted at the MAC Phase I unit in Manchester, UK. All 24 patients have received the dosing regimen, and the efficacy and safety assessments have been conducted as planned. Data analysis will now be initiated, and draft results are scheduled to be provided end of Q2 2023.

"We are pleased that we have now completed the study with the planned number of eligible patients and assessments despite the recruitment complications we previously experienced due to COVID-19. There is a clear unmet medical need within psychogenic ED, and hopefully, IP2018 can become an effective drug for these patients. We have strong faith in IP2018's mechanism of action and look forward to seeing the draft results," says Claus Elsborg Olesen, CEO at Initiator Pharma.

IP2018 is being developed to treat psychogenic erectile dysfunction (ED), which is the inability to achieve or maintain an erection during sex due to psychological factors. Up to 68% of patients receiving treatment for major depressive disorder suffer from sexual dysfunction, representing a clear unmet medical need. IP2018 will potentially relieve these patients and significantly increase their quality of life. In addition, IP2018 broadens the Initiator Pharma pipeline's scope, including first-in-class treatments for psychogenic and organic ED, IP2018 and IP2015, respectively.

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. In animal models for depression and erectile dysfunction, IP2018 has shown both an antidepressive effect and positive effects on erectile function.

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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 two clinical stage assets – IP2015 and IP2018 – and two preclinical assets. The company is currently conducting a Phase 2b trial with IP2015 in erectile dysfunction of organic origin, and successfully completed a Phase 1 proof of principle trial in neuropathic pain in 2022. With IP2018 the company is conducting a Phase 2a trial for the treatment of erectile dysfunction of psychogenic origin.

Initiator Pharma is listed on Nasdaq First North Growth Market (ticker: INIT). Redeye AB is the company's Certified Adviser. For more information, please visit www.initiatorpharma.com.

Attachments

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