

Initiator Pharma completes recruitment in Phase IIb trial with pudafensine (IP2015)

Initiator Pharma A/S, an emerging pharma company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, today announced that it has completed recruitment of all planned patients for its Phase IIb clinical trial with pudafensine (IP2015). Results are expected in Q4 2023.

"We are pleased that we have now completed the patient recruitment planned for the study with the eligible patients and assessments. There is a clear unmet medical need within organic ED and hopefully pudafensine can become an effective drug for these patients. We have strong faith in pudafensine's mechanism of action and we look forward to seeing the top line results later this year," says Claus Elsborg Olesen, CEO at Initiator Pharma.

The primary objective of the Phase IIb trial is to investigate the effects of repeat single oral doses of pudafensine on male subjects with severe or moderate erectile dysfunction (ED) on the ability to develop and maintain an erection, with weekly assessments during a 4-week treatment period. The Phase IIb trial is a randomized, double-blind, placebo-controlled, parallel dosing group trial studying the efficacy and safety of high and low doses of pudafensine as well as placebo in patients suffering from severe to moderate ED. The study is conducted at the MAC clinical sites in the UK. All planned 120 patients have been recruited and the last patients are undergoing the final dosing regimen, and the efficacy and safety assessments are being conducted as planned. Data analysis will be initiated after last patient last visit, and results are scheduled to be provided in Q4 2023.

For additional information about Initiator Pharma, please contact:

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About Initiator Pharma

Initiator Pharma A/S is a Danish clinical stage emerging pharma 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 – pudafensine (IP2015) and IP2018 – and two preclinical assets. The company is currently conducting a Phase IIb trial with pudafensine (IP2015) in erectile dysfunction of organic origin, and successfully completed a Phase I proof of principle trial in neuropathic pain in 2022. With IP2018 the company is conducting a Phase IIa 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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