Initiator Pharma reports positive statistically significant and clinically relevant Phase IIb efficacy data with pudafensine

Initiator Pharma A/S, a clinical-stage pharma company, today announced positive results from its Phase IIb clinical trial with pudafensine (IP2015) for the treatment of erectile dysfunction (ED). The study data analysis has demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events. The positive results, both regarding efficacy and safety, support further development of pudafensine aiming at registration and launch in this patient group with significant unmet medical need.

The primary objective of this study was to investigate the effects of pudafensine and placebo in 130 male patients with moderate or severe erectile dysfunction (ED) on the ability to develop and maintain an erection. The treatment was administrated as a single dose once weekly for 4 weeks. The study demonstrated statistically significant efficacy on the primary endpoint (related to improvements in intercourse settings) compared to placebo [p=0.034] and baseline [p=0.046]. Furthermore, the results were consistent throughout the study. Several other clinical endpoints related to improved intercourse activities (obtained from the International Index of Erectile Function Questionnaire, IIEF-15) demonstrated significant effects compared to the baseline. The frequency and type of adverse effects were mild to moderate and comparable to those observed in the placebo group. There was no reporting of critical safety observations.

"It is with great satisfaction that we have obtained statistically significant ED efficacy results in this phase IIb study with pudafensine. The unique study design has allowed the treatment of patients with moderate to severe ED in a home environment, and the evaluation of the sexual parameters of relevance for a future drug approval by the regulatory authorities. The clear efficacy results in moderate and severe ED support pudafensine's further development towards market authorization", says Claus Elsborg Olesen, CEO of Initiator Pharma*. "There is still a clear unmet medical need within the organic ED patient segment, and the results highlight the potential of pudafensine as a novel treatment for patients that do not respond to or do not tolerate the currently marketed drugs."*

The Phase 2b trial is a randomized, double-blind, placebo-controlled, parallel-dosing group trial studying the efficacy and safety of high and low doses of pudafensine (IP2015) and placebo in otherwise healthy patients suffering from moderate to severe ED. The study comprises 130 patients divided into 3 parallel arms receiving a higher and a lower dose of pudafensine and placebo, respectively, with treatment duration of 4 weeks with frequent assessments of erectile dysfunction, safety and pharmacokinetics. The study has been conducted at the MAC clinical sites in the UK.

Pudafensine (IP2015) is a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine followed by serotonin. Pudafensine is a candidate drug developed for the treatment of erectile dysfunction, pain indications, and female sexual dysfunction (FSD). The treatment is expected to improve the quality of life for many patients who are not responding to or cannot be treated with existing drugs on the market.

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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 has reported positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (ED) in a Phase IIa clinical trial of IP2018 in patients with mild to moderate ED.

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.**

This information is information that Initiator Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-10-06 08:14 CEST.

Attachments

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