INITIATOR PHARMA A/S
Press Release, 05 June 2023 07:25:00 CEST

Initiator Pharma reports dose-dependent significant efficacy of IP2018 in the placebo-controlled Phase IIa clinical trial of Erectile Dysfunction

Initiator Pharma A/S, a life science company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, today announced positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (ED) and no observations of serious or critical adverse events in the Phase IIa clinical trial of IP2018 in patients with mild to moderate ED.

"It is with great satisfaction that we have obtained clinically relevant and statistically significant data in this study where we, for the first time, treat patients with depression and erectile dysfunction. I am excited that we have observed a significant effect linked to administration, including a clear dose-response effect, of our product IP2018. There is a large unmet medical need within psychogenic ED, and these results establish the foundation for further development of IP2018 in this patient population. It is a significant milestone for Initiator Pharma and a great leap forward in our commitment to developing effective and safe treatment options for erectile dysfunction" says CEO, Claus Elsborg Olesen.

The Phase IIa trial is a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of a low and a high dose of IP2018 as well as a placebo in young, depressed patients who have erectile dysfunction. The primary objective of this study was to investigate the effects of IP2018 on penile rigidity and tumescence using a visual sexual stimulation test. Twenty-four patients with mild to moderate depression and erectile dysfunction completed the study. The high dose of IP2018 in single oral administration increased penile tumescence (p=0.04) and duration of rigidity (p=0.025) in a statistically significant way, sufficient for intercourse. The effect of IP2018 on erectile function was dose-dependent. The study demonstrated promising, clinically relevant efficacy data related to ED, supporting a new treatment paradigm for this patient segment. In addition, no safety observations of concern have been reported. Headache and gastrointestinal adverse events of mild character were the most common.

IP2018 is developed to treat psychogenic erectile dysfunction (ED), which is the inability to achieve or maintain an erection during sexual intercourse due to psychological factors. Up to 68% of patients undergoing treatment for depressive disorder also suffer from sexual dysfunction. The patient segment thus represents a clear unmet medical need. IP2018 has the potential to help these patients and significantly increase their quality of life. In addition, IP2018 broadens the scope of Initiator Pharma pipeline, including first-in-class treatments for psychogenic and organic ED, IP2018 and pudafensine (IP2015), respectively.

For additional information about Initiator Pharma, please contact:

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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 – pudafensine (IP2015) and IP2018 – and two preclinical assets. The company is currently conducting a Phase 2b trial with pudafensine (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.**

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 2023-06-05 07:25 CEST.

Attachments

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