Initiator Pharma announces indication expansion – clinical drug candidates active in models of female sexual dysfunction

Initiator Pharma A/S, a clinical-stage pharma company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, announced today that the drug candidates, pudafensine and IP2018, have shown significant efficacy in preclinical models for Female Sexual Dysfunction (FSD). Based on the findings, the company is reviewing the potential to extend the clinical indications for the drug candidates to include FSD.

During the last two years, Initiator Pharma has internally investigated its phase II drug candidates, pudafensine and IP2018, currently developed in two types of male Erectile Dysfunction, in preclinical models for Female Sexual Dysfunction (FSD). Significant efficacy has been shown for both pudafensine and IP2018 in the animal models tested for FSD. The tested models are highly relevant and offer a way to predict efficacy in the clinical setting.

"The results are even more positive than expected, and despite the different pharmacological profile of the two drugs, both show potential to be developed for treating female sexual dysfunction. With these data, we now see great opportunities to broaden the scope and commercial potential of our clinical assets with an indication that could provide an important treatment option for millions of underserved women worldwide and that aligns very well with our current effort in men's sexual health," said Claus Elsborg Olesen, CEO of Initiator Pharma.

Based on these promising findings, the board and leadership team are reviewing the potential for extending the previous efforts in male erectile dysfunction (ED) also to include FSD. In ED significant clinical efficacy has been shown in phase II trials, and Initiator Pharma is developing a strategy to tackle sexual health disorders covering both female and male sexual dysfunctions. The strategic review will include the data generated to establish the best development plan, positioning and commercialization strategy for these two assets going forward. The review will be executed in Q4, 2023, from both a commercial and clinical perspective, to best capture and optimize the large potential value offered by these two assets.

"We are committed to harnessing the full potential of this opportunity, ensuring the ongoing success of Initiator Pharma. This entails achieving significant value milestones while maintaining a conservative burn rate, remaining funded well into 2025," concluded Claus Elsborg Olesen, CEO of Initiator Pharma.

"Current treatment options for women with FSD are limited. My hope is that these promising preclinical results in animal models will translate into an opportunity to provide women with a safe and effective treatment," said Dr. Irwin Goldstein scientific advisory board member and world-renowned ED and FSD clinician.

About FSD and the position intended for Initiator Pharma
Female sexual dysfunction (FSD) includes a range of issues such as hypo-sexual desire disorder (low libido), difficulty achieving arousal, pain during intercourse, and inability to reach orgasm. Female hypo-sexual desire disorder (HSDD) in the US occurs in 10% of women, independent of age. FSD can profoundly affect the individual's quality of life and relationships due to the distress, low self-esteem, and anxiety it causes. There are medical treatment options for young women with FSD, but despite the current options, a large unmet need is to restore the desire for an intimate relationship with the partner. Initiator Pharma will investigate the potential for its products with a priority on postmenopausal women with FSD, where there currently is no available treatment option.

Pudafensine and IP2018 offer the potential as first-line treatment options in postmenopausal generalized, acquired HSDD – where it would be positioned as the first approved therapy. Both products offer the potential of clear differentiation from current FSD drugs, with the key differentiators:

- Non-hormonal mechanism of action
- Clean safety/tolerability, no drug interaction or contraindication issues (as shown in completed trials in men with Erectile Dysfunction)
- Convenient, oral, on-demand dosing
- Potentially improved efficacy to Addyi and Vyleesi (currently only approved for use in HSDD in premenopausal women)

About Pudafensine and IP2018
Pudafensine (IP2015) is a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine followed by serotonin. Pudafensine is a candidate drug for patients with erectile dysfunction and pain indications. 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. The phase IIb study on patients with erectile dysfunction of organic origin was completed in July 2023, and the results are expected in Q4, 2023.

IP2018 is a monoamine reuptake inhibitor that inhibits the synaptic reuptake of serotonin, dopamine, and noradrenaline. 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 anti-depressive effect and positive effects on erectile function. In Q2, 2023, positive results were reported in a phase IIa study in patients with depression and erectile dysfunction.

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 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.**

Attachments

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