Initiator Pharma expands its position to a broader Sexual Health Franchise and intensifies its business development efforts

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 company will expand the position of the company to a broader Sexual Health Franchise including both male Erectile Dysfunction (ED) and Female Sexual Dysfunction (FSD) indications. Initiator Pharma will be in San Francisco to present the company at business and investor meetings during the 42nd Annual J.P. Morgan Healthcare Conference January 8 to 11.

In September 2023 Initiator announced that the drug candidates, pudafensine and IP2018, had showed significant efficacy in preclinical models for Female Sexual Dysfunction (FSD) and that the company was reviewing the potential to extend the clinical indications for the drug candidates, to include FSD. During the fourth quarter 2023 a strategic review of the FSD opportunity has been completed. Based on the data obtained in the preclinical models, and a commercial assessment, the management and board of directors have decided to build on the strong data obtained from the Phase II clinical trials in male ED and expand the position of Initiator Pharma to a broader Sexual Health Franchise, offering great life cycle management and significant revenue and earning opportunities. Initiator will present its extended opportunity at business and investor meetings in connection with the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco.

"I am excited to be in San Francisco for the J.P. Morgan Healthcare week and to present our extended business opportunity. We are bringing with us, two strong drug candidates, pudafensine and IP2018, that both have demonstrated statistically significant and clinically relevant data in our recently completed trials. In addition, the recent strategic review of the FSD opportunity is an obvious kicker for the overall utility and value of our assets," said Claus Elsborg Olesen, CEO of Initiator Pharma.

The commercial potential within the FSD area is considered to be very attractive. The total female sexual dysfunction treatment market size is expected to grow by USD 7.76 billion from 2022 to 2027, at a CAGR of 34.28%, according to Technavio Research. Initiator Pharma's analysis of its FSD commercial opportunity, executed by the well-reputed marketing and pricing strategy firm Global Life Sciences in the UK, has conservatively concluded that a product for underserved women suffering from FSD/HSDD (Female sexual dysfunction/Hypo-Sexual Desire Disorder) has the potential to reach peak sales of USD 2 billion.

Initiator Pharma will capture the FSD opportunity in a de-risked way complementing the clinical development of the company's current programs within ED, where Initiator Pharma has already successfully completed phase 2a and 2b trials for its two lead drug candidates, respectively.

"To optimize shareholder value, and with the strong support from our existing shareholders seeing the great potential in our assets, the discussions and negotiations with potential partners are of highest priority during 2024. I am also pleased to confirm that with the current priorities set, we have enough funding well into 2025 and no significant need to invest further in pudafensine or IP2018 during 2024," concluded Claus Elsborg Olesen.

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 (ED) 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 ED of organic origin was completed in July 2023, and in October 2023 positive statistically significant and clinically relevant efficacy data was reported.

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 ED, 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 ED.

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

Initiator Pharma expands its position to a broader Sexual Health Franchise and intensifies its business development efforts