Initiator Pharma granted European patent for pudafensine in Female Sexual Dysfunction, including vulvodynia

Initiator Pharma A/S, a clinical-stage biotech company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, today announced that the European Patent Office (EPO) has granted the company's European patent application covering pudafensine for the treatment of Female Sexual Dysfunction (FSD).

Initiator Pharma's patent application 23735068.1 has been granted by the EPO on 18 February 2026, under patent number EP4551221, and provides broad protection for the use of pudanfensine in FSD. Following validation, the patent will cover a large part of Europe through the Unitary Patent system, with additional protection in selected non-unitary countries including the United Kingdom, Switzerland, Spain, Poland, Ireland and Norway. The granted patent strengthens Initiator Pharma's intellectual property portfolio and further supports the long-term commercial potential of pudanfensine.

"We are very pleased to receive this European patent grant for pudafensine in Female Sexual Dysfunction," said Claus Elsborg Olesen, CEO at Initiator Pharma. "This patent grant is particularly timely as we advance our Phase IIa proof-of-concept study in vulvodynia – an indication specifically covered by the granted claims. It demonstrates that our IP strategy is tightly aligned with our clinical development priorities and strengthens our position for future partnering and commercialization discussions."

The FSD patent family extends beyond Europe, with a granted patent in South Africa and applications pending in major global markets including the United States, Japan, China, Australia, Canada, South Korea, Brazil, Israel and additional jurisdictions. Initiator Pharma continues to pursue a broad, global patent strategy to maximize exclusivity and long-term value creation for its lead asset.

The granted European patent adds to Initiator Pharma's growing and multi-layered patent portfolio for pudafensine, which includes composition of matter and medical use patent families across multiple indications, supporting exclusivity well into the 2040s, subject to regulatory extensions.

The granted patent encompasses a broad range of female sexual dysfunctions, including hypoactive sexual desire disorder, female sexual arousal disorder, orgasmic dysfunction, and sexual pain disorder – notably including vulvodynia. This is particularly significant as Initiator Pharma is currently conducting a Phase IIa proof-of-concept study evaluating pudafensine in women with vulvodynia, expected to complete by the end of 2026. The patent grant thus provides intellectual property protection directly aligned with the company's lead clinical development programme.

Pudafensine, an orally administered drug candidate, is a triple monoamine reuptake inhibitor with a unique dual mechanism of action targeting both central pain regulation and sexual function. It is Initiator Pharma's most advanced asset, currently being evaluated in a Phase IIa clinical proof-of-concept study in women suffering from vulvodynia, which is expected to be completed by the end of 2026. In prior clinical trials involving approximately 200 participants, pudafensine demonstrated significant effects on pain and sexual dysfunction symptoms, with a favorable safety profile and no drug-drug interaction risks. The compound represents a novel mechanism of action compared to existing therapies and has the potential to address significant unmet medical needs in both neuropathic pain and Female Sexual Dysfunction, where treatment options remain limited.

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 and IP2018 – and one preclinical asset. With pudafensine the company has reported positive, statistically significant and clinically relevant efficacy data in a Phase IIb clinical trial with patients suffering from ED. 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.**

About pudafensine

Pudafensine, Initiators Pharma's most advanced asset, is a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine followed by serotonin thereby increasing the levels of dopamine in the synapses. Pudafensine is being developed for both organic Erectile Dysfunction (ED), Female Sexual 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.

Attachments

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