Initiator Pharma expands FSD program to target vulvodynia. Signs financing agreement with MAC Clinical Research worth up to GBP 2.5 million.

Initiator Pharma A/S, a clinical-stage biotech company, today announced the expansion of its program in Female Sexual Dysfunction (FSD) to include vulvodynia, a severe chronic pain condition affecting approximately 10% of women worldwide. A Phase 2a clinical proof-of-concept study is expected to start in H2 2025, evaluating pudafensine as a potential treatment for vulvodynia. Funding of the Phase 2a study is secured through a convertible credit agreement with MAC Clinical Research worth up to GBP 2.5 million. The agreement gives MAC Clinical Research the right to convert the credit into Initiator Pharma shares upon the full completion of the planned Phase 2a study at a 40% premium to the TERP in a separately announced rights issue.

Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to GBP 2.5 million, for conducting a clinical Phase 2a proof-of-concept study study evaluating pudafensine in patients suffering from vulvodynia. Upon the full completion of the study, MAC has the right to convert the credit into Initator Pharma shares
at a share price at a 40% premium to the TERP in the Initiator Pharma rights issue separately announced today. Should MAC choose not to convert, following the full completion of the study, it must notify Initiator Pharma that it prefers to have the credit repaid in cash. In this case, or if the study for any reason is terminated before its completion, the credit will convert into a three year loan with an annual interest rate of 1 percent.

“We are extremely encouraged by our partner and shareholder MAC’s commitment to finance this study, enabling us to expand the clinical development of pudafensine in FSD. There is a strong rationale for pudafensine in vulvodynia, as it addresses both pain and sexual dysfunction — the two most debilitating aspects of the condition. Considering the vast unmet need and the number of women affected, the market potential for an approved treatment is immense,” said Claus Olesen, CEO of Initiator Pharma.

”We see pudafensine as a potential first-in-class treatment for vulvodynia, backed by promising efficacy already demonstrated in the healthy volunteer pain challenge study. As existing shareholders, we recognize a significant opportunity to expand our strategic position in Initiator Pharma. With a track record of financially backing high-potential clinical programs, we find this investment both compelling and aligned with our long-term vision of developing meaningful treatments,” said Mark Dale, CEO of MAC Clinical Research.

The planned Phase 2a study will be a randomized, placebo-controlled, four-way crossover trial in 24 women with vulvodynia, assessing the pain-relieving effects and safety of single oral doses of pudafensine. The study will be conducted with MAC Clinical Research Unit in the UK, targeting a start in H2 2025 and is expected to conclude by end 2026.

Vulvodynia is a severe chronic pain condition that affects the vulvar area and occurs without an identifiable cause. The most important factors leading to the profoundly impaired quality of life in women with vulvodynia are chronic pain in the vulva and impaired sexual function. Vulvodynia affects approximately 10% of all women worldwide and there is currently no approved treatment for vulvodynia, and the potential market opportunity for an effective approved drug is expected to be significant.

Pudafensine, an orally administered drug candidate, modulates dopamine pathways involved in pain and sexual function. 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.

Initiator Pharma's expansion into pain and FSD complements its strong position in erectile dysfunction (ED), where business development efforts continue at high pace.

Extraordinary General Meeting
The convertible credit agreement with MAC Clinical Research is conditional approval at an Extraordinary General Meeting to be convened in June 2025 and that the Extraordinary General Meeting approve the convertible right and the related amendments to Initiator Pharma's articles of association.

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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 two preclinical assets. 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 as well as in a clinical proof-of-principle study in a capsaicin challenge pain trial. 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. All mentioned indications are robustly covered by patent protection in the company's IP portfolio.
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 vulvodynia
Vulvodynia is a chronic pain condition that affects the vulva. Vulvodynia affects approximately 10% of all women worldwide. Clinically, vulvodynia is defined as chronic vulvar pain lasting at least three months without a clearly identifiable cause.
Besides pain, vulvodynia patients also have impaired sexual function. Women living with vulvodynia experience excruciating pain during routine activities such as walking, sitting or even wearing tight-fitting pants. Many are unable to use tampons or engage in sexual activities. All this profoundly affects their quality of life and partner relationship.
Current therapies are off-label, frequently inadequate, and often accompanied by undesirable side effects. Therefore physicians face significant challenges in addressing vulvodynia and the patients are treated with a multitude of therapies on a trial and error basis. The economic burden of vulvodynia is substantial. Patients often try multiple health care providers and ineffective therapies in their search for a diagnosis and a cure, leading to wasted healthcare expenditures and escalating costs.

About pudafensine (IP2015)
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.

About MAC Clinical Research
MAC Clinical Research is the UK's largest independent clinical development organisation that owns a network of Dedicated Research Sites. Its clinical research organisation is committed totally to the recruitment and conduct of clinical trials and full-service delivery through the company's fully owned Dedicated Research Sites and staff. MAC conducts research for sponsors over an ever expanding group of therapeutic areas and has an extensive range of clinical research capabilities to accommodate the most complex Phase 1 trials through to Phase IV. Read more on **www.macplc.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 2025-05-19 07:45 CEST.

Attachments

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