Initiator Pharma progresses patient enrollment in Phase 2a vulvodynia study

Initiator Pharma A/S, a clinical-stage biotech company, today announced good progress in patient enrollment in its Phase 2a clinical proof-of-concept study evaluating pudafensine in women suffering from the genital pain condition, vulvodynia.

Patient recruitment is progressing as planned, with half of the study target patient population already dosed and several patients having successfully completed the trial. Additional eligible participants are currently being screened in accordance with the study's inclusion and exclusion criteria. Completion of the study and release of topline data are expected by the end of 2026.

"We have, in collaboration with MAC Clinical Research, advanced patient enrollment in our first clinical study in vulvodynia. This represents an important step forward in our mission to develop new treatments for patients living with this under-recognized and debilitating pain condition," said Claus Olesen, CEO of Initiator Pharma. "Pudafensine has already demonstrated strong clinical potential and this study is designed to deliver the first proof-of-concept data in vulvodynia—a neuropathic pain condition with significant unmet medical need and no approved therapies to date."

The randomized, placebo-controlled Phase 2a study is planned to enroll 24 women diagnosed with vulvodynia. Using a four-way crossover design, each participant will receive single oral doses of pudafensine and a placebo across different treatment periods, separated by washout intervals. The study will focus on the assessment of pain-relieving effects and the safety of pudafensine.

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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 one clinical stage assets – pudafensine – 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.

Initiator Pharma is listed on Nasdaq First North Growth Market (ticker: INIT). Redeye Sweden AB is the company's Certified Adviser. For more information, please visit **www.initiatorpharma.com.**

About pudafensine

Pudafensine, Initiator Pharma's most advanced asset, is an orally administered drug candidate with a unique dual mechanism of action targeting both central pain regulation and sexual function. Pudafensine is a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine, followed by serotonin, thereby increasing dopamine levels in the synapse. The treatment is expected to improve the quality of life for many patients who do not respond to, or cannot be treated with, currently available therapies.

Pudafensine is being developed for organic erectile dysfunction (ED), female sexual dysfunction (FSD), and pain indications. It is currently being evaluated in a Phase IIa clinical proof-of-concept study in women with vulvodynia, which is expected to be completed by the end of 2026. In previous clinical studies involving approximately 200 participants, pudafensine has demonstrated significant effects on pain and symptoms of sexual dysfunction, with a favorable safety profile and no risk of drug-drug interactions.

About vulvodnia

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.

Attachments

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