Initiator Pharma initiates patient enrollment in Phase IIa vulvodynia study

Initiator Pharma A/S, a clinical-stage biotech company, today announced the initiation of patient enrollment in its Phase IIa clinical proof-of-concept study evaluating pudafensine in women suffering from vulvodynia.

The patient recruitment has been initiated, with several women currently undergoing screening to assess eligibility for randomisation into the trial. Dosing of the first patients is expected to begin in January 2026, and completion of the study is projected by the end of 2026.

“We have reached a milestone by enrolling the first patients into our first clinical study in vulvodynia. This milestone 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 with this study, we aim to generate the first proof-of-concept data in the neuropathic pain condition vulvodynia, an area of huge unmet medical need where no approved therapies exist today.”

The randomized, placebo-controlled Phase IIa 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 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.

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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