

Initiator Pharma completes dosing of the last patient in Phase 2a study of pudafensine in vulvodynia

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

The randomized, placebo-controlled Phase 2a study including 24 women diagnosed with vulvodynia has now completed recruitment and dosing of patients. Each participant received single oral doses of pudafensine and a placebo across different treatment periods, separated by washout intervals in a four-way crossover design. The study evaluates the pain-relieving effects and the safety of pudafensine, and release of topline data is expected during February 2027.

"We have, in collaboration with MAC Clinical Research completed the recruitment and dosing in the clinical vulvodynia study. This milestone marks an important step forward in our mission to develop a new treatment for the 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 chronic pain condition with significant unmet medical need and no medications currently specifically approved for the condition."

For additional information about Initiator Pharma, please contact:

Claus Elsborg Olesen, CEO
Telephone: +45 6126 0035
E-mail: ceo@initiatorpharma.com

About vulvodnia

Vulvodynia is a chronic neuropathic pain condition that affects the vulva and 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 experience impaired sexual function. Women living with vulvodynia suffer from excruciating pain during normal daily life 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 therapies without proven effect in their search for a diagnosis and a cure, leading to wasted healthcare expenditures and considerable distress for patients. Initiator Pharma forecasts that a new and effective treatment of vulvodynia has the potential to reach peak sales of \$4.2bn across the US, Europe and Japan.

About Initiator Pharma

Initiator Pharma A/S is a Danish clinical-stage pharma company developing innovative drugs targeting key unmet medical needs within women's health, sexual dysfunction and neuropathic pain. The company's pipeline consists of one clinical-stage asset, pudafensine, and one preclinical asset, IP2016.

Initiator Pharma has reported positive, statistically significant and clinically relevant efficacy results for pudafensine in a Phase 2b clinical trial involving 130 patients with moderate to severe organic erectile dysfunction. Pudafensine is also being evaluated in an ongoing Phase 2a proof-of-concept study in vulvodynia, a chronic pain condition estimated to affect approximately 10 percent of women and for which no approved treatments are currently available. In addition, pudafensine has demonstrated efficacy in preclinical models relevant to female sexual dysfunction, supporting its potential in other areas of women's health.

Initiator Pharma is listed on Nasdaq First North Growth Market (ticker: INIT). Redeye Nordic Growth 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 a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine, followed by serotonin, thereby increasing synaptic dopamine levels. Pudafensine is being developed for both organic erectile dysfunction, vulvodynia, 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.

Attachments

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