Initiator Pharma applies to initiate Phase 2a study in vulvodynia

Initiator Pharma A/S, a clinical-stage biotech company, has submitted a clinical trial application (CTA) to the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and local ethics committee in the UK for the approval to conduct a Phase 2a clinical proof-of-concept study in women suffering from vulvodynia, a severe chronic pain condition affecting approximately 10 percent of women worldwide. The study will be conducted together with MAC Clinical Research in the UK.

In May 2025, Initiator Pharma entered a convertible credit agreement with MAC Clinical Research (MAC), in which MAC will take on the cost, up to GBP 2.5 million, for conducting a clinical Phase 2a proof-of-concept study evaluating pudafensine in patients suffering from vulvodynia. The study is expected to start enrolling patients before end of 2025 and is anticipated to conclude by end 2026.

"We are very excited about getting this study initiated together with MAC as there is a strong rationale for pudafensine in vulvodynia addressing most importantly the pain associated with vulvodynia, but also the sexual dysfunction linked to this debilitating 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.

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

The crossover study design offers several advantages:

- Each participant serves as her own control – reducing variability between individuals and allowing meaningful results from a smaller sample size.
- Direct comparison of multiple treatments within the same patient group – enabling precise head-to-head evaluation of pudafensine against placebo.
- Particularly well-suited for pharmacokinetic and pain studies – enhancing the ability to detect subtle differences in drug effect and tolerability.

"Vulvodynia is a chronic, under-recognized pain condition with limited treatment options. The proposed study design allows us to rigorously assess the potential of pudafensine to provide relief for patients, while making efficient use of a small but well-controlled trial population in cost and time efficient manner," said Ulf Simonsen, CMO of Initiator Pharma.

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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 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.

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 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**.

Attachments

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