
Initiator Pharma to fully prioritize pudafensine

Initiator Pharma A/S, a clinical-stage biotech company, today announced that the company has decided to focus fully on its most promising drug candidate, pudafensine, which is being developed for both vulvodynia and organic erectile dysfunction (ED). As part of this prioritization, the company will discontinue further development of IP2018.

"We are encouraged by the opportunities for pudafensine across multiple indications. With already strong Phase IIb proof-of-concept data for pudafensine in organic erectile dysfunction, we now hope to obtain additional proof-of-concept data in vulvodynia from our ongoing Phase IIa clinical study before the end of the year," said Claus Elsborg Olesen, CEO of Initiator Pharma. *"By focusing our resources on this asset, we aim to maximize value creation and accelerate its path toward commercialization."*

Pudafensine is an orally administered drug candidate with a unique dual mechanism of action targeting both central pain regulation and sexual function. It is being developed for the treatment of organic erectile dysfunction, vulvodynia, female sexual dysfunction and certain pain indications.

The compound is currently being evaluated in a Phase IIa clinical proof-of-concept study in women suffering from vulvodynia, which is expected to be completed by the end of 2026. Pudafensine has the potential to improve the quality of life for millions of patients who do not respond to, or cannot be treated with, currently available therapies.

"In our discussions with potential partners, we have observed the strongest interest in pudafensine, supported by its clinical data package and favorable safety profile," added Claus Elsborg Olesen. *"This strategic focus enables a more efficient allocation of resources and strengthens our ability to advance our most promising asset."*

As a consequence, Initiator Pharma will discontinue further development of IP2018 for psychogenic erectile dysfunction. Resources previously allocated to IP2018 will be redirected to the continued development of pudafensine.

For additional information about Initiator Pharma, please contact:

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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 Sweden 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.

Attachments

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