Initiator Pharma's international patent application regarding pudafensine's dosage regime for the treatment of erectile dysfunction has been published

Initiator Pharma A/S, a clinical-stage biotech company, today announced that its international (PCT) patent application no. PCT/EP2024/050061 directed to a dosage regime of pudafensine for treatment of erectile dysfunction was published on July 11, 2024, under publication number WO2024/146892. The publicly available pudafensine patent portfolio now comprises a composition of matter patent and three medical use patent families within the fields of erectile dysfunction, female sexual dysfunction, and pain. Together, they confer a multi layered patent protection for pudafensine until 2044, with possibilities for patent term extension up to an additional five years.

"Pudafensine has shown clear single agent activity and will be a new treatment paradigm with a new mechanism of action compared to existing products, whatever administration form," said Claus Olesen, CEO at Initiator Pharma. "Our patent portfolio for pudafensine and the strong data in the phase IIb study provides a basis for the development of a stand-alone product in a significant patient population or as an add-on/combination product to existing products to increase total efficacy due to its synergistic mode of action to standard of care."

The patent application derives from Initiator Pharma's aggressive patent strategy aimed to capture value from the development pipeline and to extend exclusivity around pudafensine. The European Patent Office (EPO) acting as International Searching Authority has made an initial search of the present patent application. While the EPO in the Written Opinion raises some issues that it would like the company to address, it also acknowledges novelty for all claims as filed, which constitutes a very good starting point for the coming negotiations with the patent offices around the world. It should be noted that the normal timeframe from filing to granting a patent within the pharma field is 4-6 years.

The claims of WO2024/146892 are based on the promising results of the double-blind, randomized Phase IIb study conducted on 130 patients with severe to moderate erectile dysfunction dosed once a week for 4 weeks. As previously reported, the study confirmed a significant increase in the primary endpoint Q3 (*When you attempted intercourse, how often were you able to penetrate (enter) your partner?)* of the International Index of erectile function (IIEF-15). The IIEF-15 consists of several domains, and the overall score increase compared to baseline was at follow-up 6.8 (versus placebo 1.6), which is a remarkable improvement in these difficult-to-treat patients with erectile dysfunction. The follow-up visit was done 7-10 days after the last dose (4th dose) in the study demonstrating a continuous effect during the entire trial and dosing period.

The patient cohort treated in the Phase IIb study often has insufficient effect of the standard-of-care treatment with phosphodiesterase type 5 (PDE5) inhibitors. The post-hoc analysis revealed up to 40% of the patients had used a PDE5 inhibitor within the last 12 months (PDE5i treatment was not allowed up to 4 weeks prior to first pudafensine dosing). Therefore, pudafensine provides a new path to regaining sexual function. Moreover, the safety profile for pudafensine is favourable. So far close to 200 healthy subjects and erectile dysfunction patients have been dosed with pudafensine, with no known or expected clinically relevant drug-drug interactions. The strong data obtained are sufficient to guide in the design (patient segments, dose selection etc) of a future phase III trial with pudafensine.

“In this clinical trial, the overall score increase on IIEF-15 constitutes a clinically relevant effect for these patients who do not adequately respond or do not tolerate current options e.g. the PDE5i products” said Professor Ulf Simonsen, CSO at Initiator Pharma.

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About erectile dysfunction (ED)

Erectile dysfunction is sexual dysfunction characterized by the inability to develop or maintain an erection of the penis during sexual activity. ED affects more than 150 million men worldwide. That number is expected to increase to more than 300 million by 2025, fuelled by aging demographics and increasing prevalence of lifestyle diseases such as diabetes and performance anxiety. About 30-40% of these patients will not respond to the current treatment (PDE5i non-responders) and represent a significant unmeet medical need. This is Initiator’s primary target group and will clearly distinguish us form the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the ED market generated about 4 USD billion in sales and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for pudafensine and thereby generate substantial commercial value for Initiator Pharma.

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 (IP2015) and IP2018 – and two preclinical assets. The company is currently conducting a Phase IIb trial with pudafensine (IP2015) in erectile dysfunction of organic origin, and successfully completed a Phase I proof of principle trial in neuropathic pain in 2022. 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.**

Attachments

Initiator Pharma’s international patent application regarding pudafensine's dosage regime for the treatment of erectile dysfunction has been published