

Initiator Pharma secures two European patents for pudafensine

Initiator Pharma A/S, a clinical-stage pharma company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, today announced that the European Patent Office (EPO) has granted two new patents – one covering the treatment of pain and one covering an immediate-release oral formulation, adding further patent protection for its lead drug candidate pudafensine in Europe.

“These two European patents are the result of methodical R&D and an active lifecycle-management strategy intended to protect pudafensine, its therapeutic uses and its formulation as the asset advances through development,” said Claus Elsborg Olesen, CEO of Initiator Pharma. *“Following the FSD patent grant earlier this year, the pain patent relates to our ongoing Phase 2a clinical trial in vulvodynia, while the formulation patent relates to the dosage form we are developing for clinical use in patients. Together they reinforce our multi-layered patent position in Europe and strengthen our potential in future partnering discussions.”*

The patents have been granted by the EPO on 19 August 2026 and confer additional protection on top of the European patent for pudafensine in Female Sexual Dysfunction (FSD) granted in February 2026 (EP 4 551 221) and on the underlying composition-of-matter protection. Together they extend the company's coverage across the compound itself, its use in pain and its oral formulation. Following validation, both patents can cover a large part of Europe through the Unitary Patent system, with additional protection in selected non-unitary patent countries including the United Kingdom, Switzerland, Spain, Poland, Ireland and Norway.

The two granted patents are:

EP 4 608 400 – “Compound for treatment of pain”, which protects pudafensine, and its pharmaceutically acceptable salts, for use in the treatment, prevention or alleviation of pain, including neuropathic pain and vulvodynia, together with the associated low-dose regimen (0.5–10 mg per dose). The patent runs until 2043 and is directly relevant to Initiator Pharma's lead clinical programme: the Company's ongoing Phase 2a proof-of-concept study in vulvodynia — a chronic, underserved condition involving neuropathic pain — targets an indication within the scope of the granted claims. Topline data are expected by the end of 2026, in line with previous guidance.

EP 4 731 189 – “Solid oral formulation of pudafensine”, which protects an immediate-release, pellet-based oral formulation designed to deliver fast and complete release of pudafensine despite the compound's low aqueous solubility. The patent runs until 2044. This is the dosage form being developed for clinical use, supporting a fast onset of action and once-daily dosing; formulation patents of this type are typically harder to design around and expire later than composition-of-matter patents, reinforcing long-term protection for a future marketed product.

Together with the FSD patent and the company's granted and pending rights in the United States, Asia and other major markets, the two grants extend patent protection for pudafensine into the 2040s, subject to renewal and any regulatory term extensions. Initiator Pharma continues to pursue a broad international patent strategy to protect its lead asset and strengthen its position in future partnering and licensing discussions.

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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 one clinical stage assets – pudafensine – 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.

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.

Attachments

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