

## Initiator Pharma's pudafensine preclinical pharmacology results published in the British Journal of Pharmacology

Initiator Pharma A/S, a clinical-stage biotech company, today announced that an article titled "A novel reuptake inhibitor induces erection by increasing central dopamine and peripheral nitric oxide release" was published in the prestigious peer-reviewed scientific journal *British Journal of Pharmacology*.

*"We are very encouraged about the publication in such a well-known scientific journal. We have already demonstrated statistically significant and clinically relevant efficacy with pudafensine in ED-related endpoints in a multi-centre phase IIb study, and this publication is another scientific validation of the mechanism of action and strengthens our believe in pudafensine as a novel treatment for patients who do not respond to or do not tolerate the currently marketed drugs,"* said Claus Elsborg Olesen, CEO at Initiator Pharma

The publication in the *British Journal of Pharmacology* describes the discoveries that pudafensine (IP2015), Initiator Pharma's most advanced candidate drug, is a monoamine reuptake inhibitor that induces erection by increasing dopamine. Dopamine activate dopamine D2 receptors in the brain initiating erection, while the increase in dopamine in erectile tissue leads to activation of dopaminergic receptors relaxing erectile tissue by nitric oxide release. The unique mechanism of action of pudafensine contributes to initiate erection and to maintain erection. Moreover, the effects of pudafensine are even more significant in combination with a phosphodiesterase type 5 (PDE5) inhibitor, e.g., sildenafil.

*"The scientific work underlying the discoveries is a result of strong collaborative effort, and the publication in the British Journal of Pharmacology is a recognition of novelty and solid scientific work,"* said Professor Ulf Simonsen, CSO at Initiator Pharma and the senior author of the publication.

Pudafensine (formerly IP2015) is in clinical development for both organic erectile dysfunction and neuropathic pain. Within the indication of erectile dysfunction, pudafensine has showed positive results in patients with erectile dysfunction in a phase IIa study, and demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints, with no observations of critical adverse events, in a multi-centre phase IIb study conducted by MAC Clinical Research in 120 otherwise healthy organic erectile dysfunction patients.

Erectile dysfunction is expected to affect 320 million men in 2025. The standard of care is treatment with PDE5 inhibitors, but the treatment is insufficient in 40 percent of the patients. Currently, there is no oral medication for the treatment of patients with erectile dysfunction who have insufficient effects or cannot tolerate PDE5 inhibitors (Munk et al., 2019). Initiator Pharma has developed a solid dosis of pudafensine allowing oral administration. The preclinical data suggest that pudafensine can either be dosed alone or in combination with a PDE5 inhibitor and hence provide a perspective for treating patients with insufficient effect or lack of tolerance to PDE5 inhibitors.

### References

<https://bpspubs.onlinelibrary.wiley.com/toc/14765381/0/0>

Comerma-Steffensen S, Kun A, Prat-Duran J, Mogensen S, Albayrak EA, Fais R, Munro G, Peters D, Simonsen U. A novel reuptake inhibitor induces erection by increasing central dopamine and peripheral nitric oxide release. Br. J. Pharmacol. 2024, DOI: 10.1111/bph.16362

Munk NE, Knudsen J, Comerma-Steffensen S, Simonsen U. Systematic review of oral combination therapy for erectile dysfunction when phosphodiesterase type 5 inhibitor monotherapy fails. Sex Med Rev. 2019 Jan 30. pii: S2050-0521(18)30144-6. doi: 10.1016/j.sxmr.2018.11.007.

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### **About Initiator Pharma**

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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](http://www.initiatorpharma.com).

### **Attachments**

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