

Article in Nature shows strong support for the role of dopamine in sexual function

Initiator Pharma A/S, a clinical-stage pharma company, announced today that a recent study published in the peer-reviewed scientific journal Nature shows the importance of dopaminergic neurons in the brain for sexual function (1). The findings support the mode of action used in Initiator Pharma's IPED2015 and IP2018 clinical programs targeting erectile dysfunction of organic and psychogenic origin respectively.

In the study, published in Nature (<https://pubmed.ncbi.nlm.nih.gov/34433964/>), Professor Mark Andermanns research group at Harvard Medical School, Boston, genetically altered dopaminergic neurons in the brain, the medial preoptic area of the mouse hypothalamus. This elegant technique, optogenetics, allowed the measurement of dopamine and by light also to activate these neurons. The authors found that dopamine increased when male mice were exposed to females primed in the estrus phase and decreased after successful mating. The previous evidence for dopamine as a neurotransmitter in sexual function is robust. The direct evidence in the present Nature paper further underlines the role of dopamine as a central player in sexual function of males.

A role for dopamine in sexual function has previously been suggested based on the observations that drugs that increase dopamine or stimulate dopamine receptors boost sexual function. In contrast, dopamine antagonists are associated with impairment of sexual function (2).

"These findings made by Professor Mark Andermanns and his team is a clear validation of Initiator Pharma's medical approach of modulating the levels of monoamine neurotransmitters in the brain. It strongly supports our belief that dopamine, together with other monoamine neurotransmitters such as noradrenaline and serotonin, plays a pivotal role in many important physiological functions including sexual function," says Claus Elsborg Olesen, CEO of Initiator Pharma. *"Our most advanced ED program IPED2015, aimed for treatment of erectile dysfunction of organic origin, increases dopamine levels in the brain and has previously demonstrated efficacy in a Phase 2a Proof-of-Concept study. The importance of dopamine will hopefully be established even further when presenting data from our ongoing Phase 2b study with IPED2015 in 120 otherwise healthy organic ED patients in the second half of next year."*

Dopamine levels are decreased in diabetic animals (3) and patients with Parkinson's disease, conditions associated with sexual dysfunction. Therefore, Initiator Pharma has developed IPED2015, which increases the physiological levels of dopamine in the brain by inhibiting the reuptake. IPED2015 was successful in a phase IIa Proof-of-Concept study and is currently examined in a phase IIb trial for men with erectile dysfunction of organic origin. Patients with erectile dysfunction of psychogenic origin also benefit from inhibitors of serotonin reuptake, leading to increased serotonin levels. For this group of patients, Initiator Pharma has developed IP2018, increasing serotonin and dopamine. The effect of IP2018 on erectile function in men with erectile dysfunction of psychogenic origin is currently examined in a phase IIa study.

All of Initiator Pharma's clinical programs, including IPTN2021 developed for the neurothic pain orphan indication trigeminal neuralgia, belong to the drug class monoamine reuptake inhibitors and is based on compounds modulating monoamine neurotransmitters e.g., dopamine, noradrenaline, and serotonin.

References

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3. Kleinridders A, et al. (2015) Insulin resistance in brain alters dopamine turnover and causes behavioral disorders. *Proc Natl Acad Sci U S A* 112(11). doi:10.1073/pnas.1500877112.

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About Initiator Pharma

Initiator Pharma A/S is a Danish clinical stage life science company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of three clinical programs - the drug candidates IP2018 and IPED2015 for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug candidate IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition.

Initiator Pharma is listed on Nasdaq First North Growth Market (ticker: INIT). Redeye AB, with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90, is the company's Certified Adviser. For more information, please visit www.initiatorpharma.com.

Attachments

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