

Initiator Pharma initiates dosing in the IPTN2021 program Phase I study to assess pain reducing effects

Initiator Pharma A/S, a clinical-stage pharma company, announced today that the first subject has been dosed with the drug substance IP2015 in the IPTN2021 program clinical Phase I study in healthy subjects challenged with pain inducing ingredient (capsaicin).

The dosing in Initiator Pharma's Phase I study has started as planned and according to the Authority and Ethics Committee approved study protocol. The study is a randomised, double-blind, placebo-controlled study to investigate the pharmacodynamic effects of IP2015 in 24 healthy male subjects using the intradermal capsaicin model. The study is carried out in collaboration with MAC Clinical Research, UK, as a single site study. Pending current and future Covid-19 restrictions, first results are expected sometimes during the second quarter 2022.

"I'm very pleased that we have been able to start dosing in this exploratory Phase I trial despite the ongoing pandemic. Our expectations are high on this first clinical trial in our new IPTN2021 program targeting the orphan drug indication trigeminal neuralgia, a rare but devastating disease for those affected by it. IP2015, the drug substance used in this program, has previously shown proof of concept in erectile dysfunction and we are excited about the possibility to also assess the substance in relevant pain indications. If positive outcome, we intend to follow up this trial with a Phase II trial including trigeminal neuralgia patients," says Claus Elsborg Olesen, CEO of Initiator Pharma.

IP2015

IP2015 is the drug substance used in the Phase I study in the IPTN2021 program. It is a monoamine reuptake inhibitor preferentially inhibiting dopamine and serotonin reuptake. IP2015 is superior to duloxetine in the rat formaldehyde pain model and the rat sciatic chronic constriction injury (CCI) model. Moreover, safety of IP2015 is superior compared to duloxetine, and no risk for drug interactions has been detected.

IP2015 is also the active pharmaceutical ingredient used in the IPED2015 program, that is currently undergoing Phase IIb testing in 120 patients for organic erectile dysfunction.

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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.

About neuropathic pain and trigeminal neuralgia

The clinical program IPTN2021 targets the orphan neuropathic pain indication trigeminal neuralgia, a rare disease with a prevalence of 10-20 per 100,000. Trigeminal neuralgia is a debilitating orofacial pain condition characterized by sudden onset of an extreme, short-duration yet debilitating pain, often referred to as suicidal pain. There is only one FDA-approved pharmacological treatment for trigeminal neuralgia available, Carbamazepine, which only provides limited pain relief and is associated with a significant number of side effects. Therefore, the unmet need for a new efficacious, tolerable, and safe treatment is exceptionally high. Initiator Pharma's ambition is to develop a First-Line treatment for these patients.

Attachments

[Initiator Pharma initiates dosing in the IPTN2021 program Phase I study to assess pain reducing effects](#)