Initiator Pharma receives CTA approval for IPTN2021 program Phase I study to assess pain reducing effects

Initiator Pharma A/S, a clinical-stage pharma company, announced today that it has received approval of a Clinical Trials Application for its planned Phase I study in the IPTN2021 program with the drug substance IP2015 in healthy subjects challenged with pain inducing ingredient (capsaicin).

Initiator Pharma's Clinical Trial Application (CTA) for its planned Phase I study in healthy male subjects has been approved by the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the local Ethics Committee. Subject inclusion and dosing is expected to commence in January 2022. The study will be carried out in collaboration with MAC Clinical Research, UK, as a single site study.

"I'm very pleased we have received the approval to start this exploratory Phase I trial for our new IPTN2021 program targeting the orphan drug indication trigeminal neuralgia. The study will provide important pain related efficacy, biomarker and safety information to support the planned clinical development of our drug substance IP2015 into relevant pain indications. We hope to be able to start dosing the first patients early next year. Our intention is to follow up this trial with a Phase 2 trial including trigeminal neuralgia patients", says Claus Elsborg Olesen, CEO of Initiator Pharma.

IP2015
IP2015 is the drug substance used in the IPTN2021 trial. 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.

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 deliberating 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 pharmalogical 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. Our ambition is to develop a First-Line treatment for these patients.

For additional information about Initiator Pharma, please contact:

Claus Elsborg Olesen, CEO
Telephone: +45 6126 0035
E-mail: **ceo@initiatorpharma.com**

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

Initiator Pharma receives CTA approval for IPTN2021 program Phase I study to assess pain reducing effects