Correction of previously published press release regarding CTA-filing for Phase I study

The press release published by Initiator Pharma at 03:52 p.m. today, October 19, 2021, "Initiator Pharma files CTA for Phase I study with IP2105 in relation to assessment of pain reducing effects ", included incorrect information regarding the names of Initiator Pharma's clinical programs. A corrected version of the press release is as follows.

Initiator Pharma files CTA for Phase I study for the IPTN2021 program in relation to assessment of pain reducing effects

Initiator Pharma A/S, a clinical-stage Life Sciences company, announced today that it has filed 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 has filed its Clinical Trial Application (CTA) for its planned Phase I study in healthy male subjects to the Medicines & Healthcare products Regulatory Agency, MHRA, UK. Subject inclusion and dosing is expected January 2022. The study will be carried out in collaboration with MAC Clinical Research, UK, as a single site study.

"Together with MAC Clinical Research, UK, we have designed this exploratory Phase I trial studying anti-nociceptive effects related to induction of pain - this study type and design is generally used by the pharma industry as one of the first clinical assessments related to pain. Capsaicin (ingredient in chili peppers) induces a localised release of neuropeptides resulting in localised hyperaemia (flare), hyperalgesia and allodynia. These effects are similar to those seen in neuropathic pain. Thus, this study will provide supportive pain related efficacy, biomarker and safety information to the planned clinical development of IP2015 into relevant pain indications", 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.

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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 Spotlight Stockmarket (ticker: INIT).

Read more on 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 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.