

Initiator Pharma reports positive efficacy data outcome of the IPTN2021 program Phase I study to assess pain-reducing effects

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

Initiator Pharma has received topline from the Phase I study, and the first statistical evaluations have been made. The study is a randomized, double-blind, placebo-controlled study in 24 healthy male subjects, investigating the effects on pain measures (hyperalgesia, allodynia, and subjects pain rating) of single doses of IP2015, pregabalin as active control, and placebo. The pain was induced by intradermal capsaicin. IP2015 demonstrated a statistically significant effect on allodynia ($p=0.049$) and showed a dose-dependent effect on the measured pain parameters. Pregabalin ($p=0.083$) and IP2015 ($p=0.051$) tended to reduce hyperalgesia, although the effects on hypoalgesia were not statistically significant compared to placebo-treated subjects. In addition, there were no observations of unexpected adverse events. Further analysis of incoming data is in progress. A final report is expected in the third quarter of 2022 and the company plans to update the market at that time.

"In this exploratory single-dose study, IP2015 has demonstrated promising, clinically relevant efficacy on pain, which correlates well with and confirms our findings in our preclinical models of pain. The initial findings in this study are encouraging for further development of IP2015 in neuropathic pain" says Ulf Simonsen, Chief Scientific Officer at Initiator Pharma.

"It is with great satisfaction that we have obtained the first clinically relevant, pain-related, efficacy results in this healthy volunteers study. We are looking forward to completing the analysis of the entire data set over the coming months and are very enthusiastic about these first results obtained. These data obtained support our conviction of IP2015 as a potential new treatment for Neuropathic pain. There is undoubtedly a substantial unmet medical need for improved therapy for neuropathic pain patients, as the current standard of care often is linked to severe side-effects and limited efficacy. Hence, we are not only encouraged by the clinical data on pain relief we have seen in these top-line results, but we are also very pleased that only side effects of mild severity was observed in the study" says Claus Elsborg Olesen, CEO at Initiator Pharma.

IP2015 is a monoamine reuptake inhibitor, preferentially inhibiting dopamine reuptake followed by serotonin uptake, and with markedly less effect on noradrenaline uptake in vivo. IP2015 is also in clinical development for treatment of erectile dysfunction. Pregabalin is currently recommended as first-line medication against a number of neuropathic pain indications and binds to a subunit ($\alpha 2\delta$ -subunit) of voltage-gated calcium channels and reduce presynaptic release of neurotransmitters.

For additional information about Initiator Pharma, please contact:

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

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.

This information is information that Initiator Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-05-23 01:53 CEST.

Attachments

[Initiator Pharma reports positive efficacy data outcome of the IPTN2021 program Phase I study to assess pain-reducing effects](#)