Initiator Pharma reports the final analysis of positive efficacy data from the IPTN2021 program Phase I study

Initiator Pharma A/S, a clinical-stage pharma company, announced today that the final dataset and study- report analysis have been obtained in the IPTN2021 program. The IPTN2021 program is a clinical Phase I study in healthy subjects dosed with the drug IP2015 and challenged with a pain-inducing ingredient (capsaicin). The final analysis confirms the statistically significant effects on pain measures that were observed in the analysis of the first data read-out from the study presented in May 2022.

The objective of the study in healthy subjects was to validate and demonstrate that the effect of IP2015 in preclinical animal models can be translated into pain relief in the human setting. The pain assessments in the study covered a range of pain measures, e.g., allodynia and hyperalgesia, and has provided Initiator Pharma with supportive data that will help guide the continued development and design of the IPTN2021 program.

"It was with great satisfaction we obtained the first clinically relevant, pain-related, efficacy results in this healthy volunteers study earlier this year, and we are now very pleased to report that the final data analysis confirms our previous observations from the study. These data support our conviction of IP2015's potential as a new treatment for Neuropathic pain," says Claus Elsborg Olesen, CEO at Initiator Pharma.

The Phase I study was 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 an active control, and placebo. The pain was induced by intradermal capsaicin. As previously communicated and still evident, 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 hyperalgesia were not statistically significant compared to placebo-treated subjects.

In the assessment of subjective pain ratings, the mean values for IP2015 showed 2- and 5-fold higher effects compared to pregabalin and placebo, respectively. In support of these positive results, IP2015 demonstrated data in the Quantitative Sensory Test pain assessments related to pain in line with the primary pain assessments provided above. In the heat detection and thermal sensory (warm) threshold tests, respectively, statistically significant outcomes were detected for IP2015 when tested within test subjects. In addition as communicated before, there were no observations of unexpected adverse events, and IP2015 demonstrated a supportive safety profile compared to pregabalin.

"*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 pain models. These observations support our exploration and planning of future clinical studies, particularly in relation to the most relevant patient segments within neuropathic pain e.g. Trigeminal Neuralgia. We are discussing our results and the pharmacological profile of IP2015 with a panel of pain experts to identify the most qualified patient segment for this treatment," says* Ulf Simonsen, Chief Scientific Officer 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 the treatment of erectile dysfunction. Pregabalin is currently recommended as first-line medication against a number of neuropathic pain indications and binds to a subunit (α2δ-subunit) of voltage-gated calcium channels and reduces presynaptic release of neurotransmitters.

Hyperalgesia: An increased sensitivity to feeling pain and an extreme response to pain
Allodynia: A type of neuropathic pain (nerve pain). People with allodynia are extremely sensitive to touch
Pregabalin (developed and sold under the name Lyrica by Pfizer) is a globally established and frequently used product for the treatment of neuropathic pain.

Quantitative Sensory Testing battery tests were performed at two sites on the volar surface of either forearm. One site was the most recent capsaicin injection site, and the other was at an equivalent point on the opposite forearm. The QST battery includes 12 different ways of assessing pain signals (warm, cold and pressure tests on the skin of the test subjects).

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. Initiator Pharma's 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 is the company's Certified Adviser. For more information, please visit **www.initiatorpharma.com.**

Attachments

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