Initiator Pharma gives an update on its clinical programs

Initiator Pharma A/S, a clinical-stage pharma company, announced today an update on its clinical programs IPED2015, IP2018 and IPTN2021 for erectile dysfunction and neuropathic pain. All programs are progressing according to plan, although full patient inclusion in the IP2018 Phase 2a trial is expected to occur in the first part of 2022.

IPED2015 Program
The patient recruitment rate in the ongoing Phase 2b trial with the drug substance IP2015 is progressing according to plan. Inclusion and dosing of patients should be completed in H2 2022, pending the development of the Covid-19 pandemic. The Phase 2b trial received CTA approval from the MHRA in UK and the Ethics Committee in June 2021, and the first patient was dosed in September 2021.

The Phase 2b study is a randomized, double-blind, parallel-group, repeat single oral dose study of IP2015 or placebo in otherwise healthy organic erectile dysfunction patients. The plan is to include 120 patients in the study divided into 3 parallel arms receiving a higher (also used in the first Phase 2a study) and a lower dose of IP2015 and placebo, respectively. The treatment consists of 4 dosings over four weeks with frequent assessments of erectile dysfunction, safety, and pharmacokinetics.

IP2018 Program
The patient recruitment rate in the ongoing Phase 2a study with the drug substance IP2018 has increased significantly since Initiator in July 2021 obtained approval from the regulatory authorities to modify certain inclusion criteria. However, recruitment rate is still impacted by the Covid-19 pandemic, especially the patient segment targeted in this trial seems to be significantly impacted. The patient recruitment is expected to be completed in the first part of 2022.

The Phase 2a trial is a randomised, double-blind, placebo-controlled, 3-way crossover trial (placebo, high dose IP2018 and low dose IP2018) studying the efficacy and safety of IP2018 in 24 patients depressed, erectile dysfunction patients. The primary objective of the study is to investigate the effects of IP2018 on penile rigidity and tumescence using visual sexual stimulation test. The study is conducted at the MAC unit in Manchester, UK.

IPTN2021 Program
Initiator received CTA approval from the MHRA in UK and the Ethics Committee in November 2021 for a Phase 1 study, with the drug substance IP2015, targeting the orphan drug indication trigeminal neuralgia. Subject inclusion and dosing is expected to commence in the beginning of 2022.

The planned Phase 1 study in the IPTN2021 program is a pain challenge in healthy subjects challenged with pain inducing ingredient (capsaicin) with the objective to generate PK/PD understanding of the drug substance IP2015 in the pain setting. The trial is designed as a randomised, double#blind, placebo#controlled, 4-way crossover study with 2 dose levels of IPTN2021, placebo and pregabalin. The trial will be carried out in collaboration with MAC Clinical Research, UK, as a single site study.

"I'm pleased to see that Initiator's clinical programs are progressing as expected even though we see a somewhat slower pace in the inclusion of patients due to the still ongoing Covid-19 pandemic. This has been most notable in the IP2018 drug program where we are working hard to have the inclusion and dosing completed as soon as possible. However, we maintain our position that we do not foresee the

Covid-19 pandemic pushing the overall future development of IP2018," says CEO Claus Elsborg Olesen. *"For IPTN2021, MAC has actively been recruiting volunteers ever since the approval of the CTA, which means we can kick off the clinical trial immediately after year-end. The study design, plus that we are including healthy subjects, should allow for swift completion, again pending future Covid-19 restrictions."*

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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 erectile dysfunction (ED)

Erectile dysfunction is sexual dysfunction characterized by the inability to develop or maintain an erection of the penis during sexual activity. ED affects more than 150 million men worldwide. That number is expected to increase to more than 320 million by 2025, fuelled by aging demographics and increasing prevalence of lifestyle diseases such as diabetes and performance anxiety. The number of ED patients is most likely grossly underestimated, particularly for the Psychogenic patient segment. ED patients have decreased quality of life due to psychosocial factors such as low self-esteem, depression, sadness, anger, frustration, anxiety, medication, and relationship problems (1,2,3). Erectile dysfunction can be divided into two main categories – Organic and Psychogenic ED – that require different treatments. Initiator Pharma is developing IPED2015 and IP2018, respectively, for these similar but separate patient segments.

1. Shabsigh R, et al. (1998) Increased incidence of depressive symptoms in men with erectile dysfunction. Urology52(5):848–852.
2. Mccabe MP, Althof SE (2014) A systematic review of the psychosocial outcomes associated with erectile dysfunction: Does the impact of erectile dysfunction extend beyond a man's inability to have sex? J Sex Med11(2):347–363.
3. Nguyen HMT, Gabrielson AT, Hellstrom WJG (2017) Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors. Sex Med Rev5(4):508–520.

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.

Attachments

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