Initiator Pharma provides an update on its clinical programs

Initiator Pharma A/S, a clinical-stage pharma company, announced today an update on its ongoing and planned clinical studies.

- **22 out of 24 patients have been enrolled in the ongoing Phase IIa study in the IP2018 program. The two last patients are expected to be included shortly so read-outs of the trial are expected no later than Q2 2023.**
- **A protocol amendment has been submitted to regulatory authorities for the ongoing Phase IIb study in the IPED2015 program in order to optimize patient recruitment without compromising the relevance of data readouts at completion of the trial.**
- **A pharmacokinetic study will be initiated in the IPTN2021 program to support the future clinical development program in neuropathic pain, with the aim of generating more data as a guidance to priorities going forward in the program and to enhance the IP position relating to the program.**

Initiator Pharma confirms that the above activities are fully financed through the capital raise closed during summer 2022 and that the proceeds raised during the summer of 2022 will be sufficient to fund all currently planned activities to the end of 2024.

Initiator Pharma's pipeline consists of three clinical programs - the IP2018 and IPED2015 programs for treatment of Erectile Dysfunction of psychogenic and organic origin, respectively, and the orphan drug program IPTN2021 developed for neuropathic pain. Furthermore, Initiator Pharma has entered an exclusive option agreement for a Phase II/III ready pharmaceutical asset for an undisclosed pain indication, which currently is under evaluation.

IP2018 clinical program

IP2018 is a monoamine reuptake inhibitor developed for the treatment of psychogenic Erectile Dysfunction (ED) mainly caused by anxiety and depression, targeting both the serotonin and the dopamine system. A clinical Phase IIa study in 24 depressed ED patients is being conducted at the MAC Phase I unit in Manchester, UK. Recruitment to the study has been somewhat slower than expected. 22 out of the total 24 patients in the trial have this far been enrolled. The clinical trial could still be completed before the end of the year, given that the last two patients are successfully enrolled in the near future, but it might run into the first quarter of 2023.

"It is important that all key inclusion criteria in the trial are fulfilled and the full inclustion on all patients is achieved to generate high quality of the data set on efficacy measures in this trial, as this is the first trial to be conducted in patients with psychogenic erectile dysfunction. Hence, the management has decided that it is better to have a slight delay in the trial and not compromise on the data quality. I am confident that we will have data on hand early next year," says Claus Elsborg Olesen, CEO at Initiator Pharma.

IPED2015 clinical program

IPED2015, with the active pharmaceutical ingredient IP2015, is Initiator Pharma's most advanced development program for the treatment of patients suffering from organic ED, not responding to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®).

A clinical Phase IIb study in 120 healthy organic ED patients is conducted by MAC Clinical Research MAC Clinical Research. To optimize the recruitment of all 120 patients, an amended clinical study protocol is in the approval process at the British Health Authorities and Ethics Committee. The amended protocol contains some revised inclusion criteria and an increase of the patient's stipend – all improvements will support a faster and higher recruitment rate without hampering the set of data generated. For now, the company aims for completion of the dosing part in the first half of 2023.

"The learnings from the last quarters recruitment has encouraged us to make a few modifications of the inclusion criteria. The modification of the inclusion criteria are not changing the deliverables or the quality of trial. With the amended protocol we are optimistic that we will see an increased enrolment rate," says Claus Elsborg Olesen.

IPTN2021 clinical program
IPTN2021, with the active pharmaceutical ingredient IP2015, targets neuropathic pain.

A clinical Phase I proof of principle study study in 24 healthy subjects, dosed with IP2015 and challenged with a pain-inducing ingredient (capsaicin), has recently been completed demonstrating statistically significant effects on pain measures. Following a thorough review of the final dataset and due to the very encouraging results in the above study, the company has decided to initiate a Phase I pharmacokinetic (PK) study in healthy subjects testing new oral solid dosage forms, bridging previous data sets into new future clinical studies for IP2015. The study is expected to start shortly and provide draft PK data in Q1 2023.

"We were very satisfied to report that the final data analysis of the Phase I proof of principle study confirmed our previous observations, and we are now pleased to follow up with a Phase I PK study on the back of the exciting data generated so far and our conviction in the potential of our programs in ED and our additional efforts in pain. The study will support and guide priorities in the future clinical development program in neuropathic pain. Not the least, will it offer a potential to strengthen the patent situation for the entire IP2015 program," says Claus Elsborg Olesen.

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

Attachments

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