## Initiator Pharma announces positive results from pudafensine Phase I pharmacokinetic trial

Initiator Pharma A/S, a clinical-stage pharma company developing innovative drugs targeting key unmet medical needs within the central and peripheral nervous system, announced today that it has obtained positive data from a Phase I drug formulation and pharmacokinetics study in healthy subjects evaluating optimized oral solid dosage forms of pudafensine (IP2015), enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.

The Phase I study is an open-labeled randomized study of 12 healthy subjects evaluating current and new oral solid dosage formulations of pudafensine. The study demonstrated that the new oral solid dosing formulations provide relevant drug bioavailability and pharmacokinetic drug release profiles supporting the future treatment settings in Phase II and III trials. The reported adverse events were of mild severity and only potentially related to treatment.

"We are now confident in having an ideal future product for patients and a product with strengthened patent protection. As we have communicated previously, we are very convinced of the benefits of pudafensine from the data generated in our clinical trials on erectile dysfunction and its effect on pain in healthy volunteers. This optimized product is an important milestone for us and represents a key deliverable for pudafensine in preparation for its future pivotal registration trials," says Claus Elsborg Olesen, CEO at Initiator Pharma.

## 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 emerging pharma company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of two clinical stage assets – pudafensine (IP2015) and IP2018 – and two preclinical assets. The company is currently conducting a Phase IIb trial with pudafensine (IP2015) in erectile dysfunction of organic origin, and successfully completed a Phase I proof of principle trial in neuropathic pain in 2022. With IP2018 the company is conducting a Phase IIa trial for the treatment of erectile dysfunction of psychogenic origin.

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

Initiator Pharma announces positive results from pudafensine Phase I pharmacokinetic trial