

Initiator Pharma reports positive results from the 28 days toxicology study in mini-pigs for its lead drug candidate IPED2015

PRESS RELEASE

15th December, 2017

Initiator Pharma, a biotech company developing a novel treatment of Erectile Dysfunction (ED), has successfully completed an *in vivo* 28 days toxicology study in mini-pigs for its drug candidate IPED2015, thus moving the development program forward towards the Clinical Trial Application (CTA) and with the aim of initiating a Phase 1 clinical trial next year.

During 2017 Initiator Pharma has initiated and completed several toxicology and toxicokinetic studies as well safety pharmacology and genotoxicity studies for its lead drug candidate IPED2015. The aim is to provide the regulatory guideline directed non-clinical safety data package for the Clinical Trial Application (CTA) enabling Initiator Pharma to initiate the Phase 1 clinical trial next year.

The in-life phase is now completed for the GLP (Good Laboratory Practice) 28 days mini-pig toxicology study. No apparent critical clinical findings are reported. The first safety pharmacology studies have also been completed without any critical observations.

'The progress in the pre-clinical development during the fall is very encouraging including the recent completion of the in life -phase studies. During the last few months we have gained significant insight into the behavior of IPED2015 in animals/animal studies that provides important information for the ongoing planning of the design of the first-in-man clinical trials and subsequent the phase 2 trial with ED patients,' say CEO, Claus Elsborg Olesen.

All other GLP genotoxicity and safety pharmacology studies are proceeding as planned and will be reported in the coming months. These studies will also be included in the Clinical Trial Application (CTA) that will be filed in 2018.

For additional information about Initiator Pharma, please contact:

Claus Elsborg Olesen, CEO

Telephone: +45 6126 0035

E-mail: ceo@initiatorpharma.com

This information is the information that Initiator Pharma is required to disclose under the EU Market Abuse Regulation. The information was provided under the above contact person's auspices, for publication on December 15th 2017.

About Initiator Pharma

Initiator Pharma is a Biotech company established in Aarhus, Denmark. Its main asset IPED2015 represents a novel treatment paradigm for the treatment of Erectile Dysfunction (ED) and will improve the quality of life for the growing number for patients (and their partners) that do not respond or cannot be treated with the medications currently on the market.

About Erectile dysfunction

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 and that number is expected to increase to more than 320 million by 2025, fueled by aging demographics and increasing prevalence of life style diseases such as diabetes. ED patients have decreased quality of life

Initiator Pharma A/S
2017-15-12

Initiator Pharma

due to various psychosocial factors such as low self-esteem, depression, sadness, anger, frustration, anxiety, relationship problems etc. (Althof, 2002; Shabsigh et al., 1998, Tsai, 2008; Litwin et al., 1998)