

## Initiator Pharma receives positive result from the toxicology and toxicokinetic studies for its lead drug candidate IPED2015

### PRESS RELEASE

22 November, 2017

**Initiator Pharma A/S, a Danish Biotech Company developing a novel treatment of Erectile Dysfunction (ED), has received very positive preliminary results from its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.**

The first test results from the now completed GLP (Good Laboratory Practice) 28 days rat toxicology study has been evaluated and so far, there are no apparent critical findings. This is a very important safety study result that will be included in Clinical trial Application (CTA) that Initiator Pharma expects to submit mid 2018 to obtain approval for initiate a First-in-man clinical Phase I study early autumn 2018..

“We are super excited about the positive preliminary results, it marks a major milestone in our development program. Additionally, it constitutes a major de-risking of our drug candidate IPED2015 and supports our ambition to initiate a first-in-man clinical Phase 1 trial early autumn 2018” says Claus Elsborg Olesen, CEO of Initiator Pharma.

Initiator Pharma has already proceeded to the next stage of the development program by initiating the first dosing's in the GLP 28 days toxicology study in mini pigs. The first dosing has taken place and no critical observations have been made so far. Furthermore, a series of GLP safety pharmacology and genotoxicity studies will be executed during November and December 2017.

### **For additional information about Initiator Pharma, please contact:**

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*Initiator Pharma is required to disclose the present information under the EU Market Abuse Regulation. The information was provided under the above contact person's auspices, for publication on 22 November, 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 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 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)*

