Initiator Pharma initiates toxicology and toxicokinetic studies for its lead drug candidate IPED2015

PRESS RELEASE
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Initiator Pharma A/S, a Danish Biotech Company developing a novel treatment of Erectile Dysfunction (ED), has initiated its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.

The decision to move forward with the first GLP study was based on the successful completion of preliminary dose range studies in rats and minipigs that as expected showed no critical adverse effect findings affecting the progress of the project. Furthermore, the start of the GLP study is also facilitated by the successful manufacturing of the GLP toxicological batch of our lead candidate IPED2015 that fully fulfills Initiator Pharma's expectations and the requirements by the authorities.

"*The initiation of the first GLP study is a major milestone for us and a great stride towards building a solid clinical trial application for the regulatory authorities.*", says Claus Elsborg Olesen, CEO at Initiator Pharma.

In addition, to the current toxicology and toxicokinetic study, Initiator Pharma will in the coming months initiate and execute additional safety pharmacology, genotoxicity as well as mini-pig toxicology studies. The results will provide Initiator Pharma required data for the preparation of a full regulatory approval package in accordance with Initiator Pharma's development plan, aiming for a first-in-man clinical Phase I-trial in the autumn of 2018.

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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 26 October, 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)