

## **A busy summer is providing valuable and Positive Results from the first Maximum tolerated dose toxicology for drug Candidate IPED2015**

### **PRESS RELEASE**

**7 September, 2017**

The first maximum tolerated dose toxicology and toxicokinetic mini-pig studies have been conducted at RTC, Rome, Italy, under the supervision of Initiator Pharma's CDO Mikael Thomsen. The data are in line with what was observed in comparable rat studies already executed and supports the further development of IPED2015 with the aim to start clinical trials in 2018.

#### **Comment from the CDO, Mikael Thomsen**

*'The first dosing to mini-pigs have been very successful and supportive, the results obtained are now being implemented into the preparation of the next protocols for the upcoming non-clinical safety studies.'*

The exploratory studies will be followed by a dose range repeated dose toxicology study conducted during the month of September. All of the above studies will be supporting the GLP regulatory data package needed for the start of the Phase I clinical studies. The up-scaling of API (active pharmaceutical ingredient) production to accommodate the transition into GLP non-clinical safety studies in mini pig and rat is running according to plan and now in kilogram scale.

#### **Comment from the CEO, Claus Elsborg Olesen**

*'We are pleased with the progress of the non-clinical safety studies and data that is currently being generated is fully satisfactory and in-line with our overall development plan for IPED2015'. We are now looking forward to getting data from the dose range repeated dose toxicology study over the next months'*

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

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*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 7 September, 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 current marketed medication.

#### **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 due to various

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*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)