

Positive Results from the First Exploratory Toxicology and Pharmacokinetic studies for drug Candidate IPED2015

PRESS RELEASE

July 7th 2017

The first exploratory toxicology and pharmacokinetic rat studies have been conducted at Syngene, India under the supervision of Initiator Pharma's CDO Mikael Thomsen. The data are promising and supports the next planned non-clinical safety studies for IPED2015.

Comment from the CDO, Mikael Thomsen

'The first dosing to animals have been very successful and productive, the results obtained have now been implemented into the preparation of the protocol for the upcoming pig study'

The exploratory studies will be followed by a MTD (Max Tolerated Dose) study and repeated toxicology studies conducted during the month of July. The first dosing to mini pigs will also take place late in July and we expect to have data in September. All of the above studies will be supporting the 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 of non-clinical safety studies into mini pig is running according to plan.

Comment from the CEO, Claus Elsborg Olesen

'Bringing our Drug Candidate into the first toxicology studies in animals is very exciting and we are indeed pleased with the outcome. Next month we will start dosing to a non-rodent for the first time, this represents a major milestone towards initiating a clinical phase I trial mid 2018'

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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 July 7th 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 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)