

First dosing healthy subjects in the Phase I, First-in-Man trial with IPED2015

PRESS RELEASE

August 22, 2018

We have started dosing the first healthy subjects in the Phase I, First-in-Man trial with IPED2015 at MAC Clinical research, Manchester, UK. The general conduct of the study has gone well and no clinical adverse reactions were recorded. A cardiovascular incident in one subject was observed – there were no clinical symptoms but a technical abnormality on the readout of the cardiac function was observed. The subject was free of symptoms and felt fine all time during the dosing assessment period. The plasma levels of the drug were as expected much lower than what might cause any pharmacological effect based on the significant safety data package and safety index obtained from the preclinical data. However, we need to explore this incident further including involvement of cardiovascular experts to examine and clarify the observation and also its relationship to the drug. To avoid inducing any other potential situation related to this we will await the full examination of this case before resuming dosing of further subjects.

The Principal Investigator at MAC Clinical research, Dr Peter Dewland, who has conducted numerous First-in-Man studies reports: ‘The subject had no clinical symptoms of the technical cardiovascular observation. Cardiovascular experts will examine the incident before resuming dosing of further subjects. It is important to note that the plasma drug levels were very low and not suggesting any pharmacological effect of IPED2015 leading to this observation’.

‘We are pleased with starting the First-in-Man study for IPED2015, the observed technical abnormality is something that need to be examined so we can continue the phase 1 clinical trial ’ say CEO, Claus Elsborg Olesen.

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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 August 22nd 2018.

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 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)