Initiator Pharma submits an amendment to the clinical trial protocol

PRESS RELEASE
21 September 2018

Initiator Pharma A/S, a biotech company that is developing a novel treatment of erectile dysfunction today announced that it has submitted an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC on the 21st of September.

As earlier informed, a cardiovascular incident was observed in one subject, that after further thorough and full examination of the incident from the cardiovascular point of view, fortunately, was found healthy and not in anyway been harmed by the incident. Based on this we have submitted an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC the 21st of September. The intent is to continue the Phase 1 trial for IPED2015 and dose more subjects upon approval by the MHRA and EC.

The Principal Investigator at MAC Clinical Research, Dr. Peter Dewland, who has conducted numerous First-in-Man studies reports: *'Based on a thorough investigation of the subject together with external experts as well as other relevant project data and observations we will continue the study and dosing based on approval of an amended clinical protocol.´*

'The fast and efficient turn around on completing the amendment once again demonstrates that MAC Clinical Research is a highly capable and experienced CRO and proves to be a strong partner for Initiator Pharma' says 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 21 September 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 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)