

Initiator Pharma looking forward to proceed Phase 1 Trial

PRESS RELEASE

13 September 2018

Initiator Pharma A/S, a biotech company that is developing a novel treatment of erectile dysfunction today announced that it has completed the examination of the incident reported on the 22nd of August. A cardiovascular incident was observed in one subject – there were no clinical symptoms but a technical abnormality on the readout of cardiac function. 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 be expected to cause any pharmacological effect, based on the significant safety data package and safety index obtained from the preclinical data.

We have now completed a thorough and full examination of the incident and now plan to submit an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC as soon as possible. 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: *‘We have together with external expert cardiologists conducted a thorough investigation of the subject from the cardiovascular point of view and fortunately found that the subject is healthy and has not in anyway been harmed by the incident’.*

At this stage we do not expect a major delay in our timelines, but this is very much dependent on the approval of the amendment by the MHRA and EC.

‘We are glad that the subject was and remains healthy before and after the incident. With this in order we look forward to obtaining approval for our amendment and proceeding with the 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 13 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)