

Initiator Pharma has completed first dosing of the re-started Phase I study with IPED2015

PRESS RELEASE

23 November 2018

Initiator Pharma A/S, a biotech company that is developing a novel treatment of erectile dysfunction today announced that it has completed first dosing of the re-started Phase I study.

The first healthy subjects have been dosed in re-start of the Phase I, SAD study with IPED2015. No relevant adverse clinical events or signs were recorded during the post-dosing observation period. There were no changes of any significance seen in any of the cardiac telemetry. All blood tests so far have been normal.

The amended protocol has been discussed and approved by the relevant Authorities and Ethics Committee and covers more monitoring/safety assessment and alternative doses according to standard practice after an incident.

'We are very pleased to have re-started the study. We are looking forward to continuing the execution of the up-dated Phase I study set-up based on the amended protocol' says 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 November 23rd, 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, and relationship problems (1,2, 3).

1. Shabsigh R, et al. (1998) Increased incidence of depressive symptoms in men with erectile dysfunction. *Urology* 52(5):848–852.
2. McCabe MP, Althof SE (2014) A systematic review of the psychosocial outcomes associated with erectile dysfunction: Does the impact of erectile dysfunction extend beyond a man's inability to have sex? *J Sex Med* 11(2):347–363.
3. Nguyen HMT, Gabrielson AT, Hellstrom WJG (2017) Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors. *Sex Med Rev* 5(4):508–520.