

Initiator Pharma starts dosing of last the patients in the IPED2015 Clinical Trial

PRESS RELEASE

27 September 2019

Initiator Pharma A/S, a biotech company that is developing a novel treatment of erectile dysfunction, today announced that the dosing of the last patients in clinical Phase 2a Proof-of-Concept trial with IPED2015 has started. The study data analysis will be initiated shortly and our current best estimate for releasing draft data from the study is during December 2019.

The conductance of the study, a randomized, double-blind, placebo-controlled, erotic movie challenge, cross-over trial studying the efficacy and safety of IPED2015 in Erectile Dysfunction (ED), has so far demonstrated that the patients have tolerated the treatment well with no reporting of critical safety observations. The release of the draft data will be a little later than anticipated due to slower recruitment of the final patients.

'It is with great satisfaction that we have now begun the dosing of the last patients and we are now looking forward to the end of the in-life phase of dosing in the coming weeks and subsequent data analysis in order to generate headline results' 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 27 September 2019.

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 lifestyle 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.