

Initiator Pharma reports positive Phase IIa clinical data for IPED2015 in patients with severe Erectile Dysfunction

PRESS RELEASE
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Initiator Pharma A/S, a clinical-stage biotech company that is developing a novel treatment of erectile dysfunction (ED), today announced statistically significant results on key efficacy endpoints in severe ED patients after a single administration of IPED2015. Moreover, no observations of critical adverse events were recorded.

The Phase IIa study which included patients suffering from severe Erectile Dysfunction (ED) has been completed satisfactorily. The study has demonstrated promising statistical significant efficacy data on ED. Besides, there has been no reporting of critical safety observations which is in line with the previously reported results from the Phase I trial in healthy volunteers.

“This well-executed study was able to demonstrate, under a single protocol, a favorable safety and tolerability profile from IPED2015 in healthy male volunteers, as well as showing positive effects on established markers of penile rigidity in a panel of patients with erectile dysfunction.”

John Connell, Chief Scientific Officer, MAC Clinical Research

Further analysis of the data and report writing has been initiated, and final report is expected later in first quarter of 2020.

‘It is with great satisfaction that we in this first clinical study with IPED2015 have obtained Proof of Concept in patients suffering from severe ED. These results support further clinical development of IPED2015, with the aim of bringing an efficacious and safe treatment to patients suffering from severe ED. Based on these results we will intensify our commercial activities that will be kick-started with our attends at the Biotech Showcase in San Francisco in January 2020,’ says CEO, Claus Elsborg Olesen.

Study Design

The Phase II part study for IPED2015 included twelve patients suffering from severe erectile dysfunction who were enrolled after a thorough selection and screening process and dosed with a single dose of IPED2015 and placebo in a cross-over study design. The patients were enrolled to the MAC Phase I unit, Manchester, UK and in-housed during the dosing and observation period. Efficacy assessment was done with the RigiScan device with stimulus challenge assessment (Erotic Movie presentation) to assess penile rigidity and tumescence. RigiScan is a state-of-the-art model to evaluate erectile function. Safety and PK was also assessed during the trial.

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About Initiator Pharma

Initiator Pharma is a clinical-stage biotechnology company based in Aarhus, Denmark. The company's main asset, IPED2015, is a candidate drug intended for patients with erectile dysfunction. The treatment is expected to improve the quality of life for a growing number of patients who are not responding to or cannot be treated with existing drugs on the market. Read more on www.initiatorpharma.com.

About erectile dysfunction

ED is a sexual dysfunction characterised by the inability to achieve or maintain an erection during sexual intercourse. More than 150 million men around the world suffer from ED; a number that is expected to increase to more than 320 million by 2025 due to an ageing population and an increased incidence of lifestyle illnesses such as diabetes. ED entails an impaired quality of life in patients 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.