

Initiator Pharma receives CTA approval for Phase 2b study with IPED2015 in Erectile Dysfunction patients

PRESS RELEASE

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Initiator Pharma A/S, a clinical-stage life science company, announced today that it has received final approvals for the Clinical Trial Application (CTA) for its planned Phase 2b study in Erectile Dysfunction patients with IPED2015 from both the Medicines & Healthcare products Regulatory Agency, MHRA, UK and the Ethics Committee. The patient recruitment is expected to start at end of July. The study will be carried out in collaboration with MAC Clinical Research, UK, at multiple centers across UK.

“IPED2015 is our most advanced ED candidate with potential to become a new treatment method for the large group of patients that do not respond to the currently marketed drugs in the PDE5i class, such as Viagra and Cialis. The approval to conduct this study is a major achievement and will contribute and support the further valuable exploration and development of the IPED2015 asset”, says Claus Elsborg Olesen, CEO of Initiator Pharma.

The Phase 2b study is a randomized, double-blind, parallel-group, repeat single oral dose study of IPED2015 or placebo in otherwise healthy organic Erectile Dysfunction patients. The plan is to include 120 patients in the study divided into 3 parallel arms receiving a higher and a lower dose of IPED2015 and placebo, respectively, and treatment for 4 weeks with frequent assessments of erectile dysfunction, safety and pharmacokinetics.

IPED2015 is a small molecule that preferentially binds to the dopamine transporters (DAT), and potently inhibits DAT, the noradrenaline transporter (NAT), and the sodium-dependent serotonin transporters (SERT). By binding to DAT IPED2015 increases dopamine in the brain induces erection in rats. IPED2015 also has a direct effect in erectile tissue, where it leads to relaxation of erectile smooth muscle. IPED2015 has successfully been through a Phase 2a Proof-of-Concept study. Results from the study support the goal of further developing an oral formulation of IPED2015 for the treatment of moderate and severe erectile dysfunction in patients who do not respond to current therapies.

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About Initiator Pharma

Initiator Pharma is a clinical-stage biotechnology company based in Aarhus, Denmark. The company's main clinical Phase assets are IPED2015, intended for patients with erectile dysfunction of organic origin, and IP2018 to treat erectile dysfunction of psychogenic origin. The treatments both represent First in Class treatments for psychogenic and organic ED, respectively, and are 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. Recently, Initiator Pharma has also announced its plans to expand the clinical development pipeline to include a new program for Neuropathic Pain, more specifically, the Orphan indication Trigeminal Neuralgia. Read more on www.initiatorpharma.com.

About Erectile dysfunction (ED)

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. That number is expected to increase to more than 320 million by 2025, fuelled by aging demographics and increasing prevalence of lifestyle diseases such as diabetes and performance anxiety. The number of ED patients is most likely grossly underestimated, particularly for the Psychogenic patient segment. ED patients have decreased quality of life due to psychosocial factors such as low self-esteem, depression, sadness, anger, frustration, anxiety, medication, and relationship problems (1,2,3). Erectile dysfunction can be divided into two main categories – Organic and Psychogenic ED – that require different treatments. Initiator Pharma is developing IPED2015 and IP2018, respectively, for these similar but separate patient segments.

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.