

Initiator Pharma announces MHRA approval for clinical trial

PRESS RELEASE

June 26th 2018

Initiator Pharma, a Biotech Company developing a novel treatment of Erectile Dysfunction (ED), have received approval to conduct our first clinical trial with Drug Candidate IPED2015.

Medicines & Healthcare products Regulatory Agency, MHRA, UK (MHRA) has approved Initiator Pharma's Clinical Trial Application (CTA) for IPED2015 that now enables the company to start Phase 1, First-in-Man, single ascending dose escalation trial at MAC Clinical Research Unit, Manchester, UK.

“We are very pleased with the MHRA approval, it really demonstrates that the preclinical work that has been conducted over the last 15-18 months has been of the high quality required by regulatory authorities. Once again, testifying to the agility and efficacy of the Initiator Pharma Team. Furthermore, it keeps us on track to initiate the Phase 1 trial in Q3 as planned and we are all excited about the upcoming clinical trials and we are confident that this will bring value to both shareholders and patients” says Claus Elsborg Olesen, CEO of Initiator Pharma.

For additional information about Initiator Pharma, please contact:

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Initiator Pharma is required to disclose the present information under the EU Market Abuse Regulation. The information was provided under the above contact person's auspices, for publication 26th of June 2018

About Initiator Pharma

*Initiator Pharma is a Biotech company established in Aarhus, Denmark. Its main asset IPED2015 represents a novel treatment paradigm for patient suffering from Erectile Dysfunction (ED) and will improve the quality of life for the growing number for patients (and their partners) **that do not respond to the current market PDE5i medications like Viagra, Cialis and Levitra**. Initiator Pharma is listed on AktieTorget, Sweden and has about 3400 shareholders. The company's share is traded under the ticker INIT. Learn more at initiatorpharma.com*

About Erectile dysfunction

Erectile dysfunction is 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. The large diabetic ED patient segment is often responding poorly to the current medication and is therefore of particular interest for Initiator Pharma. 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)