

## Initiator Pharma gets approval to continue the IPED2015 trial

### PRESS RELEASE

03 October 2018

**Initiator Pharma A/S, a biotech company developing a novel treatment of erectile dysfunction, today announced that it has received approval for an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC.**

*'We are really pleased with the fast approval of the amendment, and noticeable we obtained the go-head without any questions to the content. We have demonstrated that despite this unforeseen incident we are now allowed and capable to continue the study with our qualified CRO, MAC Clinical Research ' says CEO, Claus Elsborg Olesen.*

As recently informed we submitted an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC. With today's approval we are able to continue the Phase 1 trial for IPED2015 and dose more subjects. Dosing is planned to start again in November.

### **For additional information about Initiator Pharma, please contact:**

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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 3 October 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, relationship problems etc. (Althof, 2002; Shabsigh et al., 1998, Tsai, 2008; Litwin et al., 1998)*