

Initiator Pharma successfully completes the preclinical development of its Erectile Dysfunction drug candidate IPED2015 ahead of time

PRESS RELEASE

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Initiator Pharma, a Biotech Company developing a novel treatment of Erectile Dysfunction (ED), has successfully completed the preclinical development of its drug candidate IPED2015. The studies were concluded ahead of the previously announced schedule and included experimental work with most of the recent positive data from the cardiovascular telemetry study, the respiratory study and a clean genotoxicity profile.

“With the positive results from the final studies in genotoxicology and safety pharmacology of the preclinical development of IPED2015 we have passed a big safety hurdle. The fact that the study is completed earlier than anticipated is an extra bonus that points to the dedication and expertise of the entire team” says Claus Elsborg Olesen, CEO of Initiator Pharma.

During the last year Initiator Pharma has, at a very fast pace, managed to optimize the synthesis and production of the Active Pharmaceutical Ingredient (API) and drug product formulation of IPED2015 in accordance with the GMP guidelines. Furthermore, the preclinical toxicology and safety pharmacology studies have been conducted in accordance with the ICH guidelines (International Council for Harmonisation) for clinical testing of investigational medical products.

Although the final analysis and report is ongoing, it is anticipated that IPED2015 will qualify as a clinical candidate. Upon completion of the final documentation from the various studies we will proceed to prepare and submit the Clinical Trial Application (CTA) during the spring of 2018. Initiator Pharma anticipates to obtain an approval for initiating a Phase 1 study in 2018. In conclusion, the preclinical development program has been completed several months ahead of time and in accordance with the budget.

“The speedy progress of the pre-clinical development of IPED2015 has strengthened our confidence in our lead candidate. It’s really encouraging that we now have qualified IPED2015 as a clinical drug candidate well in advance of schedule” says Claus Elsborg Olesen, CEO of Initiator Pharma.

For additional information about Initiator Pharma, please contact:

Claus Elsborg Olesen, CEO

Telephone: +45 6126 0035 E-mail: ceo@initiatorpharma.com

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 on 22 January 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)