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## **Initiator Pharma secures funding for IPED2015 clinical Phase 2b study - signs financing agreement with MAC Clinical Research worth up to 23 MSEK**

PRESS RELEASE  
November 25, 2020

**Initiator Pharma A/S, a clinical-stage biotech company today announced that it has secured funding of the continued Phase 2 clinical development of IPED2015 in organic erectile dysfunction (ED), through a convertible credit agreement worth up to 23 MSEK with the UK's largest independent clinical development organization, MAC Clinical Research. The agreement gives MAC Clinical Research the right to convert the credit into Initiator Pharma shares up to approximately 23 MSEK at a share price of 7.5 SEK upon the full completion of a planned Phase 2b study.**

Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b intercourse study for IPED2015 in patients suffering from organic erectile dysfunction, not responding to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®). Upon the full completion of the study, MAC has the right to convert the accrued debt into Initiator Pharma shares at a share price of 7.5 SEK, equivalent to a premium of more than 70 percent compared to the share price at the day of signing the agreement. Upon conversion MAC will become a shareholder of Initiator Pharma on equal terms to the existing shareholders with no specific asset rights, milestones or ownership to IPED2015. Should MAC choose not to convert, following the full completion of the study, it must notify Initiator Pharma that it prefers to have the accrued debt repaid in cash. In this case, or if the study for any reason is terminated before its completion, the accrued debt will convert into a three year loan with an annual interest rate of 1 percent.

“We are extremely encouraged by MAC’s decision to finance the study with the intent to become a shareholder in our company, enabling us to continue the clinical development of our lead asset IP2015. With more than 150 million affected men worldwide, the need for a new effective treatment for ED is huge. The planned Phase 2b intercourse study in ED patients that are PDE5i nonresponders will potentially provide valuable efficacy data enabling either a pivotal Phase 3 study or an outlicensing to a suitable partner,” says Claus Elsborg Olesen, CEO of Initiator Pharma.

“The deal with MAC is favourable for Initiator Pharma in multiple ways. We get the financial support to conduct this important trial of our lead candidate drug. Furthermore, the agreement can give us a new and committed large shareholder in the form of a CRO that takes part in the risksharing with the existing investors. Lastly, we do not give away the huge potential upside we see in the company at the current valuation”, Claus Elsborg Olesen concludes.

The Phase 2b study will be conducted by MAC at multiple sites in the UK and is planned to be initiated in H1 2021 pending the development of Covid-19 situation. The final design of the study is still pending and requires approval from MHRA. Initiator Pharma and MAC are utilizing the learnings from the previous Phase 2a Proof-of-Concept study to design a Phase 2b intercourse study that also will have EIRF-questionnaires as clinical end point. The study is expected to be completed in the the second half of 2022.

“We see a high potential in developing IPED2015 as a novel treatment of erectile dysfunction We have previous experience committing financially in promising clinical projects and therefore think that an investment in Initiator Pharma is very attractive and will be of benefit for us,” commented Mark Dale, CEO of MAC Clinical Research.

The agreement is pending approval from an EGM in Initiator Pharma to be held before January 15, 2021.

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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, and IP2018, for the treatment of psychogenic erectile dysfunction. 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.

Read more on [www.initiatorpharma.com](http://www.initiatorpharma.com).

## **About MAC Clinical Research**

MAC Clinical Research is the UK's largest independent clinical development organisation that owns a network of Dedicated Research Sites. Its clinical research organisation is committed totally to the recruitment and conduct of clinical trials and full-service delivery through the company's fully owned Dedicated Research Sites and staff. MAC conducts research for sponsors over an ever expanding group of therapeutic areas and has an extensive range of clinical research capabilities to accommodate the most complex Phase 1 trials through to Phase IV. Read more on [www.macplc.com](http://www.macplc.com).

## **About IPED2015**

IPED2015, Initiator Pharma's most advanced drug candidate having successfully completed Phase 2a trials, is a novel drug candidate for the treatment of patients suffering from organic Erectile Dysfunction (ED) that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®). IPED2015 - by having a dual action, both a central effect initiating erection and a peripheral effect potentiating erection through smooth muscle relaxation - is unique and aimed for treatment of ED in patients suffering from ED due to metabolic syndrome and diabetes.

## **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, and performance anxiety. The number of ED patients is most likely grossly underestimated, particularly for Psychogenic patient segment. ED patients have decreased quality of life due to various 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 requires different treatments, Initiator Pharma are developing IPED2015 and IP2018, respectively, for these similar but separate patients segments.

## **Erectile Dysfunction (ED) Market**

The current number of ED patients is estimated to about 150 mio men worldwide and a number that is estimated to increase to more than 300 mio by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant unmet medical need. This is exactly our primary target group and will clearly distinguish us from the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the ED market generated about 4 bn USD and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for IPED2015 and IP2018 thereby generate substantial commercial value for Initiator Pharma.

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.