Initiator Pharma reports positive final Phase IIa data for IPED2015

PRESS RELEASE
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Initiator Pharma A/S, a clinical-stage biotech company that is developing a novel treatment of severe erectile dysfunction (sED), today announced the final data from the company's Phase IIa study with IPED2015, demonstrating statistically significant and clinically relevant results on key efficacy endpoints in patients with sED after a single administration of IPED2015. As previously reported, the Phase IIa study was completed satisfactorily with no observations of critical adverse events.

The Phase IIa Proof-of-Concept study was designed as an exploratory trial and included twelve patients who had severe Erectile Dysfunction (sED) with scores below 12 on the IIEF-5 scale, meaning that it was not possible to treat the condition with currently available treatment.

Important endpoints were the effect on the clinically relevant ability to increase and maintain the rigidity of the erection measured with Rigiscan. The effect of IPED2015 (n=12) was significant vs. placebo (n=12) on penis stiffness measured as 80-100% rigidity ($P<0.05$). There was also a significant effect of IPED2015 (n=12) versus placebo (n=12) on Rigidity Activity Units (base of penis: 3.50 vs. 0.83 and tip of the penis: 3.25 vs. 0.33, $P<0.05$), and Tumescence Activity Units (base of penis: 2.83 vs. 0.58, $P<0.05$ and tip of the penis: 2.17 vs. 0.42). The average events of tumescence were not different in IPED2015 versus the placebo group (base of penis: 3.49 vs. 2.80 and tip of the penis: 3.33 vs. 2.55). Thus, in the study, IPED2015 demonstrated statistically and clinically significant efficacy data on ED. The positive effects on the erectile function that were observed were closely related to the plasma concentrations and were seen in a total of 25% of the patients.

"It is with great satisfaction that we in this first clinical study with IPED2015 have obtained Proof of Concept in this challenging patient group suffering from severe Erectile Dysfunction. These patients are not treatable with the drugs available today, and to be able to show that IPED2015 helps one out of four of these patients with severe ED is promising," said CMO, Professor Ulf Simonsen. "The results support the process to plan further clinical development activities for IPED2015 in a more comprehensive randomized placebo-controlled Phase IIB intercourse and sexual activity study setting, including larger segments of relevant ED patients receiving multiple doses of IPED2015."

Taken the exploratory nature of the study and the clinical endpoint assessment setting (Rigiscan device application and visual sexual stimulation) and the severity of ED into account, the study findings are considered very promising. In conclusion, this supports the aim of the further development of an oral formulation of IPED2015 for the treatment of moderate and severe ED in patients not responding to current therapies.

"With the more elaborate analysis of the Proof-of-Concept IPED2015 data, we can now focus on a more comprehensive business development effort and accelerate on the closing of a deal with a potential buyer or a strategic partner. This will secure the continued development of IPED2015 to the benefit of the many ED patients that currently do not obtain relief by the available marketed drugs," said CEO, Claus Elsborg Olesen.

As announced earlier, and similar to the previously reported Phase I safety data, there were no unexpected adverse drug reactions observed for IPED2015 and placebo in the Phase IIa study. IPED2015 was well tolerated with adverse drug reactions of mild severity. Patients dosed with IPED2015 presented in 2 of 12 cardiovascular effects in form of heart palpitations, but with normal sinus rhythm without changes in ECG or QTc. Moreover, in the central nervous system, dizziness was observed in 2 patients. However, these adverse effects were of mild severity and only possibly related to test drug.

Study Design

The Phase II part study for IPED2015 included twelve patients who have severe erectile dysfunction. They were enrolled after a thorough selection and screening process and obtained a single dose of IPED2015 or placebo in a cross-over study design. The patients were enrolled at the MAC Phase I unit, Manchester, UK, and in-housed during the dosing and observation period. Efficacy assessment was conducted using the RigiScan device with stimulus challenge assessment (visual sexual stimulation) to assess penile rigidity and tumescence. RigiScan is a state-of-the-art model to evaluate erectile function. Safety and pharmacokinetics (PK) were also assessed during the trial. Rigidity Activity Units (RAU) and Tumescence Activity Units (TAU) describe essential parameters for the measurements of the rigidity of the penis as measured by RigiScan (1).

IPED2015

IPED2015 is a small molecule that in vitro inhibits the dopamine transporters (DAT), the noradrenaline transporter (NAT), and the sodium-dependent serotonin transporters (SERT). IPED2015 binds in vivo preferentially to DAT. IPED2015 is a potent inhibitor of DAT and has been found to increase dopamine in the synapses and to induce an erection in male rats. Besides, IPED2015 has been found to act through a peripheral pathway in erectile tissue, where increases in dopamine concentrations lead to the relaxation of erectile smooth muscle.

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This information is the type of information that Initiator Pharma (Ltd.) is obligated to publish pursuant to the EU Market Abuse Regulation. The information was provided by the contact person above, to be published at 21.45 hour CET on 15th March 2020.

About Initiator Pharma

Initiator Pharma is a clinical-stage biotechnology company based in Aarhus, Denmark. The company's main asset, IPED2015, is a candidate drug intended for patients with erectile dysfunction. The treatment is 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.

About erectile dysfunction

ED is a sexual dysfunction characterised by the inability to achieve or maintain an erection during sexual intercourse. More than 150 million men around the world suffer from ED; a number that is expected to increase to more than 320 million by 2025 due to an ageing population and an increased incidence of lifestyle illnesses such as diabetes. ED entails an impaired quality of life in patients due to various psychosocial factors, such as low self-esteem, depression, sadness, anger, frustration, anxiety and relationship problems (2, 3, 4).

1. *Hellstrom WJ, et al., (2013) A phase II, single-blind, randomized, cross-over evaluation of the safety and efficacy of avanafil using visual sexual stimulation in patients with mild to moderate erectile dysfunction. BJU Int. 111:137-47.*
2. *Shabsigh R, et al. (1998) Increased incidence of depressive symptoms in men with erectile dysfunction. Urology52(5):848–852.*
3. *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 Med11(2):347–363.*
4. *Nguyen HMT, Gabrielson AT, Hellstrom WJG (2017) Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors. Sex Med Rev5(4):508–520.*