## Synthesis route for IPED2015 Selected

Initiator Pharma has over the recent months developed a robust and efficient drug substance synthesis route together with CRO partner, Syngene, under the supervision of Initiator Pharma's CTO Dan Peters and CDO Mikael Thomsen.

***Comment from the CTO***
*'We have identified, selected and optimized the synthesis route for IPED2015 and are now focusing on the scale-up of the drug substance production.'*

The optimal synthesis route (subject to *scale, cost, sustainability, time* and quality) has now been identified and selected, and the IPED2015 drug is currently in the process of up-scaling to produce the quantities required material for the continued development which includes the non-clinical safety studies planned to start later this year.

***Comment from the CEO***
*'We are really impressed by the recent progress. The selection of synthesis route represents an important development step. Furthermore, it also provides confidence and assurance that we will stay on track with our time plan to* initiate the non-clinical safety studies later this year *'*

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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 May 9th 2017.*

**Recent study on Diabetes and Erectile dysfunction**
Erectile dysfunction (ED) is a common problem amongst men who have diabetes affecting 35-75% of male diabetics. Up to **75%** of men suffering from diabetes will experience some degree of erectile dysfunction (erection problems) over the course of their lifetime. Men who have diabetes are thought to develop erectile dysfunction between 10 and 15 years earlier than men who do not suffer from the disease. There is one class of drugs with the same mechanism of action (sildenafil (Viagra$^{R}$), tadalafil (Cialis$^{R}$), vardenafil (Levitra$^{R}$), avanafil (Stendra$^{R}$)) for treatment of erectile dysfunction. Some 50% of men with Type 1 diabetes who try the drugs report improved erections, and some 60% men with Type 2 diabetes do, too. However, that leaves a large percentage of men with diabetes and erectile dysfunction who do not respond to therapy with one of these pills. Intraurethral and intracavernosal (injected) alprostadil may be a useful alternative when oral drug therapy is ineffective or contraindicated.

Recent studies have suggested that physical exercise and testosterone supplementation and may work in mild erectile dysfunction and in men with testosterone deficiency.[1,2] **However, this leaves a lot of men with diabetes and more severe erectile dysfunction without a proper oral treatment alternative.** Erectile dysfunction in diabetes is a complex disease, since it affects both the nerves and the blood vessels. Dopamine plays a central role in erection and was recently found to be decreased in diabetic animal models[3,4] while peripheral nitric oxide bioavailability is reduced in peripheral tissues. ***Therefore, Initiator Pharma´s new drug candidate "IPED2015" that increases central dopamine as well as peripheral nitric oxide provides new hope for treatment of patients with diabetes and erectile dysfunction.***

1. Minami et al., Physical activity and prevalence of erectile dysfunction in Japanese patients with type 2 diabetes mellitus: The Dogo Study. J Diabetes Investig. 2017 Mar 28. doi: 10.1111/jdi.12660.
2. Corona G et al., Meta-analysis of Results of Testosterone Therapy on Sexual Function Based on International Index of Erectile Function Scores. Eur Urol. 2017 Apr 20. pii: S0302-2838(17)30253-1. doi: 10.1016/j.eururo.2017.03.032.
3. Kleinridders et al., Insulin resistance in brain alters dopamine turnover and causes behavioral disorders. Proc Natl Acad Sci U S A 2015;112:3463-3468.
4. Simonsen et al., Modulation of dopaminergic pathways to treat erectile dysfunction. Basic Clin Pharmacol Toxicol. 2016 Oct;119 Suppl 3:63-74.