

## **Initiator Pharma selects Syngene and Research Toxicology Centre (RTC) as primary partners for the preclinical development of IPED2015**

### **PRESS RELEASE**

**April 19th 2017**

In order to accelerate Initiator Pharma's erectile dysfunction (ED) development program, Initiator Pharma has selected Syngene, India and Research Toxicology Centre, Italy (RTC) as contract research organizations (CROs) to conduct the pre-clinical development of the drug candidate IPED2015 for the treatment of ED. The goal is to file a clinical trial application and to start a clinical Phase I trial in the early autumn of 2018 as planned. Both CROs are internationally highly recognized and serve pharmaceutical companies of all sizes worldwide (for more details on the companies please see below).

### **Comment from the CEO**

*'We are very happy and confident with our choice of CROs for the ongoing clinical trial enabling studies. Syngene and RTC are both highly experienced operators with substantial expertise and impeccable track records of delivering quality work.'*

Initiator Pharma have designed a solid preclinical development program that meets the requirements of the regulatory authorities. The program will be conducted at the Syngene and RTC facilities under direct supervision of Initiator Pharma's CDO Mikael Thomsen, who has more than 25 years' experience of taking projects from the preclinical stage to clinical Phase I and II trials.

### **Comment from the CEO**

*'Since we secured funding from preferential rights issue, we have made great progress on clinical trial enabling work and are on track to get an approval to start a clinical Phase I trial in the early Autumn of 2018'*

### **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)

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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 April 19<sup>th</sup> 2017.*

## **About Syngene**

*Syngene International Limited, (Mumbai Stock Exchange code: 539268, National Stock Exchange Id: SYNGENE, ISIN Id: INE398R01022) is one of Asia's largest Contract Research Organizations providing integrated discovery and development services for new molecular entities across multiple platforms including Small Molecules, Large Molecules, Antibody-Drug Conjugates and Oligonucleotides. Syngene with its well experienced and integrated quality and regulatory organization provides compliance across EU and US regulations to its multinational clients servicing Research and Development, all phases of Manufacturing (Pre-Clinical to Phase I – III). It offers an integrated platform for R&D focussed organizations across diverse sectors like pharma, biotechnology, nutrition, animal health, agriculture, consumer goods, specialty chemicals and cosmetics to optimize their R&D investments and develop their novel molecules with a distinctive cost advantage. Syngene has a rich scientific talent pool of over 3100 scientists and 1.3 mn sq ft of world-class research and manufacturing infrastructure that has been inspected by leading global regulatory authorities. Its client list of 250 clients includes 8 of the top 10 global pharma companies. Some of its major collaborations are with Bristol-Myers Squibb, Baxter, Amgen, Abbott Nutrition and Herbalife Nutrition. For more details, visit: [www.syngeneintl.com](http://www.syngeneintl.com)*

## **About Research Toxicology Centre (RTC)**

RTC is a leading European Contract Research Organization with more than four decades of worldwide experience, providing a broad selection of services within non-clinical studies to pharmaceutical companies and other health-related organizations. RTC's Headquarters are based in Pomezia, Rome, Italy and the company has 153 employees. All studies are performed according to international guidelines and regulations. RTC's high standard of quality is guaranteed through European, American and Japanese authorities' approval. RTC can support the Client from a very early stage of the project, providing a full range of experimental and consultancy services, in order to offer a tailored approach in the preclinical development process. Scientific and technological expertise, combined with skills in project management and communication, qualify RTC as the partner of choice for any product development. The quality of the services offered by **RTC** is assured by personnel highly specialized in their respective disciplines and with high communication skills. Our facilities and equipment are regularly updated in response to scientific, technical and regulatory demands. We constantly improve our methods and techniques to meet current standards, thus providing the best up-to-date solutions to our clients. Our organization is committed to ensuring efficient communication and timely, reliable and high quality services. For more details, visit: [www.rtc.it](http://www.rtc.it)

## **About Initiator Pharma**

Initiator Pharma is a pharmaceutical company based in Aarhus, Denmark, established via a spin out from Saniona AB (listed on Nasdaq Stockholm First North Premier). The primary focus of the Company is the pharmaceutical candidate IPED2015, which constitutes a new treatment for the indication of ED – the inability of a man to achieve and maintain an erection and thus be able to complete sexual intercourse. Initiator Pharma's new treatment method with IPED2015 is intended to treat the large group of patients suffering from ED who are none responsive to the current available treatment. The company's share is listed on Aktietorget and is traded under the ticker INIT. For more details, visit: [www.initiatorpharma.com](http://www.initiatorpharma.com)