PRESS RELEASE

Imcyse Announces Start of Phase 1b/2a IMPACT Study in Patients with Recent Onset Type 1 Diabetes

Liège, Belgium, February 03, 2021 – Imcyse, a clinical-stage biopharmaceutical company pioneering the development of a new class of active and specific immunotherapies for the treatment of severe autoimmune diseases, today announced the first patients' treatment in the **IM**CY-0098 **P**roof of **AC**tion in **T**ype 1 Diabetes (T1D) (IMPACT) study with IMCY-0098. The IMPACT trial, in collaboration with INNODIA, will evaluate the ability of the Imotope™ IMCY-0098 to preserve beta-cell function in adult and adolescent patients with recent onset T1D as well as determine the best and safe dose and regimen for continued development. Patient recruitment is ongoing. Topline data from the study is anticipated in the second half of 2023.

IMCY-0098, the most advanced Imotope™ in development, is designed to halt the progression of diabetes by stopping the body's immune system from attacking beta-cells. With early intervention the aim is to preserve the pancreas' ability to produce insulin and allow patients to manage the disease without the need for daily insulin injections. The Imcyse approach is unique and distinct to general tolerance induction or overall "immune-suppression". Imotopes™ specifically target the autoimmune pathway without harming the rest of the immune system. In the first-in-human EXALT trial, IMCY-0098 was found to be safe and well tolerated at all doses tested. Initial trends of clinical and immunological benefits were also observed.

"Imcyse is developing a new approach to treating T1D, which seeks to intervene early enough in the disease progression to preserve pancreatic function by specifically targeting the autoreactive immune cells," said **Denis Bedoret, Imcyse CEO.** "Our Imotope™ technology has great potential to result in a cure for patients suffering from this and other life altering autoimmune diseases."

Internationally renowned expert in the field of T1D and coordinator of INNODIA (the largest European T1D network), **Prof. Dr. Chantal Mathieu**, will act as principal investigator. She commented: "INNODIA is privileged to collaborate with Imcyse on the IMPACT program to

progress the development of the Imotope™ which is a very interesting and different approach to preserve beta-cells. Together we have been able to design a clinical trial that will truly benefit patients by determining the most appropriate and safe dose to test the drug for efficacy in recently diagnosed T1D patients."

Jean Van Rampelbergh, Imcyse VP Clinical & Regulatory continued: "During this difficult and unforeseeable COVID-19 situation in which we all find ourselves, it has been encouraging to continue to see dedicated activity to identify and screen patients for the IMPACT study over the last three months, which has now resulted in the treatment of the first patients. The increased incidence rate of COVID-19 patients is now a priority in many countries and as a result clinical sites are being re-allocated to meet this need. Nevertheless, thanks to the incredible commitment of all involved, we anticipate a minimal effect on the overall study timelines. We want to thank the clinical sites staff for their commitment and the patients who are willing to engage with us on this journey."

IMCY-0098 **P**roof of **AC**tion in **T**ype 1 Diabetes Study

The IMPACT Study is a multicenter, randomized, double-blind, placebo-controlled study in newly diagnosed T1D patients. Study sites will be located across Europe and the United Kingdom (UK) with around 13 sites in Belgium, Sweden, Slovenia, Italy and the UK.

Conducted with an adaptive design, the study comprises of two steps: Step one will enroll 24 participants, age 18-45 and diagnosed within 9 weeks (date of first insulin injection), who are randomly assigned (1:1:1) to one of three treatment arms and will follow patients for up to 48 weeks. This step will explore the immune signature and the safety of the treatment comparing two different doses with placebo. Results from these findings will be used to determine the best dose and regimen for IMCY-0098 to be used in the second step. During this step, 60 participants, both adults between 18 and 45 years and adolescents aged 12-17, with supportive safety data, will be recruited to evaluate the treatment effect on the preservation of beta-cell function.

This clinical study, with an estimated total investment of €10.8 million over a period of 4.5 years, is supported by the Walloon Region of Belgium in the amount of €6 million. The funding was approved on behalf of the Walloon Region by Willy Borsus, Minister of Economy and

PRESS RELEASE

Research, and underlines the Region's strong support for innovative projects carried out in the territory, in this case the development of the Imotope™ technology platform at Imcyse.

To learn more about T1D and the IMPACT trial visit: INNODIA and T1D UK Consortium.

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ABOUT IMCYSE

Imcyse is a clinical stage biopharmaceutical company pioneering the development of a new class of active and specific immunotherapies for the treatment of severe autoimmune diseases. The company's unique technology platform allows it to specifically target immune cells involved in the destruction of the diseased organ. Disease specific Imotopes™, which are modified peptides, generate cytolytic CD4 T-cells, that eliminate antigen-presenting cells and autoantigen specific lymphocytes. The Imotope™ effect, sustained over time, helps to prevent and treat diseases with no current curative alternative and to potentially cure patients without causing a generalized immune suppression. The company has established proof of concept in several indications and has completed its first clinical trial in type 1 diabetes with promising results. Beyond type 1 diabetes, Imcyse is developing a pipeline of Imotopes™ for the treatment of several autoimmune diseases. Founded as a spin-off of the Catholic University of Leuven in 2011, Imcyse subsequently relocated to Liège, Belgium.
www.imcyse.com

ABOUT INNODIA

INNODIA, a consortium of 40 European partners funded by the European Commission, brings together a large team of international academic researchers and the most important pharmaceutical companies active in diabetes research. The project has been launched to advance understanding of type 1 diabetes and develop tools and technologies that will allow health professionals to predict, evaluate and prevent the onset and progression of the condition. INNODIA has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115797 (INNODIA) and No 945268 (INNODIA HARVEST) as part of the Horizon 2020 European program.

PRESS RELEASE

ABOUT Type 1 diabetes

In T1D, beta-cells in the pancreas are destroyed due to an improper immune response. This damage to the pancreas causes the organ to stop producing insulin, the hormone that controls blood-sugar levels. In most cases, the onset of T1D occurs in children and adolescents, but it can also affect adults.

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