Imcyse reports successful first-in-human Phase 1b study in type 1 diabetes with IMCY-0098

Company's insulin-based Imotope™ IMCY-0098 shows excellent safety profile and promising clinical trends while eliciting immune responses supporting the proposed mode of action

Liège, Belgium, August 27, 2019 – Imcyse, a clinical-stage company developing active and specific immunotherapeutics for the treatment and prevention of severe chronic diseases, today announces the successful completion of its first-in-human Phase 1b study in patients with recent-onset type 1 diabetes ('T1D').

Results of the clinical trial have shown an excellent safety profile, reaching the primary study objective. In addition, promising early clinical trends and relevant immunological responses were observed, including the detection of cytolytic CD4 T cells.

Imcyse's unique technology platform is based on specifically modified peptides (Imotopes™) which drive the generation of cytolytic CD4 T cells. These cytolytic CD4 T cells are able to actively and specifically target the immune cells involved in the pathogenesis of the respective autoimmune disease. The potential to disrupt undesirable autoimmune responses which drive the process of destruction of the insulin producing beta cells in the pancreas, and to stop disease progression in T1D, can be achieved with this therapy. IMCY-0098 is the lead candidate in the company's research portfolio.

The double-blind, placebo-controlled, dose-escalation (three dose groups) study enrolled 41 adult patients with insulin-dependent type 1 diabetes diagnosed within six months prior to inclusion. It took place in seven European countries: Belgium, Denmark, France, Germany, Lithuania, Sweden and the UK. After four subcutaneous injections of IMCY-0098 at zero, two, four and six weeks, clinical and immunological read-outs were recorded at different points in time, up to a period of six months. A long-term follow-up of up to 12 months will be completed at the end of 2019.

Treated patients within all dose groups of IMCY-0098 showed no signs of disease exacerbation and no major treatment-related safety issues. The primary safety endpoint was met in this study; these results support the design of a Phase 2 study including, if needed, a higher dose of IMCY-0098.

The secondary objective of the study was to assess clinical responses by monitoring disease activity in patients. Read-outs included the assessment of reduction of decrease (i.e. 'stabilization' of disease) of C-peptide, measured by a 2h mixed meal tolerance test ('MMTT'). No statistically significant differences could be observed in the different dose cohorts, but trends towards better outcomes in higher dose cohorts were. In addition, for the first time, IMCY-0098-induced cytolytic CD4 T-cells were detected in humans, along with a concomitant decrease of effector T cells involved in the disease mechanism of T1D.

Although the study was not statistically powered for efficacy endpoints, data mining of all clinical and immunological read-outs using Paris-based Ariana Pharma's Artificial Intelligence-based KEM® technology led to the identification of immunological changes, which are early indicators of clinical effects, for selected groups of patients in the study. The potential for a selection biomarker in patients receiving this therapy transforms design options for Imcyse's future clinical trials in T1D and additional indications.

"We are thrilled by the positive results of our first clinical trial in patients with early type 1 diabetes," said Pierre Vandepapelière, CMO of Imcyse. "The in-depth analysis performed in collaboration with Ariana Pharma strongly supports our unique technology platform. These results pave the way for further clinical development of IMCY-0098 in type 1 diabetes and other Imotopes™ for diseases with high unmet clinical need."

Detailed summaries of the clinical study results will be presented on September 18 at the 55th Annual Meeting of the European Association for the Study of Diabetes in Barcelona, Spain.

The trial received European funding under the EXALT program supported by the European Union's Seventh Framework Program, and the Walloon Region (DGO6).

About type 1 diabetes
The incidence of type 1 diabetes is rapidly increasing in high-income countries at an annual rate of about 3 per cent, with the disease increasingly occurring in younger children. It affects more than 40 million people worldwide. Currently, the only available treatment is to control the blood glucose level with multiple daily insulin injections.

About Imcyse
Imcyse develops active targeted immunotherapies to treat and prevent severe chronic diseases caused by disruptions of the immune system. The company's unique active immunotherapy technology platform allows it to locally target immune cells involved in the destruction of the diseased organ. This platform is based on the administration of Imotopes™, which are specifically modified peptides, allowing for the generation of cytolytic CD4 T cells. Imcyse's approach, sustained over time, helps to prevent and treat diseases with no current therapeutic alternative and to potentially cure patients without impairing immune defense. The company has established proof of concept in several indications and has completed its first clinical trial in type 1 diabetes in seven European countries. Beyond type 1 diabetes, Imcyse is developing a pipeline of Imotopes™ for the treatment of several autoimmune diseases. Based in Liège, Belgium, Imcyse was originally founded in 2010 as a spin-off from the KU Leuven, Belgium.
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