PolTREG launches Phase 2 cell therapy trial in children with presymptomatic diabetes

- **Treating diabetes patients earlier with PTG-007 could provide functional cure**
- **Recruitment will go ahead after European Medicines Agency approval**
- **Company has 12 years' worth of safety and efficacy data for PTG-007**

Gdańsk, Poland – 24 October 2024 (07:00 CET) – PolTREG S.A. (Warsaw Stock Exchange: PTG), a clinical-stage biotechnology company developing cellular therapies for a wide range of autoimmune diseases, has launched a placebo-controlled Phase 2 clinical trial with PTG-007 Treg cell therapy in presymptomatic type-1 diabetes (T1D) patients, after receiving approval from the European Medicines Agency. The study will evaluate safety and efficacy in 150 patients, including those aged between 6 and 16 years who are at high genetic risk of developing T1D, but who have not yet shown any symptoms. Clinical sites for the study have started to open, and patient recruitment and randomization will follow later this year.

"When patients are diagnosed with diabetes, they typically have already lost the vast majority of pancreatic islets producing insulin, and the rest will follow not much later. When administering PTG-007 at an earlier stage of the disease, the number of viable islets is still sufficient to prevent symptoms from occurring. This is why PolTREG believes diabetes can become a preventable disease, with patients never developing symptoms, and remaining clinically healthy," said Prof Piotr Trzonkowski," Chief Executive Officer of PolTREG.

The company has received a grant of 31.7 million zloty (€7.3 million) from Poland's Medical Research Agency for the study. PolTREG is the only company to hold up to 12 years' worth of proprietary safety and efficacy data in patients with early-onset T1D for PTG-007, a polyclonal autologous Treg cellular therapy. The data showed that a proportion of patients remained insulin-independent up to 18 to 24 months after treatment, while another subset of patients was still in clinical remission - defined as having a low need for external insulin - 7 to 12 years

after treatment. The company is planning to launch a pivotal Phase 2/3 trial with PTG-007 in early-onset T1D, for which it is looking for external funding.

PTG-007 is an Advanced Therapy Medicinal Product (ATMP), which serves as a platform to develop therapies for a wide range of autoimmune diseases. The company has completed a total of five clinical trials in T1D, multiple sclerosis (MS) and graft vs host disease. PolTREG is the only company to develop all available Treg modalities in house, including CAR-Treg and other engineered Treg cells. Its lengthy safety and efficacy track record with PTG-007 in patients of more than a decade puts it ahead of its competitors, as the new products it is adding to its pipeline show a large degree of bioequivalence with PTG-007, leading the company to expect it will be able to develop new therapies and bring them to market quicker than others.

About PolTREG

PolTREG is a global leader in developing autoimmune therapies based on T-regulatory cells (Tregs). Its lead product, PTG-007, autologous Treg treatment for early-onset Type-1 diabetes (T1D) is ready for Phase 2/3 clinical testing, for which the company is seeking a partnership. The company will launch Phase 2 trials for PTG-007 to treat multiple sclerosis (MS) in the second half of 2024, for RRMS and PPMS. PolTREG also has engineered Tregs, including CAR-Tregs, antigen-specific Tregs and TCR-Tregs, in the preclinical stage. PolTREG has completed four clinical trials with more than 100 patients treated with Tregs.

For more information please visit www.poltreg.com.

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