PolTREG's type-1 diabetes Treg cell therapy PTG-007 demonstrates long-term safety and efficacy for up to 12 years

- **PTG-007 administration resulted in improved remission and insulin secretion**
- **Patients monitored for up to 12 years**
- **Planned pivotal Phase 2/3 study is final step for PolTREG to bring PTG-007 to market**

Gdańsk, Poland – 24 June 2024 – PolTREG S.A. (Warsaw Stock Exchange: PTG) , a clinical-stage biotechnology company developing cellular therapies for a range of autoimmune diseases, today announces that its polyclonal Treg cell therapy PTG-007 demonstrated significant insulin secretion restoration in early-onset type-1 diabetes (T1D) patients, as well as a longer period of disease remission compared to a control group receiving standard-of-care, in a long-term clinical study into the safety and efficacy of lead asset PTG-007. The study monitored pediatric patients who received the autologous treatment over a period of 7 to 12 years.

The main findings were:

- Patients who received PTG-007 continued to secrete insulin, while untreated patients in the control group did not,
- Safety measures showed no significant difference in the health status of patients who received Treg therapy compared to the control group,
- The duration of disease remission - the period of disease characterized by moderate severity of disease symptoms with low insulin requirement or insulin independence - was significantly longer in patients who received PTG-007 compared to the control group. A preliminary estimate is that the difference was between 3 and 4 years, however, that number still needs to be confirmed in final results.

"This long-term study is a confirmation that the significant efficacy we found in our Phase 1/2 clinical trial for PTG-007 is sustainable over the long term. At PolTREG, we believe that PTG-007 has the potential to prevent type-1 diabetes, freeing patients of the life-long burden of having

to take frequent insulin injections, and the serious long-term complications of the disease. The results of this study are an important step in that direction," said Prof Piotr Trzonkowski, Chief Executive Officer of PolTREG.

With the study, PolTREG has fulfilled a requirement by the European Medicines Agency to confirm the safety of Treg therapies at least 5 years after their administration. To the best of PolTREG's knowledge, no other company currently can show similar long-term safety results of Treg therapy in T1D. This is a significant competitive advantage, and paves the way for the company to launch a pivotal Phase 2/3 study of PTG-007 to treat T1D.

PolTREG is currently seeking partnership funding for this pivotal trial, the final step required before seeking regulatory authorization for commercialisation. The company will submit the data for a peer-reviewed scientific publication in the near future. "Later this year, we will also be launching a Phase 2 study in presymptomatic patients, children who are not yet showing any symptoms but in whom we are now able to detect diabetes, " Prof Trzonkowski said.

PolTREG holds one of the largest and most advanced pipelines for Treg therapies for autoimmune disease, developing both polyclonal and engineered therapies. Its lead candidate, PTG-007, an autologous polyclonal Treg treatment, is in mid-stage clinical studies for T1D and multiple sclerosis (MS). Next year, PolTREG expects to start a first-in-human trial of its engineered CAR-Tregs for treatment of two neurodegenerative diseases, MS and amyotrophic lateral sclerosis (ALS). The company also is in preclinical development with two further types of engineered Treg cells.

PolTREG manufactures all its Treg therapeutics at its own GMP-certified manufacturing facility. It is the first company in the world to administer Treg therapies to patients, and, under a hospital exemption valid in Poland, the first to start receiving revenues from a Treg therapeutic for autoimmune disease. Its GMP manufacturing facility is one of Europe's largest and most advanced, boasting over 2,100 sqm of laboratory space, including 15 production lines. PolTREG has the option to substantially expand the facility to accommodate manufacturing of next-generation engineered therapies and cell therapies. It can ship its wide range of cellular therapy products across Europe within 24 hours.

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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