PolTREG Treg cell therapy for patients with type-1 diabetes shows long-term clinical remission and insulin independence

- **PTG-007 cell therapy resulted in clinical remission in some patients for up to 12 years**
- **A proportion of patients remained insulin-independent for up to 24 months**
- **PTG-007 ready to enter pivotal study**
- **Data presented at INNODIA EASD conference**

Gdańsk, Poland – 9 September 2024 – PolTREG S.A. (Warsaw Stock Exchange: PTG) , a clinical-stage biotechnology company developing cellular therapies for a range of autoimmune diseases, today announces data showing that treatment with its Treg cell therapy, PTG-007, resulted in clinical remission for up to 12 years in patients with type-1 diabetes (T1D). A subset of these patients remained insulin-independent up to 18 to 24 months after treatment. The company will present the data at the INNODIA EASD symposium in Madrid today.

“People with type-1 diabetes understand the life-long commitment needed for their care. This is why the results of treating patients over such a long period with our cellular therapy PTG-007 is so important. Today’s results are extremely encouraging, and show that some patients remain in clinical remission for up to 12 years after initial treatment. This makes us very eager to launch a pivotal study of PTG-007 as soon as we find a suitable partner. We believe that PTG-007 has the potential to free many type-1 diabetics from the life-long burden of having to take frequent insulin injections, and the serious long-term complications of the disease,” said Prof Piotr Trzonkowski, Chief Executive Officer of PolTREG.

The clinical study monitored 54 patients who had taken part in Phase I and Phase II trials with PTG-007 to treat early-onset T1D, over a period between 7 and 12 years.

The main findings were:

- A proportion of patients treated with PTG-007 remained insulin-independent up to 18 to 24 months after treatment.
- A subset of patients was still in clinical remission 7 to 12 years after treatment with Tregs. Clinical remission is defined as having a low need for external insulin, while retaining proper metabolic/ glycemia control.
- The best results were observed in patients who had been given Treg therapy in combination with a standard anti-CD20 treatment (rituximab), when measuring own insulin levels after patients had consumed a standardized liquid meal.
- The study analysed more than 700 variables of heart functioning, microcirculation, kidney, liver, endocrine system, fertility. It found no inferiority of the variables in patients treated with Treg cells when compared to standard-of-care.
- The study noted no severe adverse effects from the treatment.

The company is working to publish the study in a peer-reviewed scientific publication, at which stage it will provide full data disclosure. The long-term safety and efficacy results of its Treg therapy in T1D presented today are a significant competitive advantage and pave the way for the company to launch a pivotal Phase 2/3 study of PTG-007 to treat T1D, for which it is currently seeking partnership funding.

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). Later this year, PolTREG will launch a Phase 2 study in presymptomatic T1D patients. Next year, PolTREG expects to start a first-in-human trial of its engineered CAR-Treg, using the PTG-007 platform, for treatment of MS and amyotrophic lateral sclerosis (ALS). The company also is in preclinical development with two further types of engineered Treg cells.

To read more about the clinical trials PolTREG has completed, please click on: https://poltreg.com/tregs-therapy/#publications

PolTREG manufactures all its Treg therapeutics at its own GMP-certified manufacturing facility. It is the first company in the world to have administered Treg therapies to patients, and, under a hospital exemption valid in Poland, the first company 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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