



## **PolTREG receives US Patent Office Notice of Allowance for Treg cell therapy to treat Type-1 Diabetes**

**Gdańsk, Poland – 16 January 2024, 07:00 CET** – PolTREG S.A. (Warsaw Stock Exchange: PTG), a clinical-stage biotechnology company in Europe developing cell therapies for use in a wide range of autoimmune diseases, announced it received a Notice of Allowance from the United States Patent and Trademark Office (USPTO), covering the manufacturing of T-regulatory cells (T-reg) to treat Type-1 Diabetes (T1D), and ways the therapy is administered. The US allowance constitutes an important addition to the intellectual property portfolio covering PolTREG’s autoimmune therapies.

“This USPTO decision complements our extensive intellectual property portfolio in the US and EU, paving the way for rapid, unimpeded commercialization of PolTREG’s cell therapies,” said **PolTREG CEO Prof Piotr Trzonkowski**. “Together with our 17 years of experience with patients at our own facilities in Poland, our dominant intellectual property portfolio demonstrates that we are leading pioneers in the field of T-reg therapeutics for autoimmune disorders. Indeed, we are the first ever to have administered Treg cell therapies to patients and the first company to begin receiving revenues from sales of our lead product; so far, 27 patients have been successfully treated commercially under the Hospital Exemption program in Poland.”

The US patent application covers the manufacturing of Treg cells, the formula of the cellular medicinal product containing Treg cells, and the ways the therapy is administered in T1D patients.

Many of PolTREG’s patent submissions are primary in the field, given that its team performed the first-in-human trials with Treg cell therapies in graft-versus-host disease in 2007-2009. PolTREG’s portfolio of patents and patent applications, in U.S. and Europe, includes the formulation of polyclonal and engineered Treg products, unique manufacturing elements of these cell therapies, details of patient recruitment and clinical efficacy. A number of the patents

have been licensed from the Medical University of Gdańsk to PolTREG through Prof Trzonkowski, who was responsible at the university for the research behind these patents.

PolTREG boasts the most advanced pipeline for Treg cell therapies in autoimmune disease, with its flagship drug candidate, PTG-007, in clinical studies for two indications in T1D and two in Multiple Sclerosis (MS).

### Upcoming milestones in 2024

- H1 2024      Results of a long-term efficacy and safety study of PTG-007, in which the company followed early-onset T1D patients over a period of 10 years
- H2 2024      Initiate Phase 2 clinical trial of PTG-007 in presymptomatic T1D patients  
Initiate Phase 1/2a trial in relapsing-remitting (RRMS) patients  
Initiate Phase 1/2a trial in primary progressive (PPMS) patients  
Preclinical proof-of-concept for product(s) from engineered Treg pipeline

**T-regulatory cells (Treg)** are the regulators of the immune system, seeing to it that other leukocytes do not attack the body's own cells. PolTREG has developed patented processes by which it takes Treg from a patient's own body, multiplies them *ex vivo*, and then injects them back in the patient's own bloodstream for therapeutic effect. Treg therapeutics have advantages over traditional drugs in that they only act at the site of the inflammation, and switch off when the inflammation is over. A Phase 2 clinical study in T1D showed half of patients in clinical remission 24 months into the study, demonstrating the strong potential PolTREG's cell therapies have to become powerful disease-modifying treatments.

**PolTREG** (Gdańsk, Poland; WSA:PTG) 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 to start Phase 2/3 clinical testing, upon 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 is developing engineered Tregs, including CAR-Tregs, antigen-specific Tregs and TCR-Tregs, all of which are 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](http://www.poltreg.com).

**For further information please contact:****PolTREG S.A.**

Prof Piotr Trzonkowski  
Chief Executive Officer

[ir@poltreg.com](mailto:ir@poltreg.com)

+48 512 532 401

**Investor Relations**

Chris Maggos  
Cohesion Bureau  
+41 79 367 62 54

[chris.maggos@cohesionbureau.com](mailto:chris.maggos@cohesionbureau.com)

**Media Relations**

Douwe Miedema  
Cohesion Bureau

[douwe.miedema@cohesionbureau.com](mailto:douwe.miedema@cohesionbureau.com)

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