PolTREG receives CGMP certification to produce cell therapies at its state-of-the-art manufacturing site in Poland

Gdańsk, Poland – 11 March 2024 – PolTREG S.A. (Warsaw Stock Exchange: PTG) , a clinical-stage biotechnology company developing cellular therapies for a range of autoimmune diseases, today announces it has received CGMP certification from Poland's Chief Pharmaceutical Inspectorate, allowing it to produce cellular therapies (Advanced Therapy Medicinal Products – ATMP) in its own site. The certification also enables it to seek permission from Poland's Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) to perform clinical trials in the facility, for diseases such as Type-1 Diabetes (T1D) and Multiple Sclerosis (MS).

PolTREG was the first company in the world to administer T-reg therapies to patients, and the first to start receiving revenues from its lead product under a hospital exemption valid in Poland. Its 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 from future partners. The company now has more than 17 years of experience treating patients, having administered Treg cells to more than 100 people over that period, either in hospital exemption procedures or in clinical trials.

"This certification is an important recognition of PolTREG's leading capabilities in manufacturing cellular therapies, a highly sophisticated process that requires deep experience to master," said Prof. Piotr Trzonkowski, Chief Executive Officer of PolTREG. "From our brand-new facilities, we can in the future ship these live cells anywhere in Europe within 24 hours. This is a significant potential expansion in treatment options for patients, and an important consideration as our pipeline of Treg cell therapies comes closer to market."

PolTREG has developed one of the most advanced pipeline for Treg therapies for autoimmune disease, with both polyclonal and engineered cells. Its lead candidate, PTG-007, is in mid-stage clinical studies for two indications in T1D and two in MS. For CAR-Tregs, it expects to start a First-in-Human trial for two neurodegenerative diseases - MS and Amyotrophic Lateral Sclerosis (ALS) – in early 2025. It is also in preclinical tests with two further types of engineered cells.

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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those predicted by the forward-looking statements. The company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.