China patent notification boosts PolTREG's development of Treg cell therapy in multiple sclerosis

- **China's National Intellectual Property Administration has issued notification to grant patent to PolTREG**
- **Chinese patent covers intrathecal administration of PolTREG's PTG-007 Treg cell therapy to treat multiple sclerosis**
- **Intrathecal administration demonstrated promising result in Phase I clinical trial**
- **PolTREG set to launch one Phase 2 study in each of two types of MS: relapsing-remitting (RRMS) and primary progressive (PPMS) in Q4 2024**

Gdańsk, Poland – 16 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 that China's National Intellectual Property Administration, PRC (CNIPA) has issued a notification to grant a patent for the intrathecal administration of the company's cellular therapies in patients with multiple sclerosis (MS). The intrathecal administration is an established method used to deliver a therapy across the blood-brain barrier via injection into the subarachnoid space.

"We are about to launch two new clinical studies with PTG-007 in patients with multiple sclerosis, so it is welcome news that China has issued us a patent for the intrathecal administration of the therapy. This method has shown superior results to systemic administration in our earlier work in neurodegenerative diseases, as it bypasses the blood-brain barrier. Having just presented our unrivalled long-term data in type 1 diabetes patients treated with systemically administered PTG-007, we will continue to highlight the potential of Treg cell therapies in a widening range of autoimmune diseases, including neurodegenerative diseases like MS and Amyotrophic Lateral Sclerosis," said Prof Piotr Trzonkowski, CEO of PolTREG.

In an exploratory Phase 1/2a safety study of PTG-007 in RRMS, patients who had received intrathecal administration showed no increase in existing lesions in the brain, and almost no new lesions, a far superior result compared to patients who had received PTG-007 intravenously, and a surprisingly positive signal for such a small study in 14 individuals, only 3 of whom received intrathecal administration. Two large studies to be launched in Poland later this year will aim to confirm these encouraging results. The studies will have a combined 105 patients: 60 for PPMS and 45 for RRMS. Each trial will have three arms, with primary endpoints a reduced deterioration in new and existing lesions, and the number of serious adverse events.

PolTREG is advancing one of the largest and most advanced pipelines for Treg therapies for autoimmune disease, developing both polyclonal and engineered cells. Its lead candidate, PTG-007, an autologous polyclonal Treg treatment, is in mid-stage clinical studies for type 1 diabetes (T1D). Earlier this September, PolTREG presented results from a long-term monitoring study showing that a proportion of early-onset T1D patients having received PTG-007 remained in clinical remission up to 12 years later, and several patients were insulin-independent for up to two years after PTG-007 treatment. PolTREG is preparing to launch a Phase 2 study in presymptomatic T1D patients during the fourth quarter and, next year, PolTREG expects to start a first-in-human trial of its engineered CAR-Treg, using the proven PTG-007 platform, for treatment of MS and amyotrophic lateral sclerosis. The company also is in preclinical development with two additional types of engineered Treg cell therapies, Antigen-specific Tregs and T-cell receptor (TCR) Tregs.

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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