



PoITREG starts preclinical CAR-Treg development for neuroinflammatory autoimmune diseases

- **Over a decade of clinical data, experience and know-how with lead polyclonal Treg cell therapy PTG-007 in type-1 diabetes will accelerate CAR-Treg candidate development**
- **New CAR-Treg cell therapy candidate is most advanced in growing engineered pipeline**
- **Two new patents granted for engineered cell therapies, in U.S. and Japan**

Gdańsk, Poland – 26 September 2024 – PoITREG S.A. (Warsaw Stock Exchange: PTG), a clinical-stage biotechnology company developing cellular therapies for a range of autoimmune diseases, today announces it has launched a study with CAR-Treg cells in a humanized mouse model of neuroinflammatory disease. Data from the study are anticipated by March 30, 2025, and will help determine the pathway to clinical evaluation. The study will measure safety and efficacy of the CAR-Treg cell therapy, which will be administered systemically as well as intrathecally. PoITREG’s CAR-Treg cells are manufactured using the same technology platform as its lead product PTG-007, a polyclonal Treg cell therapy, for which PoITREG has gathered over a decade of clinical safety and efficacy data, largely in type-1 diabetes (T1D) patients.

“This first preclinical study of our CAR-Treg cell therapy program to treat neurodegenerative disease is a significant milestone for PoITREG. This may be our first CAR-Treg cell therapy candidate, but we expect it to benefit tremendously from the experience our team built up during more than a decade in manufacturing, developing and treating patients with PTG-007. This lengthy track record gives us several competitive advantages, as the next-generation engineered Tregs that we are adding to our pipeline come from the same platform, and show a large degree of bioequivalence with PTG-007. Because of our proprietary technology and expertise, we expect to be able to develop our engineered therapies with greater ease than others in this field,” said Prof Piotr Trzonkowski, Chief Executive Officer of PoITREG.

PoITREG’s CAR-Treg cells are derived from its PTG-007 Treg cells, an advanced autologous polyclonal product candidate for which the company has [gathered 12 years of patient safety](#)

[and efficacy data](#) in Type 1 diabetes (T1D), using its leading technological and wholly owned GMP manufacturing facility in Poland. To the best of its knowledge, PolTREG is the only company in possession of such expertise, giving it potential technical, clinical safety and efficacy advantages in the autoimmune therapy field.

In an exploratory Phase 1/2a safety study in relapsing-remitting multiple sclerosis (MS), patients who had received intrathecal administration of PTG-007 showed no increase in existing lesions in the brain, and almost no new lesions, a far superior result compared to those who had received the therapy intravenously, and a surprisingly positive signal for a small study of just 14 patients. [To read the 2021 results of the study, click on this link.](#)

On successful completion of preclinical testing of the CAR-Treg, PolTREG expects to initiate, as early as next year, the first-in-human trial of the engineered candidate to treat MS and amyotrophic lateral sclerosis (ALS). The company also is developing two additional modalities of engineered Treg cell therapies, Antigen-specific Tregs and T-cell receptor (TCR) Tregs for autoimmune diseases, which are in early, proof-of-concept preclinical stages.

PolTREG receives three new patents

Separately, the United States Patent and Trademark Office (USPTO) has granted AZTherapies, a private, late-stage clinical biopharmaceutical company developing treatments for neurological conditions, from Boston, Massachusetts, a patent for the use of CAR-Treg therapy in autoimmune neurodegenerative diseases. PolTREG holds the exclusive global license to the therapy for all indications. Also in September, the Japanese Patent Office issued a patent for PolTREG's method of producing antigen-specific Treg cells, under the product name PTG-020. Earlier in the month, PolTREG had already announced in a press release that the Chinese Patent Office issued a patent for PolTREG's method of administering Treg cell therapy in MS directly into the central nervous system (intrathecal administration).

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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