Press release

PolTREG S.A. - a biotechnology company at the clinical stage developing an innovative generation of medicines using T-regulatory cells (TREGS) in the treatment of autoimmune diseases - submitted the prospectus to the Polish Financial Supervision Commission (in PL: KNF), plans to debut on the WSE (in PL: GPW) in the fourth quarter of 2021

Gdańsk, July 7, 2021 - PolTREG S.A. is currently at various stages of clinical research and development (therapy of type 1 diabetes in children, and multiple sclerosis) using T-regulatory cells (TREGS). The company's strategy assumes the development of a platform for therapies based on the use of TREGS in the treatment of autoimmune diseases and achieving the position of one of the leaders of such therapies in the world.

The Company submitted at the end of June, to the Polish Financial Supervision Commission (in PL: KNF) prospectus in connection with the intention to carry out an initial public offering (IPO), and admission and introduction of shares to trading on the regulated market of the Warsaw Stock Exchange in Warsaw S.A. (in PL: GPW).

PolTREG plans to debut on the stock exchange in the fourth quarter of 2021. The funds that the Company intends to obtain from the public offering (IPO) shall be used to finance the current research and development projects related to the next stages of clinical trials on the treatment of type 1 diabetes in children and the treatment of multiple sclerosis.

- *We decided to issue shares in a public offering and enter into the Warsaw Stock Exchange (GPW) to raise funds to carry out the next stages of clinical trials, both for the treatment of type 1 diabetes and the treatment of multiple sclerosis, and bring them to the moment when it will be possible to conclude partnering agreements, probably at the stage of an advanced or completed phase II/III of study* - **says Mariusz Jabłoński, member of the management board of PolTREG S.A.**

PolTREG is an innovative biotechnology company developing therapies using T-regulatory cells (TREGS) at an advanced clinical stage, which cells target unmet medical needs in the field of autoimmunology - incl. treatment of type 1 diabetes and multiple sclerosis.

In 2015, the Company completed the I phase of clinical trials in type 1 diabetes in children, and in 2020, the phase I/II study was completed. Currently, following the Scientific Advice procedure with the European Medicines Agency (EMA), a phase II/III study is in preparation for the treatment of patients with newly diagnosed type 1 diabetes. The second study in type 1 diabetes will be a study I/II involving the identification and treatment of the patients in the pre-symptomatic period. As part of this study, the Company intends to conduct a study on people who, due to genetic conditions, are at high risk of developing type 1 diabetes. This study may open a completely new chapter in the approach to this disease, because currently, due to the lack of available treatment, no screening and no treatment are used at an early

stage in the development of the disease. Dissemination of screening tests, allowing for the quick diagnosis of the disease and the initiation of treatment will be important for the application of the treatment of type 1 diabetes in the pre-symptomatic phase.

The Company also completed with very promising results a phase I clinical trial in relapsing-remitting multiple sclerosis.

The TREG method gives patients opportunity to treat autoimmune diseases for which modern medicine does not yet offer disease-changing treatments, such as in the case of type I diabetes (unmet medical need). For other autoimmune diseases such as multiple sclerosis, TREGS therapy may benefit patients who do not show significant improvement after using currently available medicines. Due to the different mechanism of action of TREGS cells, therapies using this method may be a significant supplement to the range of agents used in the treatment of this disease.

The Company finances the implementation of research and development projects based on grants and funds obtained from private investors. So far, the Company has obtained about PLN 22.8 million from grants, of which PLN 12.2 million for the development of the TREG Method.

PolTREG is also developing its own research and development facilities. This year, the Company began work on creating its own, modern laboratory, for which the Company obtained funding from the European Regional Development Fund. The planned investment outlays amount to PLN 23.7 million, and the co-financing amount is PLN 10.6 million. Part of the investment outlays will be covered by the Company from own funds. The Company assumes that the construction of the laboratory and its equipment will be completed by the end of 2021. At the beginning of 2022, all the required certifications should be obtained and it will be possible to launch the laboratory.

Work on the use of Tregs in the treatment of type 1 diabetes had already begun in 2006 at the Gdansk Medical University and was conducted among by the founders and major shareholders of the Company: prof. dr. hab. n. med. Piotr Trzonkowski, prof. dr. hab. n. med. Małgorzata Myśliwiec and prof. dr. hab. N. med. Natalia Marek-Trzonkowska. The research conducted in the following years has showed the effectiveness of the developed solutions, which led to the establishment of the PolTREG company in 2015 as a spin-off from the Medical University of Gdańsk, the purpose of which was to conduct further stages of clinical trials, develop new therapies, and commercialize solutions. The Company continues scientific cooperation with the Medical University of Gdańsk in the field of TREGS therapy development.

- The Company focuses on the treatment of autoimmune diseases, i.e. those in which the disease is caused by a malfunction of our immune system which attack its own tissues. We have developed an innovative platform of treatment for such diseases based on regulatory T cells. They are a small group of lymphocytes that can stop the autoimmunity of the immune system. We were the first in the world to introduce this therapy in the graft-versus-host disease after bone marrow transplantation. On the other hand, the Company developed this method for patients with newly diagnosed type 1 diabetes. In these patients, the number of regulatory T cells is often too low or they do not reach the pancreas at the right time. This can lead to a situation where the own cells of the immune system destroy the insulin-producing cells of the pancreas. In the patented TREG method, the patient's own cells are collected, multiplied in the

laboratory and given to the patient again. By increasing the number of TREG cells in the body, people with newly diagnosed type 1 diabetes have a chance to, at least partially, maintain the function of the pancreas - **says Prof. dr. hab. n. med. Piotr Trzonkowski, president of the management board, co-founder and shareholder of PolTREG S.A.** - *There is currently no registered medicines in the world that has a causal effect in the treatment of newly diagnosed type 1 diabetes, so we have a huge unmet medical need on a global scale. We see a great opportunity to develop a breakthrough therapy that is already well advanced from the clinical point of view, with a relatively large number of examined patients. We see enormous potential, both clinical and commercial, in regulatory T-cell therapies (TREGS)* - **adds Piotr Trzonkowski**.

Currently, the Company's team consists of 20 people, and after the launch of the new laboratory and completion of preparations for the next phases of clinical trials, the target will be approximately 40 people.

The Company's goal is to develop effective, based on regulatory T cells, therapies for the treatment of autoimmune diseases that will become the world's first-choice treatment and will improve the lives of patients and their families, and become one of the leaders of such therapies in the world. The Company focuses on developing a platform which is the starting point for the development of therapies based on the use of TREGS in the treatment of autoimmune diseases. The development of the platform will be carried out in parallel and based on the effects of subsequent phases of work on therapies for the treatment of type 1 diabetes in children and multiple sclerosis. In the long term, the Company plans to use the created platform for the development of further therapies in diseases such as rheumatoid arthritis, inflammatory bowel disease and other autoimmune diseases. One of the main goals of the Company's strategy is to seek partners - global pharmaceutical companies - for further stages of clinical trials and the final commercial implementation of therapies developed by the Company.

The therapies on which PolTREG is working are classified as the so-called cell therapies that involve the use of human cells and belong to the most advanced group of medicines, the so-called "Living medicines". They also include, for example, CAR-T therapies, i.e. immunotherapies with genetically modified T lymphocytes, or therapies with mesenchymal stem cells. Cell therapies are a very dynamically growing area of medicine, where a chances are seen to create effective, breakthrough, targeted therapies.

Regulatory T cells (TREGS) are a special population of cells of the immune system. Although they represent less than 1% of peripheral blood leukocytes, TREGS regulate the immune response, thanks to which the immune system copes quickly with infections and the body's own tissues remain protected from autoimmunity. TREGS play a role in many pathological and physiological processes in the human body, such as autoimmunity, chronic infections, allergies, interaction with the bacterial flora, organ transplantation, maternal-fetal tolerance, and anti-cancer response. Reduction of the number of TREGS or their malfunction are the basis for the occurrence of autoimmune diseases.

The solutions and technologies developed by the Company allow to increase the number of TREGS in a patient. The method consists in taking the patient's blood, isolating the TREGS from it, multiplying them in the laboratory and preparing them as a form of a medicines, and then administering the TREG preparation to the patient. In this field, the Company is a pioneer on a global scale - it has conducted the world's first administration of TREG in humans, and its

treatment with TREGS in type 1 diabetes in children and in multiple sclerosis is - according to the Company's knowledge - the most advanced in clinical development.

The Company's advisers in the IPO process are: IPOPEMA Securities S.A. as an Investment Company, cc group as an advisor to the Management Board and advisor in the field of investor relations and public relations, and Chabasiewicz, Kowalska and Partners Attorneys-at-law (Chabasiewicz, Kowalska i Partnerzy Radcowie Prawni) as a Legal Adviser.

More information about PolTREG S.A .:
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