



MARKET INSIGHT FORM

In relation to the execution of the project entitled "Cell therapy of prediabetes based on artificially multiplied regulatory lymphocytes CD4+CD25+CD127- and anti-CD20 antibody", co-financed from the national budget funds as part of the competitions organized by the Medical Research Agency, we would like to ask you for a quote for the planned order described below.

The aim of the Project is to carry out industrial research and development work aimed at conducting clinical trials and implementing a therapy for patients with type 1 diabetes on the market.

Order specification

- 1) Subject of the contract: acting as a Member of the Audit Monitoring Committee. The work will be carried out as part of task no. 2, the aim of which is to obtain preparations and placebo for clinical trials and to conduct a phase II clinical trial.
- 2) Number of people planned to be involved: 4.
- 3) Type of contract: civil-law contract (commission contract).
- 4) The monthly engagement for each contractor will be: max. 40 hrs
- 5) Work date: the works will be carried out in the period from the date of signing the contract to 24.11.2028, however, in the event of extending the implementation of the project referred to at the beginning, it is possible to extend the term of the contract by analogy. The planned date of conclusion of the agreement is I/II quarter of 2024.
- 6) The service will be performed remotely. The Contracting Authority anticipates that it may be necessary to meet in person, not more often than once a quarter.
- 7) Responsibilities of the Members of the Audit Monitoring Committee:
 - a) an evaluation of the collected data from one or more studies,
 - b) making recommendations to the sponsor for modifying, continuing or terminating the study,
 - c) a risk/benefit assessment to consider a possible reduction in safety with a possible increase in effectiveness,
 - d) making possible recommendations to the sponsor to improve the quality of the study,
 - e) to ensure the integrity and reliability of the ongoing study,
 - f) meeting as needed (and whenever SAEs are suspected) to assess the severity of adverse events and their relationship to therapy, and to discuss individual patient outcomes.
- 8) Conditions of participation in the procedure:
 - a) In terms of education:
 - education in the field of medical, biological or biotechnological sciences;
 - hold the qualifications of at least an independent researcher (habilitation in the field of medical, biological or biotechnological sciences) or the title of professor;
 - b) In terms of experience:
 - Proven experience in conducting clinical trials, a good understanding of the issues and limitations of clinical trials, and a proven track record in research in type 1 diabetes or autoimmunity attested to at least:
 - 10 experimental papers in the field in impacted peer-reviewed journals (at least in the Q2 range), or
 - 2 years of experience in leading a research team, or
 - 2 years of experience in managing scientific or clinical unit(s).



- 9) Along with the offer, the Contractor is obliged to submit:
- CV – a professional curriculum vitae containing at least information on education, professional experience and/or
 - other documents that attest to the requirements for candidates set out in this section.

10) 10) GDPR information clause:

In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), hereinafter referred to as "GDPR", pursuant to Article 13 of the GDPR, PolTREG S.A. with its registered office in Gdańsk (hereinafter referred to as "PolTREG") informs about the rules related to the processing of personal data by PolTREG and about your rights related to it.

- The administrator of your personal data is PolTREG S.A. with its registered office at 20 Botaniczna Street, 80-298 Gdańsk, entered into the Register of Entrepreneurs of the National Court Register kept by the District Court Gdańsk Północ in Gdańsk, VII Commercial Division of the National Court Register under KRS 0000637215, NIP 9571079577, REGON 361945318, with a share capital of PLN 466,344.80 fully paid.
- In matters concerning the manner and scope of processing of your personal data by the Administrator, as well as in matters related to your rights, you may contact the Administrator via the e-mail address: office@poltreg.com or in writing by sending a letter to the following address: PolTREG S.A., 20 Botaniczna Street, 80-298 Gdańsk.
- Your personal data will be processed for the purposes related to the conclusion and performance of the contract and on the basis of Article 6(1)(b) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). EU L 119, 04.05.2016, p.1).
- Your personal data may be made available to entities authorized to do so on the basis of separate regulations.
- Your personal data will be stored for the period necessary to achieve the purposes of processing, including until the expiry of the limitation period for the tax liability of 5 years and not shorter than the period indicated in the archiving regulations.
- Your personal data will not be subject to automated decision-making or profiling.
- Providing data is voluntary, but necessary to conclude a contract.
- You have the right to access your personal data and rectify them.
- You have the right to lodge a complaint in connection with the processing of the above-mentioned personal data to the President of the Office for Personal Data Protection, address: 2 Stawki Street, 00-193 Warsaw, if you find that the processing of personal data concerning you violates the provisions of the GDPR.
- You also have the right to delete or limit processing, the right to object to processing and the right to transfer data – however, taking into account the legal basis and purpose of processing indicated in paragraph 3, the administrator may not be able to meet the requests resulting from the rights set out in this paragraph.

11) CPV code: 73200000-4 – Research and development consultancy services.

12) The contact person is: Ewelina Bróskowska, e.broskowska@poltreg.com

13) Please sign the offer form and send a scan of it (in PDF format) to the following address: przetargi@poltreg.com by 23 February 2024.