REQUEST FOR QUOTATION no. 2/2024/G/RZ dated 29.11.2024r.

Application number KPOD.07.07-IW.07-0260/24

In connection with the planned implementation of the project entitled "Highly purified new generation GLP-1 analogue with reduced risk of immunogenicity" as part of the competition for entrepreneurs for the implementation of research in the area of drug safety, innovative therapies and medicines of the future (2024/ABM/05/KPO), recruitment: KPOD.07.07-IW.07-003/24, application number: KPOD.07.07-IW.07-0260/24.

CONTRACTING AUTHORITY:

Celon Pharma S.A.

Ogrodowa 2A,

05-092 Kielpin

VAT no.: 118-16-42-061

PARTIAL BIDS ACCEPTED: NO

ACCEPTANCE OF VARIANT OFFERS: NO

ORDER COMPLETION DATE: no later than 31.10.2025

I. ORDERING PROCEDURE:

- This order is not subject to the provisions of the Act of 11 September 2019. *Public Procurement Law*;
- This procurement is carried out in accordance with the principles of competitiveness, openness, transparency and equal access;
- The Contracting Authority reserves the right to cancel the procedure at any stage, without giving reasons;
- The Contracting Authority shall inform the Bidders and publish relevant information on the website of the Competitiveness Database in the event of changes to this request for proposal;
- The Contracting Authority reserves the right to ask the Bidders supplementary questions regarding additional information, documents or explanations;

- In justified cases, before the deadline for submission of tenders, the Contracting Authority reserves the right to modify or amend the content of the invitation to submit tenders;
- This invitation to submit tenders does not oblige the Contracting Authority to conclude a contract;
- Contracting Authority permits rejecting bids whose essential content clearly raises reasonable doubts.

II. DESCRIPTION OF THE SUBJECT OF THE REQUEST FOR QUOTATION

CPV code: 73300000-5; 98390000-3

Development of pen injector for GLP-1 analogue-based drug. Celon Pharma S.A. seeks qualified vendors to develop a multidose, pre-filled pen injector tailored for its generic GLP-1 drug. The initial phase includes customization, technical documentation, regulatory support, and delivery of devices for clinical readiness. Required scope of the work:

The scope of work encompasses the comprehensive development and customization of a state-of-the-art pen injector tailored for the administration of GLP-1, with the aim of supporting Celon Pharma's generic product pipeline. This project requires leveraging the pen platform, ensuring compliance with ISO 11608-3 standards for multidose delivery systems. The vendor will be responsible for adapting the platform to multiple specific configurations, each reflecting different drug concentrations and delivery mechanisms.

The development phase includes a detailed design and realization process, starting with technical adjustments to accommodate the specified cartridge dimensions and ensuring compatibility with GLP-1's formulation. The vendor must conduct design verification and validation activities, covering functionality, usability, and risk management processes. Usability engineering will involve compliance with IEC 62366 standards, addressing user-related risks and ensuring the final product meets safety and efficacy expectations in diverse patient settings.

Additionally, the project requires the preparation of regulatory documentation necessary for filing the pen injector as a combination product. This includes compiling design input documentation, producing

design verification reports, and preparing the technical file for regulatory submissions in target markets. The vendor must also provide support during the regulatory approval process and respond to potential post-submission inquiries.

The deliverables for this phase include the manufacture and supply of pre-assembled pen injector units for clinical testing **(1500 pieces)**. Defined amount of devices for ISO-compliant testing, will be required to validate the functionality and compatibility of the system. The vendor is expected to ensure timely delivery within 10 months from the project initiation, meeting all technical and quality standards.

The scope also involves coordination with Celon Pharma for the provision of drug cartridges and alignment on the final assembly process, which will be conducted at Celon's facility or a designated partner site. The vendor will provide technical guidance and documentation to facilitate this process, including recommendations for assembly equipment and operational procedures.
It must meet the technical and functional requirements specified in the description of the subject of the order (Att. 2) including transport and regulatory. The completed Att. 2 must be submitted together with the offer.

III. TERMS AND CONDITIONS OF PARTICIPATION IN THE REQUEST FOR QUOTATION

1. Bidders who confirm that they meet the conditions in **Att. 1, Att. 2 and Att. 3** are invited to submit a RfQ (**must be attached to the offer**);
2. The offer should also be accompanied by the "*Statement of lack of personal and capital ties with the Contracting Authority*", which is attached as **Att. 1** to the RfQ;
3. The Ordering Party requests the following declaration (**Att. 3**) confirming that:

   a) The Bidder has the necessary experience and capabilities to perform the subject of the order,

   b) The Bidder has the necessary technical infrastructure to perform the order referred to in this request for quotation,

   c) The financial and economic situation of the bidder enables the execution of the order.
4. **The schedule and scope of activities** must be submitted along with the offer.

IV. CRITERIA FOR THE SELECTION OF TENDERS

1. **Price (P) – 80 points (80%)**

Method of assessment:

Criterion	Weight (%)	Maximum number of points to be obtained	Method of evaluation according to the following formula
Price	80%	80 pts	$P = \frac{Price_{lowest}}{Price\ _{service}} \times 80\ points$ Where: $Price_{lowest}$ – the lowest price among quotes. $Price_{service}$ – price for the given tenderer.

2. **Unit price for pen-injector (P1) – 20 points (20%)**

Method of assessment:

Criterion	Weight (%)	Maximum number of points to be obtained	Method of evaluation according to the following formula
Unit price for pen-injector	20%	20 pts	$P1 = \frac{The\ lowest\ unit\ price\ for\ a\ pen-injector}{Unit\ price\ for\ the\ pen-injector\ of\ the\ considered\ offer} \times 20\ points$

The total number of points that a given offer will receive will be calculated according to the following formula:

L = P + P1

L – total number of points;

P – points obtained in the "Price" criterion;

P1 – points obtained in the " Unit price for pen-injector" criterion.

V. ADDRESS AND DEADLINE FOR SUBMISSION OF TENDERS

1. The offer should be submitted via the website of the Competitiveness Database https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/;
   Below is instruction how to add an offer:
   https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/pomoc/59-help-for-abroad-users-registration-pomoc-dla-uzytkownikow-zagranicznych-wersja-angielska

https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/pomoc/60-help-for-abroad-users-offers-pomoc-dla-uzytkownikow-zagranicznych-wersja-angielska

2. Withdrawal from the communication referred to in point 1 is permissible if:
   a) the nature of the order requires the use of tools, devices or file formats that are not supported with BK2021, or
   b) file format applications that are suitable for the preparation of bids or competition entries, use file formats that cannot be supported by any other open source or generally available applications, or are licensed and cannot be made available for download or remote use by the Contracting Authority, or
   c) the procurer requires the submission of a physical model, scale model or sample that cannot be provided via BK2021, or
   d) this is necessary due to the need to protect sensitive information, which cannot be sufficiently guaranteed by BK2021.

   In such cases, the offer with the required attachments should be submitted to the e-mail address paulina.gruszka@celonpharma.com.
3. The offer must be submitted no later than **06.12.2024.**;
4. Offers submitted after the deadline indicated above will not be considered;
5. Offers will be evaluated no later than **20.12.2024.**;
6. Offers submitted in foreign currency will be converted according to the exchange rate of the National Bank of Poland as of the date of publishing of the RfQ;
7. Information on the selection of offers will be published on the website of the https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ Competitiveness Database.

VI. PRESENTATION OF OFFERS

1. Each Bidder may submit only one offer in Polish or English;
2. The offer must include:
   - The number of the request for quotation
   - Date of preparation of the offer
   - The details of the Tenderer: address, telephone number, e-mail address, Tax Identification Number (NIP) (if available),
   - Include detailed information on the compliance of the proposed subject matter of the RFP with the specification,

- If the offer was submitted by the Bidder operating in Poland: net price, gross price and tax due,
- If the offer was submitted by the Bidder operating outside Polish: net price and information on the absence of VAT and other taxes.

3. The offer must remain valid until **January 31, 2025**;
4. The costs of preparing the offer shall be borne by the Tenderer;
5. **The due date of each invoice must be at least 30 days;**
6. **The offer must be signed by persons authorised to represent the Contractor/Supplier (according to the National Court Register or power of attorney).**

VII. CONCLUSION OF THE CONTRACT

The bidder, whose offer is assessed as the most advantageous, is obliged to conclude a contract with the Contracting Authority. If the Tenderer whose offer has been selected refuses to conclude the contract, the Contracting Authority has the right to select the next Tenderer whose offer was the most advantageous among the remaining offers.

Comments:

- Due to the necessity to maintain the continuity of research, the Contracting Authority provides for the possibility of placing a supplementary order in the amount not exceeding 50% of the contract value specified in the contract concluded with the selected Contractor/Supplier;
- The Contracting Authority allows for the possibility of cancelling the order or resigning from the order of goods and services included in the partial procedure or from the entire procedure, in the event of failure to obtain funds for the performance of this contract or in other cases when the performance of the order will not be in the interest of the Contracting Authority;
- Entities related to the Contracting Authority personally or by capital are excluded from participation in this procedure. Capital or personal ties shall be understood as mutual relations between the Contracting Authority or persons authorised to incur liabilities on behalf of the Contracting Authority or persons performing activities on behalf of the Contracting Authority related to the selection of the contractor and the contractor, consisting in particular of:
  a) participation in a company as a partner in a civil law partnership or a partnership,
  b) holding at least 10% of shares, unless the lower threshold results from the law or has not been determined by the MA PO,
  c) acting as a member of a supervisory or management body, proxy, proxy,
  d) being married, in a relationship of consanguinity or affinity in the direct line, in a relationship of the second degree or affinity in the collateral line of the second degree, or in a relationship of adoption, guardianship or guardianship.
- The Contracting Authority reserves the right to amend the contract concluded with the selected Tenderer as a result of the public procurement procedure for the following reasons:

a) justified changes in the manner in which the subject matter of the contract is performed,
b) objective reasons beyond the control of the Contracting Authority or the Tenderer,
c) changes in legal regulations in force on the date of signing the agreement,
d) Majeure
e) the occurrence of another obstacle beyond the control of the Tenderer, preventing the performance of the work,
f) in the event of introducing changes to the Subject of the Agreement exceeding the material and/or financial scope indicated in the Offer, the Parties undertake that such changes will be introduced on the basis of an appropriate annex.

- In connection with the entry into force of the Act of 13 April 2022 on Special Solutions for Counteracting Support for Aggression against Ukraine and for the Protection of National Security (Journal of Laws, item 835), entities or citizens from the Russian Federation subject to the sanctions specified in Article 1 of the above-mentioned Act are excluded from participation in this procedure, provided that they are on the list of persons and entities on the date of submission of the offer, against which sanctioning measures should be applied, maintained on the website of the Public Information Bulletin of the Minister of the Interior and Administration.