REQUEST FOR QUOTATION no. 17/2025/G/KONGO2

dated 16.07.2025r.

Application number KPOD.07.07-IW.07-0258/24

In connection with the planned implementation of the project entitled " Design, optimization of production and Preclinical Safety Assessment of a Novel Dual-Action Conjugate with Immunomodulatory and Cytotoxic Properties as a New Anticancer Drug Candidate" (recruitment KPOD.07.07-IW.07-003/24, application no. KPOD.07.07-IW.07-0258/24)co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers.

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 30 November 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.

II. DESCRIPTION OF THE SUBJECT OF THE REQUEST FOR QUOTATION

CPV: 73100000-3 – Research, experimental and development services

The Ordering Party hereby invites proposals for the subcontracted provision of R&D services for production of an enzyme: Y289L variant of **bovine β-1,4-galactosyltransferase 1** (**β4GalT1**). The enzyme will be used for an antibody modification and shall be delivered in purified form for further development and evaluation activities with documentation that will be provided for IND application.

The scope of the services includes gene synthesis, cell pool generation and screening, fed-batch evaluation, and scale-up production with appropriate quality control and documentation. The final product must meet specified purity and potency criteria and be produced using technologies that allow for future process scalability and potential GMP transferability.

The Ordering Party does not have the resources to complete the task. The detailed scope of work is specified in the table below.

Production, purification and characterization of the β4GalT1
The selected contractor shall be fully responsible for the execution of all stages of the project, covering molecular biology, cell line development, upstream processing, protein purification, and analytical characterization. The service is expected to be conducted in compliance with industry standards for reproducibility, traceability, and scalability, with consideration of downstream regulatory or commercial requirements. The selected contractor will be responsible for the full execution of the following milestones: **1. Project Initiation and Management** The selected subcontractor will manage the project using a multidisciplinary team operating under the supervision of this Project Manage, responsible for overall coordination, execution, and communication. A formal joint kick-off meeting will be conducted to initiate the project, during which essential documentation will be transferred, quality attributes defined, and the detailed work plan finalized. An integrated project schedule outlining all key milestones and deliverables will be developed and maintained throughout the project duration. Regular progress updates will be provided, and all Joint Project Team (JPT) meetings will be documented to ensure alignment, transparency, and effective collaboration. **2. Gene Optimization, Synthesis and Plasmid** The contractor will perform codon-optimized gene synthesis for the bovine β4GalT1 (Y289L), respectively, ensuring compatibility with CHO expression system. Following synthesis, the gene will be

cloned into a proprietary expression vector compatible with the glutamine synthetase (GS) selection system. Plasmid constructs validation (e.g., restriction analysis, sequencing) will be conducted to confirm integrity prior to transfection.

Timeline: max. 3 weeks

Deliverables:

- A detailed development report covering gene synthesis, optimization and plasmid construction, including maps and sequence data

3. Stable Cell Pool Development, Screening and Cryopreservation (CHO GS System)

Stable transfection of CHO-K1-derived host cells will be carried out using the GS selection system. The contractor will conduct expression screening of the generated cell pools under standardized culture conditions. The screening process will involve an initial selection phase to identify stable cell populations exhibiting constitutive expression of the target enzyme. Quantitative assessment of expression levels, utilizing methods such as SDS-PAGE, ELISA, or Western blot, will be performed to evaluate both enzyme yield and cell growth performance. Based on these data, the highest-expressing and most robust pools will be selected for further development.

Timeline: max. 5 weeks

Deliverables:

- Technical report summarizing transfection procedure, selection strategy, expression screening methodology and data, including quantitative results from SDS-PAGE, ELISA, or Western blot analyses
- At least three (3) cryovials of stable cell pools (1 ml per vial, at a density of 1.0×10^7 viable cells/ml, each) with respective Certificate of Analysis (CoA) or equivalent documentation confirming viability, identity, and absence of mycoplasma contamination

4. Fed-Batch Evaluation

Small-scale fed-batch cultures will be conducted to evaluate the performance of the selected stable cell pools under production conditions. This includes testing of growth kinetics, viability, and specific productivity across the culture duration. Collected data will be analysed to inform process scalability, identify potential bottlenecks, and optimize future production parameters.

Timeline: max. 3 weeks

Deliverables:

Comprehensive data package on clone performance, productivity, and growth, summarizing fed-batch performance metrics and providing technical recommendations for scale-up

5. Protein Production and Purification

The contractor shall perform scale-up fed-batch bioreactor production runs using the previously selected high-expressing CHO-K1-derived stable cell pools to obtain production-scale quantities of the recombinant enzyme β4GalT1 (Y289L). Following harvest, a one or two-step purification process will

be implemented. The purification strategy shall prioritize scalability, regulatory compliance, and consistent batch-to-batch performance. Acceptable techniques include ion-exchange chromatography (IEX), hydrophobic interaction chromatography (HIC), or other industry-standard, scalable methods. Affinity-based methods, such as Ni-NTA IMAC, shall be deemed acceptable only upon the Subcontractor's declaration and provision of a certificate confirming either non-detectable or acceptably low residual levels of nickel (Ni).

The purified enzyme shall be formulated in a mutually agreed buffer system (e.g., PBS or other suitable formulation buffer) and subjected to full quality control testing prior to batch release. Quality control will include endotoxin quantification using a validated method such as the Limulus Amebocyte Lysate (LAL) assay. The final product must meet a strict endotoxin limit of <1 EU/mg protein, consistent with specifications for critical raw materials used in preclinical research.

Timeline: max. 6-7 weeks

Deliverables:

- A minimum of 4 grams of purified β4GalT1 (Y289L) enzyme
- Certificate of Analysis (CoA) or equivalent release documentation, detailing yield, purity, and analytical methods used
- Endotoxin test report, including assay methodology, measured levels, and confirmation of compliance with acceptance criteria

6. Analytical characterization (QC) and activity assessment

The Contractor shall perform comprehensive analytical quality control (QC) and enzymatic activity assays to confirm the identity, purity, and functionality of the produced β4GalT1 Y289L. All methods must be conducted in accordance with industry standards and be suitable for regulatory submission in future preclinical or clinical applications. The following analyses are required:

- **Determination of protein concentration and purity**, using UV absorbance at 280 nm or a comparable validated method.
- **SDS-PAGE** under both reducing and non-reducing conditions to assess protein integrity, purity, and potential aggregation.
- **Size exclusion chromatography (SEC)** using HPLC or UPLC to evaluate monomeric content, aggregation profile, and overall molecular size distribution.
- **Capillary electrophoresis (CE-SDS)** for high-resolution assessment of molecular homogeneity and potential degradation products.

Functional assays shall be performed to evaluate enzymatic activity, using validated methods suitable for each enzyme:

- **β4GalT1 (Y289L)**: Galactosylation assay employing UDP-Galactose as donor substrate and an appropriate acceptor (e.g., N-acetylglucosamine or glycan structures), with quantification by fluorescence, HPLC, or LC-MS.

Timeline: max. 2 weeks

Deliverables:

- Analytical QC report for each enzyme, including data on protein concentration, purity, and molecular homogeneity, accompanied by raw data files (e.g., chromatograms, gel images, assay readouts).
- Bioactivity report detailing assay parameters, results, and conclusions regarding enzymatic potency.
- Certificates of Analysis (CoA) for each batch, summarizing key specifications, assay methodologies, and notes on regulatory applicability.

Additional:

1. Commercial license
   Commercial license fee will not be applied if production of the material will be carried by subcontractor.

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

The offer should also be accompanied by the "*Statement of lack of personal and capital ties with the Contracting Authority*", which is attached as Appendix 1 to this RFQ.

IV. CRITERIA FOR THE SELECTION OF TENDERS

Method of assessment:

Criterion	Weight (%)	Maximum number of points to be obtained	Method of evaluation according to the following formula
Price (P)	80%	80 pts	$P = \frac{Lowest\ quoted\ price}{Quoted\ price}\ x\ 80\ points$
Time (T)	20%	20 pts	$T = \frac{Shortest\ study\ completion\ time}{Offered\ study\ completion\ time}\ x\ 20\ points$

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

L = P+T

L – total number of points;

C – points obtained in the "Price" criterion.

T – points obtained in the "Time" 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

   https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/pomoc/61-help-for-abroad-users-asking-questions-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 **23.07.2025.**;
4. Offers submitted after the deadline indicated above will not be considered;
5. Offers will be evaluated no later than **08.08.2025.**;
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 settlement of the inquiry;
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
   - Date of completion order/service
   - 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 RFQ 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 August 29, 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. PROHIBITION OF CONFLICT OF INTEREST

A conflict of interest is inadmissible, therefore the Bidder is obliged to sign a declaration (Annex 1) on the absence or absence of influence of personal or capital links with the Ordering Party on the impartiality of the proceedings consisting of:

a) participating in a company as a partner in a civil partnership or a partnership, holding at least 10% of shares (unless a lower threshold results from legal provisions), performing the function of a member of the supervisory or management body, proxy, attorney,

b) b) being in a marital relationship, in a relationship of kinship or affinity in a direct line, kinship or affinity in a collateral line up to the second degree, or being related by adoption, care or guardianship or being in cohabitation with the Ordering Party, its legal representative or members of the management or supervisory bodies of the contractors applying for the award of the contract;

c) being in such a legal or factual relationship with the Ordering Party that there is a justified doubt as to their impartiality or independence in connection with the procedure for awarding the contract

A conflict of interest means any situation in which persons involved in the preparation or conduct of a procurement procedure or who may influence the outcome of that procedure have, directly or indirectly, a financial, economic or other personal interest that may be perceived as compromising their impartiality and independence in connection with the procurement procedure.

VIII. 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.

IX. CONTRACTUAL PENALTIES

The Tenderer shall pay the Contracting Authority the following contractual penalties:

- for delay in the delivery date of the subject of the contract, for each commenced day of delay, unless the delay is due to the fault of the Contracting Authority,
- in the event that the results of studies conducted with an equivalent product are not in line with expectations,
- the supplier agrees to deduct the amount of contractual penalties directly upon payment of the VAT invoice for the delivery.

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 allows for the possibility of negotiating the presented offer;
- 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.