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Warsaw, February 26, 2025

REQUEST FOR QUOTATION No. 1/FENG-GBM2/2025

In connection with applying for co-financing of the project “Development and clinical trials of innovative allogeneic macrophage immunotherapy for glioma” from the European Union funds under The European Funds for Smart Economy 2021-2027, operation: SMART Path, Cellis Sp. z o. o. announces an invitation to submit offers for:

Production of macrophages for phase I and II clinical trials.

1. ORDERING PARTY

Cellis Sp. z o. o. [Ltd.]
ul. Generała Zajączka 26
01-510 Warsaw, Poland
VAT EU: PL5252640606

2. THE SUBJECT OF THE ORDER:

2.1 The subject of the order is:

Production of macrophages for phase I and II clinical trials.

2.2 The above-mentioned order consist of:

Isolation of monocytes from mobilized fresh leukopak, 7-days macrophage culture, macrophages loading with ferritin-drug complex provided by the Ordering Party in order to produce the final product MDC-735, filling and aliquoting of the product into appropriate vials and preparation of the product for shipment – max. 13 production batches.

The scope of the order also includes - performance of material analytics during the process and analytics for the final product. Analytics should be performed using verified/qualified methods, compliant with the Pharmacopoeia.

Product analytics (i.e. conducting its qualification in accordance with the methods established by the Ordering Party, compliant with the Pharmacopoeia) is necessary for production batch release tests.



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The final release of the material to the clinic (approved by a qualified person) will be carried out by the Contractor (QP services – "Quality Person" – a person responsible for the product quality).

All above-mentioned stages of the order should be carried out in accordance with GMP standards.

- Production will be carried out in accordance with the approved batch record.
- The Contractor must have a laboratory adapted to work with cytotoxic substances.
- Individual stages of production or analysis must be covered by the document quality management system, be performed in accordance with the approved procedures, SOPs or in accordance with the Pharmacopoeia.
- Vial inspection will be carried out in accordance with the Contractor's SOP.
- The Contractor will be obliged to sign a quality agreement with the Ordering Party before starting the process.
- Together with the production batch, the Contractor shall provide the Ordering Party with a Certificate of Analysis (CoA), Certificate of Conformity (CoC), executed batch records, analytical results and any other documents related to production (e.g. variance report, etc.).

The Ordering Party informs that **the process of technology transfer from laboratory scale to GMP scale has already been developed and the appropriate analytical methods have been qualified.**

Production of macrophages will be carried out based on protocols established by the Ordering Party, in accordance with the requirements for Phase I/II clinical trials, the European Medicines Agency (EMA) and the Food and Drug Administration (FDA).

The cost of the leukopacks necessary to complete the order and its delivery to the Contractor will be covered by the Ordering Party **and is not included in the scope of this request for quotation.**

The ferritin-drug complex (produced by a separate CDMO) will be delivered to the Contractor by the Ordering Party via a dedicated courier **at the expense of the Ordering Party.**



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The Contractor shall be obliged to plan the supply of reagents and consumables so that they are available to the Contractor on time for the execution of the order. **The costs of the aforementioned reagents and materials shall be covered by the Ordering Party.**

The equipment necessary to complete the order (i.e. CliniMACS Prodigy, plate reader, cell counter, flow cytometer, laminar chamber, incubator, shakers, centrifuges) **should be provided by the Contractor and qualified for use in GMP standards**, including the **CliniMACS Prodigy device dedicated exclusively to the Ordering Party's project**. The Ordering Party shall provide software adapted to the project in the GMP standard for CliniMACS Prodigy.

Planned start date of the order: May 2025.

The Ordering Party reserves the right to execute the order in any part, and the Contractor shall not be entitled to any claims in this respect.

2.3. The subject of the order specified in point 2.1 shall be performed no later than December 31, 2029.

2.4 Under this invitation to tender Ordering Party does not allow partial receipt of tenders or variant offers.

2.5 CPV code:

73100000-3 Research and experimental development services

3. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS

3.1 Contractors participating in the proceedings must fulfil following conditions:

- 1) must have the necessary knowledge and experience, including documented experience in the production of cell preparations in accordance with the GMP standard confirmed by participation in at least seven projects/orders in the last five years;
- 2) must have technical potential, including a GMP cell culture laboratory equipped with the equipment for cell isolation from leukopak, and culture them, including CliniMACS Prodigy, laminar flow hood and incubator, a laboratory adapted to work with cytotoxic substances, an analytic and quality control department with all the necessary analytical equipment, including a flow cytometer, cell counter, plate reader;



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- 3) must have technical potential in the form of a clean room for the production and portioning of GMP material in sterile conditions and equipment - tanks for storing the material in liquid nitrogen;
- 4) must have a list of qualified suppliers and subcontractors;
- 5) must have staff potential specialized in the production of cell preparations in accordance with the GMP standard and a staff of quality control specialists (along with a GMP documentation management system);
- 6) must have staff potential specialized in project management, including an available project manager who will be dedicated to the Ordering Party's project;
- 7) must be in an economic and financial situation that ensures timely execution of the order and in accordance with the requirements set out in the request for quotation.

The statement about fulfilling conditions for participation in the proceeding is attached as Appendix 2 to this request for quotation 1/FENG-GBM2/2025.

3.2 The Contractor may not be personally, or equity related to the Ordering Party.

In order to avoid conflicts of interest, orders cannot be awarded to entities connected with the Ordering Party personally or by capital. Personal or capital connections consist of:

- a) participating in a company as a partner in a civil partnership or a partnership, holding at least 10% of shares or stocks (unless a lower threshold results from legal regulations), performing the function of a member of a supervisory or management body, proxy, attorney,
- b) being in a marital relationship, in a relationship of consanguinity or affinity in a direct line, consanguinity or affinity in a collateral line up to the second degree, or in a relationship due to adoption, care or guardianship or being in cohabitation with the contractor, his legal representative or members of the management bodies or supervisory bodies of the contractors applying for the contract award,
- c) being in such a legal or factual relationship with the Contractor that there is a reasonable doubt as to their impartiality or independence in connection with the contract award procedure.

The Bidder is obliged to submit a relevant statement contained in Annex 3 to the Request for Quotation 1/FENG-GBM2/2025.

3.3 The Ordering Party will assess compliance with the conditions for participation in the proceeding based on the information from Bidder contained in the Bid form and Annexes. Assessment of compliance with the requirement will be made by the method meets / does not meet.



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3.4 The Ordering Party before signing the Agreement reserves the right to verification statements of the Bidder (meets / does not meet) about conditions for participation in the proceedings based on the documents confirming the Bidder's statements.

3.5 For the proceeding only offers that meet all the conditions for participation in the proceedings will be allowed.

4. PREPARATION AND SUBMISSION OF OFFERS

4.1 Each Bidder may submit only one offer.

4.2 Offer should be prepared in the bid form (Appendix 1 to the request for quotation 1/FENG-GBM2/2025). The offer must be initialled and signed by the authorised representative of the Bidder. If the offer would be signed by the person not listed in registered documents of the Contractor, the offer shall be accompanied by the appropriate power of attorney.

4.3 Contractor must submit with the offer copy (scan) of relevant Register of Business Activity, applicable to country of residence of Contractor, to demonstrate the absence of grounds for exclusion.

4.4 The offer must be submitted by March 28, 2025 (11:59 p.m.).

4.5 The offer must be submitted via website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>

4.6 Offers received after deadline or incomplete will not be considered.

4.7 The offer should include the validity date (at least 60 days from the submission deadline).

4.8 Submitting the tender means acceptance of the conditions stated therein.

4.9 The Bidder may request the Ordering Party to clarify the content of the request for quotation. Inquiries can be submitted on the website: <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>. The awarding entity shall answer questions that have been received no later than by the end of half of the deadline for submission of tenders, except that the answer should be given at least 2 (two) days before the submission deadline. Answers to questions will be published on the website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>.

5. OFFER EVALUATION CRITERIA

5.1 The Ordering Party will evaluate offer based on the following criteria:

Methods of assessment – according to the formula below:

$$P_i = P_i(C) + P_i(T)$$

where:



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Pi – the amount of points received

Pi(C) – points for the „Price” criterium

P(T) – points for the “Time of service completion” criterium

- Criterium „Price” – weight 80%

„Price” criterium will be calculated as follows:

$$Pi(C) = (Cmin : Ci) \times 80$$

where:

Pi(C) – the number of points given for the „Price” criterium

Cmin – the lowest price among all valid and non-rejected offers

Ci – the price of the currently evaluated offer

In the “Price” criterium Bidder may obtain 80 points.

- Criterium “Time of service completion” – weight 20%

„Time of service completion” criterium should be understood as the maximum time required to produce one production batch of the MDC-735 product together with the provision of a certificate of analysis (CoA), counted from the date of placing the order by the Ordering Party, and will be assessed as follows:

3 months and under – 20 points,

Over 3 months – 0 points.

5.2 All calculations will be made to two decimal places.

5.3 The most advantageous offer will be considered the one which obtains the highest number of points.

5.4 The Ordering Party reserves the right to ask the Bidder about the content of submitted bids, including to supplement missing powers of attorney, statements or documents indicated in the request for quotation (except for the extent to which they are subject to evaluation in the bid evaluation criteria).

6. ORDER COMPLETION DATE: 56 months.



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7. NOTICE OF SELECTION OF THE BEST TENDER

Information of the results of the proceedings will be published on the website

<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>.

8. CONDITIONS FOR CHANGING THE AGREEMENT

8.1 All modification to the agreement, which will be concluded as a result of the proceeding, must be in writing under pain of nullity.

8.2 It is not possible to make significant changes to the provisions of the concluded agreement regarding the content of the offer on the basis of which the contractor was selected, unless:

- a) the changes were provided for in the request for quotation in the form of clear contractual provisions that define their scope and nature and the conditions for introducing the changes,
- b) the changes concern the implementation of additional supplies, services or construction works from the current contractor, not covered by the basic order, provided that they have become necessary and the following conditions have been met:
 - i) the change of contractor cannot be made for economic or technical reasons, in particular concerning the interchangeability or interoperability of equipment, services or installations ordered under the basic contract,
 - ii) the change of contractor would cause significant inconvenience or a significant increase in costs for the ordering party,
 - iii) the value of the changes does not exceed 50% of the order value originally specified in the agreement,
- c) the change does not lead to a change in the general nature of the agreement and the following conditions have been met:
 - i) the need to change the agreement is caused by circumstances that the ordering party, acting with due diligence, could not have foreseen,
 - ii) the value of the changes does not exceed 50% of the order value originally specified in the agreement,
- d) the contractor to whom the contracting authority awarded the contract is to be replaced by a new contractor:
 - i) as a result of succession, assuming the rights and obligations of the contractor, as a result of takeover, merger, division, transformation, bankruptcy, restructuring, inheritance or



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acquisition of the previous contractor or its enterprise, provided that the new contractor meets the conditions for participation in the procedure and does not entail other significant changes to the agreement, and is not aimed at avoiding the application of the principle of competition, or

- ii) as a result of the ordering party taking over the contractor's obligations towards its subcontractors - in the event of a change of subcontractor, the ordering party may conclude an agreement with a new subcontractor without changing the terms of the order, taking into account payments made for work performed to date,

- e) the change does not lead to a change in the general nature of the agreement, and the total value of the changes is less than EUR 5,382,000 in the case of construction works and EUR 140,000 in the case of supplies and services and at the same time is less than 10% of the value of the order originally specified in the agreement in the case of orders for services or supplies or, in the case of orders for construction works, is less than 15% of the value of the order originally specified in the agreement.

An amendment to a procurement agreement is significant if it causes the nature of the agreement to change significantly in relation to the original agreement, in particular if the amendment: introduces conditions which, if they had been applied in the procurement procedure, other contractors would or could have participated in it or offers of different content would have been accepted; disturbs the economic balance of the parties to the agreement to the benefit of the contractor in a manner not provided for in the original agreement; significantly extends or reduces the scope of services and obligations arising from the agreement; consists in replacing the contractor to whom the ordering party has awarded the contract with a new contractor in cases other than those indicated in letter d.

9. ADDITIONAL INFORMATION

9.2 The Ordering Party reserves the right to cancel this procedure at any stage, without providing reasons.

9.3 This request for quotation does not oblige Cellis Sp. z o.o. [Ltd.] to conclude an agreement.

10. CONTACT

Cellis Sp. z o.o. [Ltd.]

ul. Generała Zajęczka 26

01-510 Warsaw, Poland

Contact person: Małgorzata Sęktas



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11. GDPR INFORMATION CLAUSE

Pursuant to Art. 13 sec. 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals regarding the processing of personal data and on the free movement of such data (Journal of Laws UE L 119 of 04/05/2016, p. 1), hereinafter referred to as "GDPR", it is hereby informed that:

- The administrator of your personal data is: Cellis Sp. z o.o. with its seat in Warsaw at gen. Jozefa Zajaczka 26, 01-510 Warsaw, Poland.
- In all matters related to the protection of personal data please contact the Data Protection Inspector appointed by the administrator. Such contact may take place via e-mail to the following e-mail address: daneosobowe@cellis.eu or in writing to the address of the administrator's registered office.
- Your personal data will be processed on the basis of art. 6 lit. b and c of GDPR for the purposes related to the contract award procedure conducted in the competition principle procedure.
- The recipients of your personal data will be persons or entities to whom the documentation of the procedure will be made available (including the Polish Agency for Enterprise Development PARP, ul. Pańska 81/83, 00-834 Warsaw) and other entities authorized under general provisions.
- Your personal data will be processed based on legal regulations, for the period necessary to achieve the purposes of processing, i.e., 10 years from the date of project completion.
- Your personal data may be transferred to entities processing personal data at the request of the administrator, among others IT service provider: NETLAB Paweł Majewski, where such entities process data based on a contract with the administrator and only in accordance with the administrator's instructions.
- Regarding your personal data, decisions will not be made in an automated manner.
- You have the right to request the Administrator to access personal data, rectify it, delete, or limit data processing, data transfer and the right to withdraw consent.
- If you believe that we are processing your personal data contrary to the provisions of the law, you have the right to lodge a complaint with the supervisory body dealing with the protection of personal data, i.e., the President of the Personal Data Protection Office.



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Appendices:

Appendix 1 Bid form

Appendix 2 Statement on the compliance with conditions for participation in the proceedings

Appendix 3 Statement concerning personal / capital connections between the Bidder and the Ordering Party.



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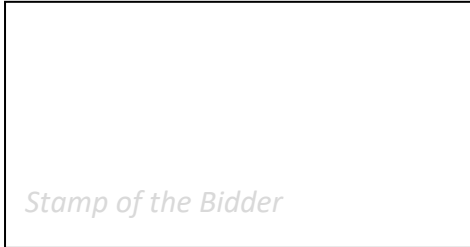


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Appendix 1 BID FORM for request for request for quotation no. 1/FENG-GBM2/2025



Name _____

Address _____

Phone no. _____

Tax Number _____

Contact person: _____

e-mail: _____

Ordering Party:

Cellis Sp. z o.o.

Generała Zajęczka 26

01-510 Warsaw, Poland

VAT EU: PL5252640606

In response to the Request for Proposal No. 1/FENG-GBM2/2025 regarding the project „Development and clinical trials of innovative allogeneic macrophage immunotherapy for glioma” applying for co-financing from European Union funds under The European Funds for Smart Economy 2021-2027, operation: SMART Path, I submit an offer of the following content:

I offer a net price _____ PLN / USD / EUR / OTHER.....*

(in words _____ PLN / USD / EUR / OTHER.....)

and gross price _____ PLN/ USD/ EUR/ OTHER

(in words _____ PLN / USD / EUR / OTHER....)

* Confirm by ticking or adding relevant information



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1. Detailed calculation of the cost:

Stage No.	Description	Maximum number of production batches [PLN/ USD/ EUR/ OTHER]	Net price per production batch [PLN/ USD/ EUR/ OTHER]	Net amount [PLN/ USD/ EUR/ OTHER]	Gross amount [PLN/ USD/ EUR/ OTHER]
1.	<p>Production of macrophages for phase I and II clinical trials: Isolation of monocytes from mobilized fresh leukopak, 7-days macrophage culture, macrophages loading with ferritin-drug complex provided by the Ordering Party in order to produce the final product MDC-735, filling and aliquoting of the product into appropriate vials and preparation of the product for shipment – max. 13 production batches. Performance of material analytics during the process and analytics for the final product. Analytics performed using verified/qualified methods, compliant with the Pharmacopoeia.</p> <p>The Contractor will perform the final release of the material to the clinic approved by a qualified person.</p>	13			
TOTAL		X	X		



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2. The Bidder declares that the term of service completion, understood as the maximum time required to produce one batch of the MDC-735 product, counted from the date of placing an order by the Ordering Party, is _____ months.
3. The Bidder declares that all costs of the completion the order have been included in the price.
4. The Bidder declares that the offer will be valid for 60 days from the deadline for submission.
5. The Bidder declares that is familiar with Request for quotation, accept the conditions stated therein and does not raise any objection to completion the order in accordance with these conditions.

Date and place

Signature of the Bidder /
Person authorized to act on behalf of the Bidder



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Appendix 2 STATEMENT ON THE COMPLIANCE WITH CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS for Request for quotation no. 1/FENG-GBM2/2025

Bidder

(name and address of the Bidder)

1. The Bidder declares to:

Statement	YES/NO
a) having the necessary knowledge and experience, including documented experience in the production of cell preparation in accordance with the GMP standard confirmed by participation in at least seven projects/orders in the last five years.	
b) having the necessary technical potential, including:	
- GMP cell culture laboratory equipped with the necessary equipment for cell isolation from leukopaks and cell culture, including CliniMACS Prodigy, laminar flow cabinet and incubator;	
- laboratory adapted to work with cytotoxic substances;	
- Analytics and Quality Control department with all necessary analytical equipment, including flow cytometer, cell counter, plate reader;	
- clean room for the production and portioning of GMP material in sterile conditions and equipment - tanks for storing the material in liquid nitrogen;	
c) having a list of qualified suppliers and subcontractors.	
d) having the staff potential specialized in the production of cell preparations in the GMP standard and a staff of quality control specialists (including the GMP documentation management system).	
e) having the staff potential specialized in project management, including an available project manager who will be dedicated to the Ordering Party's project.	



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2. The Bidder declares that is in an economic and financial situation that ensures the execution of the order within the time specified in the request for quotation no. 1/FENG-GBM2/2025.
3. The Bidder declares its readiness to comply with the Ordering Party's production protocols and national and European legal and regulatory conditions.
4. The Bidder declares that the data contained in the offer are true and adequate.

Date and place

Signature of the Bidder /
Person authorized to act on behalf of the Bidder



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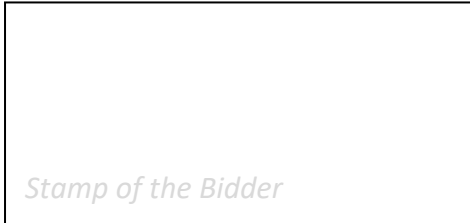
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**Appendix 3 STATEMENT CONCERNING PERSONAL / CAPITAL CONNECTIONS BETWEEN THE BIDDER
AND THE ORDERING PARTY for request for quotation no. 1/FENG-GBM2/2025**

(Place) _____, date _____



Statement concerning personal / capital connections between the Bidder and the Ordering Party

I, undersigned _____ declare, that:

have not any personal or capital connections with the Ordering Party

In order to avoid conflicts of interest, orders cannot be awarded to entities linked to the Ordering Party personally or by capital. Personal or capital connections consist of:

- a) participating in a company as a partner in a civil partnership or a partnership, holding at least 10% of shares or stocks (unless a lower threshold results from legal regulations), performing the function of a member of a supervisory or management body, proxy, attorney,
- b) being in a marital relationship, in a relationship of consanguinity or affinity in a direct line, consanguinity or affinity in a collateral line up to the second degree, or in a relationship due to adoption, care or guardianship or being in cohabitation with the contractor, his legal representative or members of the management bodies or supervisory bodies of the contractors applying for the contract award,
- c) being in such a legal or factual relationship with the Contractor that there is a reasonable doubt as to their impartiality or independence in connection with the contract award procedure.

Place and date

Signature of the Bidder /
Person authorized to act on behalf of the Bidder