

Warsaw, November 4, 2024

REQUEST FOR QUOTATION No. 1/ABM/2024

In connection with the implementation of the project „Preparation of the technology for clinical trials of the innovative MDC-735 cell based therapy” (call for applications No. KPOD.07.07-IW.07-003/24) Cellis Ltd. request to submit price quotation for:

Regulatory advice regarding regulatory aspects.

1. ORDERING PARTY

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

2. DESCRIPTION OF THE ORDER:

2.1 The subject of the order:

Regulatory advise on drug manufacturing (CMC) and clinical trials for Phase I in Europe and the United States and Phase II in the United States.

2.2 The above mentioned order consist of:

2.2.1 Regulatory advice on manufacturing (CMC) of the drug MDC-735, including ongoing consultation on the preparation manufacturing process in accordance with the GMP standard and documentation compliance with the requirements for biotechnological preparations set by regulators (for a maximum period of 15 months);

2.2.2 Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for Phase I clinical trials in Europe (Poland, Germany, Switzerland), including advice and ongoing consultation on the compliance of documentation with the requirements for biotechnological preparations set by the regulator(s) (for a maximum period of 6 months);

2.2.3 Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for phase I and II clinical trials in the USA (two different administrations of the preparation: intraperitoneal in phase I, intratumoral in phase II), including advice and ongoing consultation

on the compliance of the documentation with the requirements for biotechnological preparations set by the regulator(s) (for a maximum period of 15 months).

The Ordering Party informs that the MDC-735 product is macrophages loaded with a complex ferritin - active substance (ATMP classification assigned by EMA) and is manufactured in three (3) CDMOs.

2.3 The subject of the order shall be completed by 31.03.2026 at the latest.

2.4 Under this invitation to submit offers Ordering Party does not allow partial offers or variant offers.

2.5 CPV code:

73200000-4 Research and development consulting services

3. CONDITIONS FOR PARTICIPATION IN THE PROCEEDING

3.1 Contractors participating in the proceeding must fulfil following conditions:

- 1) must be in a business and financial situation that ensure timely and requirement compliant performance of the contract;
- 2) must have the necessary specialist knowledge and all the necessary support and qualified personnel;
- 3) must have a minimum of 15 years of experience in the international biotechnology market in the field of regulatory advice regarding cell therapies and the preparation of product documentation from a regulatory perspective in order to obtain approval for the product's admission to phase I and phase II clinical trials in Europe and the USA.

The statement about fulfilling conditions for participation in the proceedings is attached as Appendix 2 to this Request for Quotation no. 1/ABM/2024.

3.2 The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the Agreement could be compromised for conflict of interests. The Contractor may not be personally or equity related to the Ordering Party (prohibition of conflict of interest).

Equity or personal relationship is understood as relations between the Ordering Party and the Contractor, including in particular:

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

e) being in cohabitation with the contractor, his legal representative or members of the management or supervisory bodies of the contractors applying for the award of the contract,

f) being in such a legal or factual relationship with the contractor that there is a justified 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 no. 1/ABM/2024.

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.

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 no. 1/ABM/2024). 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 December 5, 2024 (23:59).

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

4.6 The offer should be valid at least 60 days from the submission deadline (point 4.4).

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

4.8 The Bidder may request the Ordering Party to clarify the content of the request for quotation. Inquiries can be submitted on the website: <https://bazakonkurencyjnoscifunduszeuropejskie.gov.pl/>. The Ordering Party 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://bazakonkurencyjnoscifunduszeuropejskie.gov.pl/>.

5. OFFER EVALUATION CRITERIA

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

Methods of assessment – according to the formula below:

$$P_i = P_i(C)$$

where:

P_i – the amount of points received

$P_i(C)$ – points for the „Price” criterium

- Criterium „Price” – weight 100%

„Price” criterium will be calculated as follows:

$$P_i(C) = (C_{min} : C_i) \times 100$$

where:

$P_i(C)$ – the amount of points given for the „Price” criterium

C_{min} – the lowest price among all valid and non-rejected offers

C_i – the price of the currently evaluated offer

In the “Price” criterium Bidder may obtain 100 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:

The subject of the order must be completed by 31.03.2026 at the latest.

7. NOTICE OF SELECTION OF THE BEST TENDER

The Bidder will be notified by e-mail (to e-mail address indicated in the bid form). Additionally, information on the results of the procedure will be placed in the competitiveness database, i.e.

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

8. CHANGES IN 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 interchange ability 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 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 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.

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.

8.3 The Ordering Party allows for a change to the contract in the form of an annex in a situation where a statutory change in the VAT rate occurs.

9. ADDITIONAL INFORMATION

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

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

9.3 The Ordering Party reserves the right to perform the contract in any part, and the Contractor will not make any claims in this respect.

10. CONTACT

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

ul. Generała Zajączka 26

01-510 Warsaw, Poland

Contact person: Małgorzata Sęktas, e-mail office@cellis.eu.

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 with regard to 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 with 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 (i.a. Medical Research Agency, ul. Chmielna 69, 00-801 Warsaw) and other entities authorized under general provisions.
- Your personal data will be processed on the basis of 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 on the basis of a contract with the administrator and only in accordance with the administrator's instructions.
- With regard to 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.

Appendices:

Appendix 1 Bid form.

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

Appendix 3 Statement concerning conflict of interest between the Bidder and the Ordering Party.

Appendix 1 BID FORM for Request for Quotation No. 1/ABM/2024

Stamp of the Bidder

Name _____
Address _____
Phone no. _____
tax/registration no. _____
Contact person: _____
e-mail: _____

Ordering Party:

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

According to the Request for Quotation no. 1/ABM/2024 as a part of the applied for founding project „Preparation of the technology for clinical trials of the innovative MDC-735 cell based therapy” financed by European Union under measures of the National Recovery and Resilience Plan, I submit tender:

I offer a maximum net price per hour _____ PLN / USD / EUR
/ OTHER.....* and maximum gross price (with tax) per hour _____ PLN / USD / EUR /
OTHER.....*

1. Detailed calculation of the cost:

Task	Description of task	The maximum number of hours	Maximum cost of providing the task (net price)
Regulatory advice on drug manufacturing (CMC) and clinical trials for Phase I in Europe and the United States and Phase II in the United States.	1. Regulatory advice on manufacturing (CMC) of the drug MDC-735, including ongoing consultation on the preparation manufacturing process in accordance with the GMP standard and documentation compliance with the requirements for biotechnological preparations set by regulators (for a maximum period of 15 months)	252	
	2. Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for Phase I clinical trials in Europe (Poland, Germany, Switzerland), including advice and ongoing consultation on the compliance of documentation with the requirements for biotechnological preparations set by the regulator (for a maximum period of 6 months)	125	
	3. Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for phase I and II clinical trials in the USA (two different administrations of the preparation: intraperitoneal in phase I, intratumoral in phase II), including advice and ongoing consultation on the compliance of the documentation with the requirements for biotechnological preparations set by the regulator (for a maximum period of 15 months).	120	
	Total		

2. The Bidder declares that the order completion deadline for individual tasks is:

- a) Regulatory advice on manufacturing (CMC) of the drug MDC-735, including ongoing consultation on the preparation manufacturing process in accordance with the GMP standard and documentation compliance with the requirements for biotechnological preparations set by regulators - maximum period of 15 months;
- b) Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for Phase I clinical trials in Europe (Poland, Germany, Switzerland), including advice and ongoing consultation on the compliance of documentation with the requirements for biotechnological preparations set by the regulator - maximum 6 months;
- c) Regulatory advice on: obtaining authorization to perform a clinical trial, submitting documentation to the regulator, etc. for phase I and II clinical trials in the USA (two different administrations of the preparation: intraperitoneal in phase I, intratumoral in phase II), including advice and ongoing consultation on the compliance of the documentation with the requirements for biotechnological preparations set by the regulator - maximum 15 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 a period of 60 days from the deadline for submission of offers.

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

**Appendix 2 STATEMENT ON THE COMPLIANCE WITH CONDITIONS FOR PARTICIPATION
IN THE PROCEEDING for Request for Quotation No. 1/ABM/2024**

Bidder

(name and address of the Bidder)

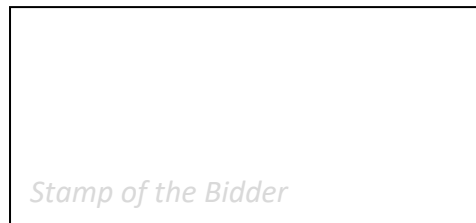
- a) The Bidder declares to be in a business and financial situation that ensure timely and requirement compliant performance of the contract;
- b) The Bidder declares to have the necessary specialist knowledge and all the necessary support and qualified personnel;
- c) The Bidder declares to have a minimum of 15 years of experience in the international biotechnology market in the field of regulatory advice regarding cell therapies and the preparation of product documentation from a regulatory perspective in order to obtain approval for the product's admission to phase I and phase II clinical trials in Europe and the USA;
- d) 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

**Appendix 3 STATEMENT CONCERNING CONFLICT OF INTEREST for Request for Quotation
No. 1/ABM/2024**

(Place) _____, date _____



I, undersigned _____ declare, that:

Have not any personal or capital connections with the Ordering Party.

Equity or personal relationship is understood as relations between the Ordering Party or individuals authorized to take commitments on behalf of the Ordering Party or those acting on behalf of the Ordering Party in order to prepare and implement the contractor selection procedure, and the Contractor, including in particular:

- a) participating in the company as a partner in a civil partnership or partnership,
- b) holding at least 10% of shares or stocks (unless a lower threshold results from legal regulations),
- c) performing the function of a member of a supervisory or management body, proxy, attorney,
- d) 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,
- e) being in cohabitation with the contractor, his legal representative or members of the management or supervisory bodies of the contractors applying for the award of the contract,
- f) being in such a legal or factual relationship with the contractor that there is a justified 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