



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



Warsaw, October 10, 2024

## REQUEST FOR QUOTATION No. 1/ FENG-GBM2/2024

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:

### **Advisory services on regulatory matters.**

#### **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:

Advisory services on regulatory matters in the glioma indication, including the manufacturing (CMC) of MDC-735.

**Planned date of starting of the order: November 01, 2024**

2.2 The above-mentioned order consist of:

- 1) Advisory services on regulatory matters in the glioma indication concerning Phase I clinical trials conducted in Europe, including the production of MDC-735 – maximum number of hours: 140.
- 2) Regulatory advisory services in the glioma indication for Phase II clinical trials conducted in Europe, including the production of MDC-735 – maximum number of hours: 300.

**The Ordering Party informs that the MDC-735 preparation consists of macrophages loaded with a protein-drug conjugate (the drug in the conjugate is an active compound with an increased level of risk - a cytotoxic substance).**

**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.**



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



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:

73200000-4 Research and development consultancy services

### **3. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS**

3.1 Contractors participating in the proceedings must fulfil following conditions:

- 1) must have the necessary specialist knowledge and experience – must have at least 10 years of experience in the development of biotechnological products, including consulting on regulatory requirements for cell therapies in Europe, supported by obtaining permission to conduct phase I and II clinical trials for at least 2 cell preparations,
- 2) must have personnel qualified in the regulatory requirements for cell therapies in Europe;
- 3) must be in a business and financial situation that ensure timely and requirement compliant performance of the contract.

The statement about fulfilling conditions for participation in the proceedings is attached as Appendix 2 to this request for quotation 1/FENG-GBM2/2024.

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.



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



The Bidder is obliged to submit a relevant statement contained in Annex 3 to the Request for Quotation 1/FENG-GBM2/2024.

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 1/FENG-GBM2/2024). 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 October 17, 2024 (23:59).

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/>.



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



## 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:

$P_i$  – the final number of points that the “i” offer will receive

$P_i(C)$  – points that the “i” offer will receive for the „Price” criterium

$P_i(T)$  – the number of points that the “i” offer will receive for the “Service completion date” criterion

- Criterium „Price” – weight 80%

„Price” criterium will be calculated as follows:

$$P_i(C) = (C_{min} : C_i) \times 80$$

where:

$P_i(C)$  – points that the “i” offer will receive 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 “i”

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

- Criterium „Time for service completion” – weight 20%

„ Time for service completion” criterium will be calculated as follows:

up to 2 business days – 20 points,

2-3 business days – 10 points,

over 3 business days – 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.



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



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:** 62 months.

## **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,



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



- 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 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**

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



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



9.2 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 Zajączka 26

01-510 Warsaw, Poland

Contact person: Małgorzata Sęktas

### 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.



European Funds  
for Smart Economy

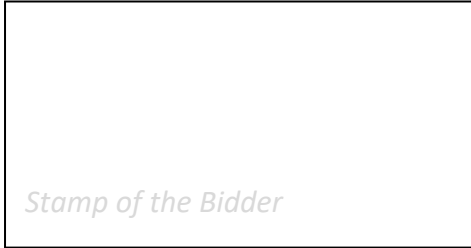


Republic  
of Poland

Co-funded by the  
European Union



**Appendix 1 BID FORM for request for request for quotation no. 1/FENG-GBM2/2024**



Name \_\_\_\_\_

Address \_\_\_\_\_

Phone no. \_\_\_\_\_

Tax Number \_\_\_\_\_

Contact person: \_\_\_\_\_

e-mail: \_\_\_\_\_

**Ordering Party:**

Cellis Sp. z o.o.

Generała Zajączka 26

01-510 Warsaw, Poland

VAT EU: PL5252640606

In response to the Request for Proposal No. 1/FENG-GBM2/2024 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



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



1. Detailed calculation of the cost:

Stage No.	Activity	Maximum number of hours	Net price per hour [PLN/ USD/ EUR/ other currency]	Net value [PLN/ USD/ EUR/ other currency]	Gross value [PLN/ USD/ EUR/ other currency]
1.	Regulatory advisory services in the glioma indication regarding Phase I clinical trials conducted in Europe, including the production of MDC-735.	140			
2.	Regulatory advisory services in the glioma indication regarding Phase II clinical trials conducted in Europe, including the production of MDC-735.	300			
	TOTAL				

2. The Bidder declares that the time limit for the performance of the service, understood as the maximum time specified by the Contractor for responding to the Ordering Party as part of the consultancy, is \_\_\_\_\_ business days.

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



European Funds  
for Smart Economy



Republic  
of Poland

Co-funded by the  
European Union



**Appendix 2 STATEMENT ON THE COMPLIANCE WITH CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS for Request for quotation no. 1/FENG-GBM2/2024**

Bidder

---

(name and address of the Bidder)

- 1) The Bidder declares that have the necessary specialist knowledge and experience – at least 10 years of experience in the development of biotechnological products, including consulting on regulatory requirements for cell therapies in Europe, supported by obtaining permission to conduct phase I and II clinical trials for at least 2 cell preparations.
- 2) The Bidder declares that have personnel qualified in the regulatory requirements for cell therapies in Europe.
- 3) The Bidder declares that is in a business and financial situation that ensure timely and requirement compliant performance of the contract.
- 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



European Funds  
for Smart Economy



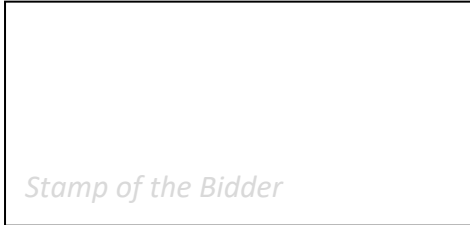
Republic  
of Poland

Co-funded by the  
European Union



**Appendix 3 STATEMENT CONCERNING PERSONAL / CAPITAL CONNECTIONS BETWEEN THE BIDDER  
AND THE ORDERING PARTY for request for quotation no. 1/FENG-GBM2/2024**

(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