Warsaw, 5.01.2024 r.

REQUEST FOR QUOTATION No. 4/FENG-PAN/2024

In connection with applying for the project „Cell therapy for pancreatic cancer" co-financed by European Union Founds under measures of the European Funds for Modern Economy under „SMART track", Cellis Ltd. request to submit price quotation for:

Phase I of clinical trials - hospital procedures.

1. ORDERING PARTY

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

ul. Generała Zajączka 28

01-510 Warsaw, Poland

VAT EU: PL5252640606

2. THE SUBJECT OF THE ORDER:

2.1 The subject of the order is:

Phase I of clinical trials - hospital procedures.

Planned date of starting of the order: July 01, 2027.

2.2 The above-mentioned order consist of:

Performing hospital procedures in PDAC patients with recurrence after first-line treatment with FOLFIRINOX (5-Fluorouracil/Leucovorin/Oxaliplatin/Irinotecan) without brain metastases recruited for a phase I clinical trial, including:

1) Intraperitoneal or intratumoral administration (MDC-PAN) via an intraperitoneal catheter (e.g. Braun, Celsite Drainaport) in combination with intravenous gemcitabine,

2) Care and delivery of patient treatment (12 patients in total: 4 dose groups of 3 patients each):

a) minimum 7 patient visits (screening test, 1 application of the cell drug product + gemcitabine intravenously, +4 days, 2nd application of the cell drug product + gemcitabine intravenously, +4 weeks, +12 weeks, +24 weeks) – performing physical and subjective examinations, imaging tests, laboratory tests,

b) maksimum 4 applications of the cell drug product + gemcitabine intravenously (in max. 7 day intervals),

c) 6-month follow-up period for progression-free survival,

d) 12-month follow-up of overall survival,

3) Tumor assessment at 4 days, 4 weeks, 3 months (12 weeks), 6 months (24 weeks) after study treatment starts,

4) Confirmation of the first progression using follow-up imaging (MRI) at least three months after the first examination documenting progressive disease (PD) unless the researcher selects to initiate alternative therapeutic interventions,

During the confirmation period, treatment may continue as planned if the patient, in the investigator's judgment, demonstrates demonstrable clinical benefit with minimal and acceptable toxicity.

5) Assessing tumor evaluation according to RECIST w. 1.1. or iRECIST criteria,

6) Assessing blood flow within the tumor using angio-TK,

7) Qualifying tumor response as Complete Response (CR), Partial Response (PR), Stable Disease (SD) or Progressive Disease (PD),

8) Performing survival update monitoring for each patient until death or for a minimum of 12 months.

The clinical trial will be monitored by an external CRO company (Contract Research Organization).

The main aim of the study is to assess the safety of local administration of the cell drug product in patients with glioma during the first recurrence and to establish the recommended dose (RD) for phase II, considering the main endpoint: Occurrence of dose-limiting toxicity (DLT).

The final scope of the request for quotation will depend on the development of the project and will result from the current needs of the Ordering Party.
The Ordering Party reserves the right to complete the order in any part, and the Contractor is not entitled to any claims in this respect.

2.3. The subject of the order specified in point 2.1 shall be perform no later than June 30, 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) they must have necessary expertise, experience and technical potential ie.:

a) must have the necessary knowledge and documented experience - staff specialized in at least the following fields: oncology, neurology, neuro-oncology, surgery and in performing chemotherapy treatment in patients with pancreatic cancer with first recurrence and in performing intraperitoneal catheter implantation procedures and in conducting early-phase clinical trials - especially I, II, First in Human – within the last 3 years;

b) must have the necessary technical potential, including:

*technical resources:

- hospital imaging diagnostic facilities - mandatory with magnetic resonance imaging,
- hospital neurosurgical facilities,
- hospital oncology facilities,
- hospital facilities for laboratory tests,

*equipment:

- Laminar chamber for clean work to specimen preparation (thawing),
- Freezer -80C,
- Liquid nitrogen container;

3) they must be in a business and financial situation that ensure timely and requirement compliant performance of the contract;

4) they must declare readiness to comply with the study protocol, as well as the latest version of the Helsinki Declaration, ICH-GCP and national legal and regulatory conditions.

The statement about fulfilling conditions for participation in the proceedings is attached as Appendix 2 to this Request for Quotation no. 4/FENG-PAN/2024.

3.2 The Contractor may not be personally, or equity related to 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 contract award procedure, and the Contractor, including in particular:

a) Being a partner to civil law partnership or commercial law partnership,
b) Holding at least 10% of shares, if lower threshold does not result from law,
c) Being a member of a supervisory or management corporate body, a holder of general commercial power of attorney, an authorised representative,
d) Being married to, being in direct consanguinity or affinity, second degree consanguinity or affinity of the second degree collaterally or by adoption or guardianship or being in cohabitation with the Contractor, its legal representative or members of management or supervisory bodies of economic operators competing for the contract award,
e) 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 no. 4/FENG-PAN/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. 4/FENG-PAN/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 Offer must include all attachments required by the Ordering Party confirmed to be true by the authorised representative of the Bidder.

4.4 Contractor must submit with the offer copy (scan) of relevant Register of Business Activity, applicable to country of residence of Contractor, issued not earlier than three (3) months before the deadline for submission the offer to demonstrate the absence of grounds for exclusion.

4.5 The offer must be submitted by March 5, 2024 (23:59).

4.6 The offer must be submitted via website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/

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

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

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

4.10 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.funduszeeuropejskie.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://bazakonkurencyjnosci.funduszeeuropejskie.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:

$$Pi=Pi(C)$$

where:

Pi – the amount of points received,

Pi(C) – points for the „Price" criterium.

- Criterium „Price" – weight 100%

„Price" criterium will be calculated as follows:

$$Pi(C) = (Cmin : Ci) \times 100$$

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 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: 24 months.

7. NOTICE OF SELECTION OF THE BEST TENDER

Information of the results of the proceedings will be published on the website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/.

8. CHANGES IN THE AGREEMENT

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

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.

10. CONTACT

Cellis Sp. z o.o. [Ltd.]
ul. Generała Zajączka 28
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.

Appendix 1 BID FORM for Request for Quotation no. 4/FENG-PAN/2024

Stamp of the Bidder

Name _____
Address _____
Phone no._____
Tax Number_____

Contact person: _____
e-mail: _____

Ordering Party:
Cellis Sp. z o.o.
Generała Zajączka 28
01-510 Warsaw, Poland
VAT EU: PL5252640606

According to the Request for Quotation no. 4/FENG-PAN/2024 as a part of the applied for funding project „Cell therapy for pancreatic cancer" co-financed by European Union Founds under measures of the European Funds for Modern Economy under „SMART track", Cellis Ltd., I submit tender:

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

1. Detailed calculation of the cost:

Stage No.	Activity	Total cost
1.	Intraperitoneal or intratumoral administration (MDC-PAN) via an intraperitoneal catheter (e.g. Braun, Celsite Drainaport) in combination with intravenous gemcitabine.	
2.	Care and delivery of patient treatment (12 patients in total: 4 dose groups of 3 patients each): a) minimum 7 patient visits (screening test, 1 application of the cell drug product + gemcitabine intravenously, +4 days, 2nd application of the cell drug product + gemcitabine intravenously, +4 weeks, +12 weeks, +24 weeks) – performing physical and subjective examinations, imaging tests, laboratory tests, b) maksimum 4 applications of the cell drug product + gemcitabine intravenously (in max. 7 day intervals), c) 6-month follow-up period for progression-free survival, d) 12-month follow-up of overall survival.	
3.	Tumor assessment at 4 days, 4 weeks, 3 months (12 weeks), 6 months (24 weeks) after study treatment starts.	
4.	Confirmation of the first progression using follow-up imaging (MRI) at least three months after the first examination documenting progressive disease (PD) unless the researcher selects to initiate alternative therapeutic interventions.	
5.	Assessing tumor evaluation according to RECIST w. 1.1. or iRECIST criteria.	
6.	Assessing blood flow within the tumor using angio-TK.	
7.	Qualifying tumor response as Complete Response (CR), Partial Response (PR), Stable Disease (SD) or Progressive Disease (PD).	
8.	Performing survival update monitoring for each patient until death or for a minimum of 12 months.	
9.	Other costs	
SUM		

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

Appendix 2 STATEMENT ON THE COMPLIANCE WITH CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS for Request for Quotation no. 4/FENG-PAN/2024

Bidder

_____

(name and address of the Bidder)

1) The Bidder declares that have:

Statement	YES/NO
a) the necessary knowledge and documented experience - staff specialized in at least the following fields: oncology, neurology, neuro-oncology, surgery.	
b) the necessary knowledge and documented experience - staff specialized in performing chemotherapy treatment in patients with pancreatic cancer with first recurrence and in performing intraperitoneal catheter implantation procedures.	
c) the necessary knowledge and documented experience - staff specialized in conducting early-phase clinical trials - especially I, II, First in Human – within the last 3 years.	
d) appropriate technical resources, including:	
- hospital imaging diagnostic facilities with magnetic resonance imaging,	
- hospital neurosurgical facilities,	
- hospital oncology facilities,	
- hospital facilities for laboratory tests.	
e) appropriate equipment, including:	
- Laminar chamber for clean work to specimen preparation (thawing),	
- Freezer -80C,	
- Liquid nitrogen container.	

2) The Bidder declares that is in a business and financial situation that ensure timely and requirement compliant performance of the contract.
3) The Bidder declares its readiness to comply with the test protocol, as well as the latest version of the Helsinki Declaration, ICH-GCP and national 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

Appendix 3 STATEMENT CONCERNING PERSONAL / CAPITAL CONNECTIONS BETWEEN THE BIDDER AND THE ORDERING PARTY for Request for Quotation no. 4/FENG-PAN/2024

(Place)_____, date_____

Stamp of the Bidder

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

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) Being a partner to civil law partnership or commercial law partnership,
b) Holding at least 10% of shares, if lower threshold does not result from law,
c) Being a member of a supervisory or management corporate body, a holder of general commercial power of attorney, an authorised representative,
d) Being married to, being in direct consanguinity or affinity, second degree consanguinity or affinity of the second degree collaterally or by adoption or guardianship or being in cohabitation with the Contractor, its legal representative or members of management or supervisory bodies of economic operators competing for the contract award,
e) 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