



REQUEST FOR QUOTATION no. 233/2022/M/RNA dated 21.10.2022 for CELON PHARMA SA with its registered office in Kielpin

In connection with the implementation of the project no. 2021/ABM/05/00005 under the name "**Development of Innovative Therapeutic Solutions using RNA technology (TransformRNA - mRNA Therapeutics generation platform)**" co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers.

DATE OF PUBLICATION: 21.10.2022

LOCATION: Kazuń Nowy

ANNOUNCEMENT PUBLICATION: obligatory

ORDERING PARTY: Celon Pharma SA, ul. Ogrodowa 2a, 05-092 Kielpin

OFFICIAL WEBSITE ADDRESS OF THE ORDERING PARTY

www.celonpharma.com, telephone: 22 7515933

TYPE OF THE ORDERING PARTY: Private entity

A PARTIAL TENDER ALLOWED - NO

A VARIANT TENDER ALLOWED - NO

DATE OF COMPLETION OF THE CONTRACT: until 31th March 2023

PROCEDURE

Request for quotation

CONTRACT AWARD PROCEDURE:

1. This contract award procedure is not governed by the provisions of the Act of 29 January 2004 – the Public Procurement Law.
2. This contract award procedure shall be conducted with due observance of the principles of competitiveness, openness, transparency and equal access.
3. The Ordering Party reserves itself the right to nullify the procedure at any stage thereof without stating the reason.
4. The Ordering Party shall inform Suppliers about any changes made by publishing relevant information on its website.
5. The Ordering Party reserves itself the right to request additional information, documents or explanations.

CELON PHARMA S.A.

Biuro: ul. Ogrodowa 2A, 05-092 Łomianki / Kielpin, Dział R&D: ul. Marymoncka 15, 05-152 Kazuń Nowy / Czosnów,
tel.:+48 22 751 59 33; fax: +48 22 751 74 77 e-mail: info@celonpharma.com, www.celonpharma.com

Organ rejestrowy: Sąd Rejonowy dla m. st. Warszawy, XIV Wydział Gospodarczy Krajowego Rejestru Sądowego

Prezes Zarządu: Maciej Wieczorek, **Wysokość kapitału zakładowego:** 5.103.500 PLN

KRS: 0000437778, **NIP :** 118 16 42 061



6. In justified cases, at any time before the expiry of the deadline for the submission of tenders, Celon Pharma SA may modify or supplement the content of the invitation to tender.
7. This invitation to tender imposes no obligation on Celon Pharma SA to conclude a contract.

DETAILS CONCERNING THE OBJECT OF A CONTRACT:

CPV CODE: 73100000-3

Subcontracting: Study in humanized mice engrafted with tumor cell line MDA-MB-231

Effectiveness test:

1. Study: 90 hu-NOG mice humanized by engraftment of CD34+ stem cells from human cord blood (mice with a humanization rate (hCD45/total CD45) above 25%), 1 model (cell line MDA-MB-231), 10 mice per group, 9 groups - 6 compounds (mRNA-LNP) and 3 controls, 3 injections (subcutaneous) in 7-day long intervals,
2. Subcutaneous treatments should start when the average tumor volume reaches 50-100 mm³. The mice should be randomized based on tumor volume, CD34+ cell donors and humanization rate into 9 groups, 10 mice in each group.
3. All test compounds will be formulated by the Sponsor formulation,
4. Readouts: Clinical observations and body weight, Tumor growth monitoring, Sample collection: blood (2 time points), Flow cytometry analysis: blood (2 time points)
5. Tumor collection in case the tumors would be large enough at the end of the study (and sending frozen to the Sponsor) - to be agreed with the Sponsor. The collection of 3 organs - (and sending frozen to the Sponsor) - to be agreed with the Sponsor.
6. Blood will be collected (2 time points): before the first treatment and once during the treatment (to be discussed with the Sponsor).
7. Flow cytometry analysis of peripheral blood samples at 2 time point: before the first treatment and once during the treatment (to be discussed with the Sponsor). One panel for the analysis - to be discussed with the Sponsor.
8. The tumor volume should be monitored 3 times per week using caliper. The mice should be checked daily for unexpected signs of distress. The body weight should be monitored at least weekly.
9. Animal weighing, and tumors measurement 2x per week. Data will be reported by the Project Leader once weekly, using the Bidder template,
10. All collected samples and any remaining drugs will be shipped to the Ordering Party up to 4 weeks after completion of the final model in the study.
11. The price should include: Project management, data collection and analysis, interim and final study reports
12. Draft and final reports in PDF format should be sent at the end of the study. The written report should provide the following information: Description of all experimental procedures, Raw and analyzed data, Discussion and executive summary.

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Requirements to be met by bidders:

Bidder have to deliver a statement concerning compliance with the following criterions. Lack of such statement will result in excluding Bidder's offer from tender:

1. The Bidder should have the necessary experience and technical and laboratory infrastructure to deliver the subject of the order.
2. The Bidder should possess scientific personnel specialized in areas related to the subject of this request.
3. The Bidder should hold all licenses required by law to deliver the subject of the order.
4. The Bidder's financial and economic position should ensure proper realization of the ordered study.

POINT SCORING SYSTEM:

TENDER EVALUATION CRITERIA:

Criterion	Weight [%]	Evaluation formula
Price	100%	<p>Price – (max. 100 points – this is 100% of the maximum number of points to gain). The points will be awarded as follows: The lowest offered price will be considered 100% and awarded maximal number of points (100 points). The points for consequent offers will be given based on the formula:</p> $\frac{Price_{lowest}}{Price_{service}} \times 100 \text{ pts}$ <p>where: Price_{lowest} – lowest price amongst offers. Price_{service} – price proposed in evaluated offer.</p>

Total scoring = criterion "Price" (100 points maximally to gain)

Address and deadline for the submission of tenders:

1. Tenders must be submitted to the Ordering Party to the address of its registered office: ul. Marymoncka 15, 05-152 Kazuń Nowy, Poland, if sent by traditional or courier mail, or to the e-mail address: przemyslaw.pietrasiuk@celonpharma.com, if sent by electronic mail.
2. Tenders must be submitted on **28.10.2022** at the latest. If a tender is sent by traditional or courier mail, it shall be deemed submitted on the day of its delivery to the registered office of the Ordering Party.
3. Tenders submitted after the expiry of the deadline shall not be processed.
4. Tenders shall be evaluated at the registered office of the Ordering Party by **30.11.2022** at the latest.
5. The tenders submitted in a foreign currency will be converted at the average exchange rate of the National Bank of Poland (NBP) applicable on the date of drawing up the protocol of the request for tender.

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Presentation of tenders:

1. Each Tenderer may submit only one tender.
2. The tender must include the following details:
 - a. the number of the request for quotation,
 - b. the date of preparation,
 - c. the details of the Tenderer: address, telephone number, e-mail address, Tax Identification Number (NIP) (if available),
 - d. detailed information about the compliance of the proposed device with the specification.
3. The tender must be submitted along with the "Declaration of no personal or capital connections with the Ordering Party". Att. 1
4. The number of the request for quotation must also appear in the titles of e-mail messages, traditional or courier mail.
5. The tender must remain valid for at least 30 days after date of submission.
6. The payment term of each issued invoice must be at least 60 days.
7. The tender preparation costs shall be borne by the Tenderer.
8. The tender must be initialled and signed by persons authorised to represent the Economic Operator/Supplier.

Note:

1. The Purchaser will place the order with the bidder whose bid meets all the requirements set forth in this RfQ and is deemed the best relative to the selection criteria set forth herein.
2. The Purchaser reserves the right to close the bidding process without selecting the successful Bidder. In such case the purchaser doesn't need to specify its reasons for doing so.
3. In the course of evaluation and assessment of the bids, the Purchaser may request that the bidders provide clarifications regarding their bids.
4. The bidder may alter or withdraw its offer before the submission deadline.
5. Bids submitted past the submission deadline will not be considered.
6. Bids that do not meet the formal requirements set forth herein will not be considered.
7. The Purchaser does not accept variant bids.
8. The Purchaser does not accept partial bids.
9. The Purchaser permits rejecting bids whose essential content clearly raises reasonable doubts.

NOTIFICATION OF THE CONTRACT AWARD

Information about the result of the contract award procedure shall be published on the Celon Pharma website

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Please Note:

1. In connection with the entry into force of the Act of April 13, 2022 on special solutions in the field of counteracting aggression against Ukraine and serving the protection of national security (Journal of Laws, item 835), entities or citizens from the Russian Federation are excluded from participation in these proceedings, while subject to the sanctions specified in Art. 1 above of the Act, provided that on the day of submitting the offer they are on the list of persons and entities against which sanction measures should be applied, kept on the website of the Public Information Bulletin of the Minister of Internal Affairs and Administration,
2. In connection with the entry into force of the Act of April 13, 2022 on special solutions in the field of counteracting aggression against Ukraine and serving the protection of national security (Journal of Laws, item 835), entities or citizens from the Russian Federation are excluded from participation in these proceedings, while subject to the sanctions specified in Art. 1 above of the Act, provided that on the day of submitting the offer they are on the list of persons and entities against which sanction measures should be applied, kept on the website of the Public Information Bulletin of the Minister of Internal Affairs and Administration,
3. The Contracting Party reserves the right to amend the agreement concluded with the awarded tenderer as a result of the procurement for the following reasons:
 - a) justified changes in the manner of performance of the subject-matter of the order,
 - b) objective reasons beyond the control of the Contracting Party or tenderer,
 - c) changes in legal regulations in force on the day of signing the contract,
 - d) force majeure,
 - e) occurrence of another obstacle, beyond the control of the tenderer, which prevents the performance of works,
 - f) in the event of changes to the Subject of the Agreement exceeding the material and/or financial scope indicated in the Tender, the Parties undertake that such changes will be introduced by way of an amending Annex and according to the "Guidelines on the eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for 2014-2020".
4. Entities related to the Contracting Party either personally or by capital are excluded from participation in this procurement. Capital or personal relationships are understood as mutual relations between the Contracting Party or persons authorised to contract obligations on behalf of the Contracting Party or persons performing on behalf of the Contracting Party activities related to the conduct of the procedure for selecting a contractor and the contractor, consisting in particular of the following:
 - a) participation in a company as a partner in a civil law partnership or a partnership,
 - b) owning at least 10% of shares as long as the lower limit does not result from legal provisions or was not defined by IZ PO,
 - c) fulfilling the duties of member of the supervisory body or as manager, proxy or power of attorney,
 - d) being married, a direct family member, direct affinity, second-level relative or second degree affinity in lateral line or in relation to adoption, care or guardianship.
5. Each invoice issued should be due for at least 30 days.
6. Due to the necessity to maintain the continuity of tests, the Ordering Party provides for the possibility of submitting a supplementary order in the amount not exceeding 50% of the order value specified in the contract concluded with the Contractor.
7. The Ordering Party allows for the possibility of canceling the order or resigning from the order of goods and services included in the partial procedure or the entire procedure if funds are not obtained for the performance of this order or in other cases when the performance of the order will not be in the Ordering Party's best interest.
8. The Ordering Party admits the possibility of negotiating the presented offer.

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