

REQUEST FOR THE PROPOSAL No. 21/2021 - ARG**I. ORDERING PARTY**

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II. OBJECT FOR THE REQUEST

Professional consulting services related to the preparation of the specification for impurity and conducting a gap analysis for the CMC data package in the OATD-02 research program.

The order is carried out as a part of the project titled:

— **ARG:** "PRE-CLINICAL AND CLINICAL DEVELOPMENT OF ARGINASE INHIBITOR FOR CANCER IMMUNOTHERAPY" (POIR.01.01.01-00-0415/17)

co-financed by the European Union Funds and because of the competitiveness principle.

III. THE FORM OF THE ORDER

- III.1 The request is not made under the Act of 11 September 2019 - Public Procurement Law (Journal of laws of 2019, item 2019 as mentioned).
- III.2 This order is carried out in accordance with the principle of competitiveness, openness, transparency and equal access.
- III.3 The Ordering Party reserves the right to cancel this procedure without providing reasons and also to complete the procedure without choosing the winner tender.
- III.4 In the course of examination and evaluation of the offers, the Ordering Party may require Contractors to present explanations concerning the content of submitted bids.
- III.5 In justified cases, at any time, before the deadline for the submission of tenders, OncoArendi Therapeutics SA reserves the right to change the content of this request. If the changes can affect the content of tenders, the Ordering Party shall extend the tender submission deadline. The Ordering Party shall inform potential Contractors about the changes made by publishing relevant information on its website, on Concurrency database website and by e-mail to all Contractors to which the request was sent or to all Contractors who submitted bids.
- III.6 This procedure does not set the obligation for OncoArendi Therapeutics SA to sign any formal contracts.
- III.7 It is not possible to make and offer for part of order.
- III.8 For the avoidance of doubts, the selection of an offer as the best in the procedure does not constitute a contract or an order to perform any services or perform any deliveries.

IV. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS AND A DESCRIPTION OF THE MANNER OF ASSESSING THE FULFILMENT OF THOSE CONDITIONS

IV.1 The Request for offers relates to potential Contractors whose scope of business activity is in full compliance with the subject of this Request.

IV.2 The offers may be issued by Contractors who:

- A) have the necessary qualifications to carry out the described activity and have the appropriate technical potential and personnel capable of performing the contract, regarding human resources, the Ordering Party requires the Service Provider to engage multi-disciplinary team of experts:
 - i. with understanding of recent EMA's (European Medicines Agency) and US FDA's (US Food and Drug Administration) regulations referring to Investigational Medicinal Products for clinical trials in human as well as ICH guidelines (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use),
 - ii. with documented experience in preparation of regulatory documentation required during drugs development process like Gap Analysis;
- B) have at least 5 years of experience in providing, to pharma and biotech companies, professional consulting service related to innovative drug development in the field of CMC and regulatory affairs, and building EMA and US FDA compliant regulatory strategies for drug candidates;
- C) are in a good economic and financial standing, which assures proper execution of the order;
- D) will pursue the contract in a way that is beneficial to the environment by minimizing the consumption of materials, raw materials, energy, etc.

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about fulfilling conditions for participation in the proceedings and the CV's of the experts planned to be engaged in the project, who fulfils the above mentioned requirements. The model statement is attached as Appendix 2 to this request for proposal.

IV.3 Excluded from the proceedings shall be those Contractors who are 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 Contractor selection procedure and the Contractor, including in particular:

- A) participation in the company, in a civil or limited partnership;
- B) holding at least 10% shares or interests;
- C) serving a function of a member of the supervisory organ, a member of the management organ or proxy;
- D) having family ties, such as by marriage, by lineage at first or second degree, by adoption, guardianship or custody.

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about not being related to the Ordering Party. The model statement is attached as Appendix 3 to this request for proposal.

IV.4 Submitting the offer represent the full acceptance of the rules set in this Request and in particular the essential terms of the contract.

V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST

CPV Code: 73200000-4 (Research and development consultancy services)

Order description:

OncoArendi Therapeutics is developing a low-molecular-weight arginase inhibitor OATD-02 as an innovative cancer treatment. OncoArendi research team has developed highly potent, selective, orally active inhibitors of arginases which restored functional efficacy of T lymphocytes and demonstrated significant antitumor efficacy in multiple animal models of cancer, either as a monotherapy or in combinations with other immunotherapies. The lead compound, OATD-02, has been nominated for a clinical development. OATD-02 is designed to target a novel immune check point mechanism and represents a promising new immunotherapy for multiple types of cancer, in particular in combination with other immunotherapies and other modalities.

In the middle of last year, Ordering Party completed the Drug Substance (DS) production campaign GMP quality. Currently, the Ordering Party is conducting a tender procedure to select a manufacturer of a Drug Product (DP).

The scope of this order includes (more details are presented in Table 1):

- conducting a gap analysis for the CMC data package in the OATD-02 research program: audit of CMC documentation and identification of gaps,
- Expert consulting service related to the preparation of the specification for impurity occurring in all API batches.

Table 1. Detailed scope of the Order

No.	Task
1.	<p>Conducting a gap analysis for the CMC data package in the OATD-02 research program: audit of CMC documentation and identification of gaps</p> <ul style="list-style-type: none"> • Kick-off project meeting (remotely) <p>During the meeting with OAT Team, the following persons shall be present: project manager (PM), core experts that would be responsible for the contract execution (i.e. CMC expert, regulatory expert)</p> <ul style="list-style-type: none"> • Review of the project documentation in the field of CMC • Preparation of the consultancy reports after a gap analysis, which will have a two-stage character: first for Drug Substance (DS), and then for Drug Product (DP) • Periodic TCs and preparation of meetings minutes
2.	<p>Expert consulting service related to the preparation of the specification for impurity occurring in all API batches</p> <ul style="list-style-type: none"> • Task kick-off meeting (remotely)

	<p>During the meeting with OAT Team, the following persons shall be present: PM and expert/experts responsible for task no. 2 execution</p> <ul style="list-style-type: none"> • Review of documentation related to task no. 2 • Meeting after reviewing the shared documentation (remotely) • Preparation of the consultancy report (impurity limit justification) including all the proposed recommendations for task no. 2
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Due to the protection of business secrets, in case of questions regarding this Request, requiring the disclosure of confidential data, the Ordering Party reserves the right to provide explanations after the Contractor has sent by e-mail a scan of a hand-signed Confidential Disclosure Agreement (CDA).

The CDA (Appendix no. 5) will be provided electronically at Contractor's request. The scan of the filled and hand-signed CDA should be sent by email to: malgorzata.borkowska@oncoarendi.com.

**The hand-signed original of the confidentiality agreement should be sent to the following address:
OncoArendi Therapeutics SA, Żwirki i Wigury 101, 02-089 Warsaw**

The contract will be valid until: 30.09.2022

VI. EVALUATION OF THE OFFERS

VI.1 Price – weight: 90% (90 pts.)

In this criterion points will be calculated (to two decimal places) according to the formula below:

$$Pc = \frac{C_{min}}{C_{evaluated}} \times 90$$

Pc – Points received

C_{min} – The lowest Net price

C_{evaluated} – Net price of the offer being evaluated

90 – weight of the criterion (90%)

VI.2 Payment deadline – weight: 10% (10 pts.)

The number of points for the criterion payment deadline will be awarded according to the following scheme:

10 points – when the payment deadline is 30 days from the date of delivery of a correctly issued invoice

5 points – when the payment deadline is set between 15-29 days from the date of delivery of a correctly issued invoice

0 points – when the payment deadline is 14 days or less from the date of delivery of a correctly issued invoice

10 – weight of the criterion (10%)

VI.3 In the case of two or more tenders with equal number of points awarded, the Ordering Party shall call Contractors who submitted equally evaluated offers to submit, within the period specified, additional offers. Contractors cannot offer higher prices than offered in the tenders.

VII. HOW TO PREPARE AND SUBMIT THE OFFER

- VII.1 The offer should be signed by the person authorized to represent the Contractor. If the offer is signed by an attorney, a power of attorney must be attached to the offer.
- VII.2 Each contractor may submit only one offer.
- VII.3 Costs of the offer preparation shall be incurred by the offering party.
- VII.4 Offers must be submitted no later than: **12/04/2021 23:59** CET and must be written on the form as in Appendix 1 to the request for proposals.
- VII.5 Offers shall be issued via email to: malgorzata.borkowska@oncoarendi.com or by Concurrency database website available at <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl>
- VII.6 The receipt of the offer via electronic means indicated in point VII.5 shall be considered as a date of submitting the offer.
- VII.7 Offers that do not meet the deadline, are incomplete (despite a request for supplementation, if such a request was possible and in accordance with the regulations) or sent to the wrong email address will not be taken into consideration.
- VII.8 Any questions concerning the Object of the tender should be addressed to malgorzata.borkowska@oncoarendi.com (+48 505 374 848) no later than 08/04/2021 13:00 (CET). Contact person is: Malgorzata Borkowska.
- VII.9 Any questions concerning the formal issues of the tender should be addressed to k.kosinska@oncoarendi.com (+48 573 975 784) no later than 08/04/2021 13:00 (CET). Contact person is: Karolina Kosinska.
- VII.10 The offer should include the validity date (at least 30 days from the submission deadline).
- VII.11 The price should be set in both Net and Gross.
- VII.12 The values in the offer (Net and Gross) should be rounded to two decimals with the mathematical rule of rounding the numbers (according to § 5 section 6 of the regulation of Ministry of Finance of 28 November 2008 (Journal of Laws of 2008, No. 212, item 1337, as mentioned).
- VII.13 The offer price should include VAT. The correct determination of VAT is responsibility of the contractor – in accordance with the provisions of the Act of 11 March 2004 on Goods and Services Tax (Journal of Laws of 2004 No. 54 item. 535 as mentioned).
- VII.14 The offer shall not be prepared in price variants.
- VII.15 The financial settlements between the Ordering Party and the Contractor may be made in PLN, EUR, GBP or USD.

VIII. TENDER RESULTS

Bidder will be informed about choosing his offer via email. Formal results will be also published on the Ordering Party's website (www.oncoarendi.com) and on Concurrency database website.

IX. MOST IMPORTANT PROVISIONS OF THE AGREEMENT

- IX.1 Contractor will be obligated to enter into the agreement including all conditions presented in this Request and in the offer.

- IX.2 It is not possible to introduce significant changes to the content of the agreement in relation to the content of the offer, which was the base for the Contractor selection, unless:
- A) The amendments concern performing additional supplies or services by the Contractor, not covered by the basic contract, provided they are necessary and the following conditions are met:
 - i. The change of the Contractor cannot be made due to the economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of basic contract,
 - ii. The change of the Contractor would cause significant inconvenience or substantial cost increase to the Ordering Party,
 - iii. The value of any subsequent changes do not exceed 50% of the basic contract value.
 - B) The amendment does not lead to change in the nature of the contract and the following conditions are met:
 - i. The need for the contract change is brought about by circumstances which the Ordering Party, acting with due diligence, could not foresee,
 - ii. The value of a change does not exceed 50% of the basic contract value.
 - C) The amendment does not lead to change in the nature of the contract and the total value changes is less than 214 000 EUR, and at the same time is less than 10% of the basic contract value.

Any contract amendment must be done in writing, otherwise will not be valid.

X. APPENDENCIES TO REQUEST FOR PROPOSAL

- A) Appendix No. 1 - The offer form,
- B) Appendix No. 2 - Statement concerning fulfillment of all the requirements set out in part IV of the Request for offers,
- C) Appendix No. 3 - Statement regarding personal and capital connections with the Ordering Party,
- D) Appendix No. 4 - Declaration of compliance with the information obligations provided for in Article 13 or Article 14 of the GDPR