

REQUEST FOR PROPOSAL No. 17/2021-ARG**I. ORDERING PARTY**

OncoArendi Therapeutics S. A. ul. Żwirki i Wigury 101 02-089 Warsaw VAT ID: 728 27 89 248	Contact person: Kinga Woźniak e-mail: k.wozniak@oncoarendi.com phone no. +48 573 900 610
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II. OBJECT FOR THE REQUEST

Advisory services and expert advice in the field of clinical oncology in designing a clinical trial and preparing the documentation necessary to start a clinical trial

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.01.01.01-00-415/17)

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 Competitiveness 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 doubt, 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 and experience to carry out the described activity and have the appropriate technical potential and personnel capable of performing the contract.

In terms of human resources, the Ordering Party requires the Contractor to engage an expert, who:

- holds a scientific degree, at least Doctor of Medicine- **MD PhD**
 - practices a profession of a physician (doctor), e.g. part-time
 - has appropriate knowledge in the area of clinical oncology and early phase clinical trials, including studies in which the investigational medicinal product is administered to a human for the first time (first in human trials)
 - has an experience in both design and conduct of early phase (I/II) oncology clinical trials, including first-in-human trials
 - has knowledge of current scientific guidelines related to oncology, clinical pharmacology and clinical trials on humans (including first-in-human trials) issued by European Medicines Agency (EMA)
 - has an experience in preparation of scientific and regulatory documents related to clinical trials, in particular the clinical study protocols
 - is experienced in providing consulting services to clinical trial sponsors
 - is well oriented in current pre- and clinical development programs of novel oncology therapeutics worldwide;
- B) will ensure that involvement of expert in other professional ventures will not interfere with the implementation of this order and that he will be able to efficiently answer the questions / problems raised (In urgent matters*, the Ordering Party requires a reply or establishing a further path of procedure (course of action) within max. 2 business days);
- C) are in a good economic and financial standing, which assures proper execution of the project;
- D) will pursue the contract in a way that is beneficial to the environment by minimizing the consumption of materials, raw materials, energy, etc.

* Urgent matters are understood as crucial for the trial project, which will be clarified at the cooperation initiation meeting (kick-off meeting).

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. The model statement is attached as Appendix 2 to this request for proposal. The Contractor is obliged to attach the CV of the person dedicated to perform the service, that meets the requirements indicated above.

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 Issuing 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 - Advisory services in the field of research and development

Description of subject of the order:

OncoArendi Therapeutics SA (OAT) is developing the low-molecular OATD-02 arginase inhibitor as an innovative drug in oncological indication. Therefore, OAT is looking for an oncology expert who will be involved in designing a clinical trial and preparing the documentation necessary to start a clinical trial.

The subject of the order is expertise and scientific advice (before starting a clinical trial) in the field of:

- development of new small molecule drugs in oncological indications
- designing early-stage oncological clinical trials (including preparation of documents for a Scientific Advice meeting)
- preparation of scientific and regulatory documents related to clinical trials e.g. clinical trial protocol

In addition, the expert will participate in external and internal meetings (before the commencement of the clinical trial) related to the above scope of tasks.

The commencement of a clinical trial is tantamount to obtaining the permission of the relevant Regulatory Authority and a positive opinion of the Bioethics Committee.

The expert's estimated number of involvement hours will be: **100 working hours** (12.5 working days) **

In urgent matters, the Ordering Party requires an answer or development of a further procedural strategy within max. 2 working days (Urgent matters are understood as crucial for the research project, in the case of e-mail correspondence, the appropriate marking should be used, e.g. by adding in the subject of the message: URGENT).

** The Ordering Party reserves the right not to use the full estimated number of hours indicated above. The Contractor is not entitled to claim the Ordering Party to use the full estimated number of hours and will receive remuneration only for the man-hours ordered by the Ordering Party and performed.

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 will be provided electronically at Contractor's request. The scan of the filled and hand-signed CDA should be sent by email to: k.wozniak@oncoarendi.com.

The hand signed original of the confidentiality agreement should be sent to:

OncoArendi Therapeutics S.A., ul. Żwirki i Wigury 101, 02-089 Warsaw

The duration of the contract: up to 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 smallest Net price

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

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

In the payment deadline criteria points will be awarded according to the following scheme:

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

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

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

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: **30/03/2021, 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: k.wozniak@oncoarendi.com or via the Competitiveness Database 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 k.wozniak@oncoarendi.com or by phone **+48 573 900 610** no later than 26/03/2021 13:00 (CET). Contact person is: Kinga Woźniak.
- VII.9 Any questions concerning the formal issues of the tender should be addressed to k.kazimierczak@oncoarendi.com no later than 26/03/2021 13:00 (CET). Contact person is: Kinga Kazimierczak.
- 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, USD or GBP.

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 Competitiveness Database.

IX. MOST IMPORTANT PROVISIONS OF THE AGREEMENT

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

- 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