



Warsaw, 07/12/2018

REQUEST FOR PROPOSAL NO 73/2018- ARG

I. Ordering Party

OncoArendi Therapeutics S. A. ul. Żwirki i Wigury 101 02-089 Warszawa VAT ID: 728 27 89 248	Contact person: Anna Lipińska a.lipinska@oncoarendi.com tel. +48 573 900 610
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II. OBJECT FOR THE REQUEST:

Preparation of drug development plan (DDP) for OATD-02 compound and clinical trial protocol synopsis for a Phase 1 evaluation of OATD-02, as a single agent and in combination molecularly targeted agents therapy, in patients with advanced/metastatic solid tumors.

The order carried out as a part of the projects titled:

— **ARG:** „PRE-CLINICAL AND CLINICAL DEVELOPMENT OF ARGINASE INHIBITOR FOR CANCER IMMUNOTHERAPY” (POIR.01.01.01-00-415/17)

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

III. THE FORM OF THE ORDER:

- III.1 The request is not made under The Public Procurement Law (Journal of laws of 2013, item 907 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 The Ordering Party reserves the right to change the content of this request. If the changes can affect the content of tenders submitted in the procedure, the Ordering Party shall extend the tender submission deadline. Any changes made shall be provided promptly to all tenders to which the request was sent and shall be binding on them.
- 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.

IV. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS:

- 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, i.e. to a Contract Research Organization (CRO) dedicated to design & conduct clinical oncology studies, with particular expertise in early phase and immuno-

oncology studies.

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

- A) Have the necessary expertise level to perform the contract.
- B) Are in a good economic and financial standing, which assures proper execution of the project in the declared time.
- C) Will pursue the contract in a way that is beneficial to the environment by minimizing the consumption of materials, raw materials energy, etc. (with environmental certificates such as ISO 14001:2015)

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.

IV.3 In terms of knowledge and experience, the Ordering Party requires that the Contractor:

- During the last 5 years has been involved in design of at least 10 early phase oncology studies, what includes immuno oncology studies.
- is able to provide strategic oncology drug development consulting and expert advice.

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.

IV.4 In terms of resources, the Ordering Party requires that the Contractor engage experts with documented experience that meet the following requirements for the implementation of the Order

1) A Drug Development Expert

- Having at least 5 years of experience in providing expert advice on the drug development, in accordance with current relevant guidelines of ICH-GCP (International Harmonization Council for Technical Requirements for Registration of Medicinal Products for Human Use) Technical Requirements for Pharmaceuticals for Human Use), EMA (European Medicines Agency) and FDA (American Food and Drug Administration).

- Being an author of at least 10 scientific publications in the field of drug development, clinical study design or related.

2) A Therapeutic Area Expert (Oncology/Immunooncology)

- holds PhD, MD or MD/PhD

- Expert in oncology research, being able to provide a scientific, medical and clinical advice on the development of anticancer drugs/immunotherapies.
- Familiar with health authority, GCP and ICH requirements, being able to advice on the development of anticancer drugs also from the regulatory perspective
- Has sufficient experience in protocol writing and study execution, collected within last 5 years

3) Biostatistician:

- graduated or postgraduated in (bio)statistics
- within last 3 years, has gained a sufficient experience in designing study protocols, statistical analysis plans, as well as in performing study results analysis.
- has been involved in early phase (phase I or II) studies in the Oncology Therapeutic area.

4) Quality Assurance Expert

- with a minimum of 3 years of experience in assessing compliance of clinical trial protocols with relevant ICH-GCP (International Harmonization Council for Technical Requirements for Registration of Medicinal Products for Human Use | International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), EMA (European Medicines Agency) and FDA (American Food and Drug Administration) guidelines.

As a proof of the above the Ordering Party requires that the Contractor submit, along with the tender documents, some example CVs of experts planned to be involved.

IV.5 Excluded from the proceedings shall be those contractors who are personally or equity related to the Ordering Part by 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.6 Issuing the offer represent the full acceptance of the rules set in this Request.

V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:

CPV Code: 73200000-4 (Advisory services in the field of research and development)



V.1 The object of the request is:

Preparation of drug development plan (DDP) for OATD-02 compound and clinical trial protocol synopsis for a Phase 1 evaluation of OATD-01, as a single agent and in combination with molecularly targeted agents therapy, in patients with advanced/metastatic solid tumors.

It is expected that the task will be completed by the end of March 2019, according to the proposed course of work:

- the Service provider will get acknowledged with the Ordering Party documentation and will meet in person or remotely) in order to agree the most efficient design for the Phase I study. This meeting will involve an Expert on Drug Development (for study design), a Therapeutic Expert and a Biostatistician.
- Once the design is agreed, the service provider will develop a full Drug Development Plan and ICH-compatible Study Synopsis for the planned trial, using their template and according to the relevant guidelines.
- An appropriate expert input is expected on the key assumptions of the study, especially on:
 - selection of appropriate patient populations
 - selection of appropriate dose escalation methods
 - selection of an adequate agent for combination therapy
 - selection of appropriate safety and tolerability monitoring methods of OATD-02, as well as its pharmacokinetics
 - selection of appropriate endpoint to measure efficacy (biomarkers and tumor treatment response), for OATD-02 alone and in combination with molecularly targeted agents therapy
- The service provider will provide two drafts and a final version of the protocol synopsis; each draft protocol will undergo QC (quality control), prior to provision to OncoArendi Therapeutics.
- The Ordering Party will provide one set of consolidated comments to each draft;
- The final version of the document will be assessed by a Quality Assurance Specialist as for compliance with applicable ICH-GCP/EMA/FDA guidelines and regulations

V.2. Attachment No.5 that contains some basic information about OATD-01 compound and its expected mechanism of action (in the form of Power Point slides) will be distributed to a potential Service Provider only if they express the intention of participation in the tender . It has to be done via email sent to a.lipinska@oncoarendi.com. Attachment No.05 will be provided by email within 16 business hours following the receipt of request.

VI. EVALUATION OF THE OFFERS:

VI.1 Price – weight: 90% (90 pts.)



A) In this criterion points will be calculated 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

90 – weight of the criterion (90%)

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

In the payment deadline, points will be awarded according to the formula:

10 points – when the payment deadline is over 60 days of the invoice delivery date

5 points – when the payment deadline is between 30 and 60 days of the invoice delivery date

10 – weight of the criterion (10 %)

VI.3 In the case of two or more tenders with equal number of points awarded, to guarantee performance of the contract in a manner favorable to the environment, by providing minimize the consumption of materials, raw materials, energy etc. any environmental certifications will be taken onto consideration (eg. ISO 14001:2015).

If the abovementioned does not allow to choose the best offer, 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 institution.

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: **14/12/2018 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 only via email to: **a.lipinska@oncoarendi.com**

VII.6 The date of receiving the email shall be considered as a date of issuing the offer.

VII.7 Offers that do not meet the deadline, are incomplete 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 a.lipinska@oncoarendi.com (+48 573 900 610) no later than 11/12/2018 23:59 (CET). Contact person is: Anna Lipińska.

VII.9 Any questions concerning the formal issues of the tender should be addressed to m.skrzek@oncoarendi.com (+48 22 552 67 24) no later than 11/12/2018 23:59 (CET).

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 concurrency database.

IX. MOST IMPORTANT PROVISIONS OF THE AGREEMENT:

- IX.1 Supplier will be obligated to enter into the agreement including all conditions presented in the Request for the Offer in the place and time specified by the Ordering Party.
- 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 Service Provider selection, unless:
- A) The amendments concern performing additional services by the Service Provider, not covered by the basic contract, provided they are necessary and the following conditions are met:
 - i. The change of the Service provider cannot be made due to 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 Service Provider 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 contact 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 209 000 EUR, and at the same time is less than 10% of the basic value.

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

- IX.3 Information regarding contractual penalties:
- A) If the offered project execution time (as defined in the offer) extends for at least 15 days, the Service Provider shall pay the Ordering Party a contractual penalty of 1,5% of the net offer price for exceeding the time limit, and then another 2% of net offer price for each additional 15 days of delay. Moreover, the Ordering Party will gain a right to withdraw from the contract of the project



execution time is exceeded by at least 60 days. The Ordering Party may withdraw from the agreement until 31st Dec 2019.

- B) Due to the termination or withdrawal from the Agreement by either Party for reasons caused by the Service Provider, the Ordering Party will change a contractual penalty of 25% of net offer price.
- C) The formal basis for changing contractual penalties will be a debit note the Ordering Party delivers to the Service Provider. The Ordering Party shall be entitled to deduct contractual penalties from payments due to the Service Provider.
- D) The Ordering Party has the right to claim damages in the amount exceeding contractual penalties based on general principles.
- E) The Ordering Party has the right to claim damages in the amount exceeding contractual penalties based on general principles.
- F) Contractual penalties sum up.

X. APPENDENCIES:

- A) The offer form.
- B) Statement concerning fulfilment of all the requirements set out in part IV of the Request for offers.
- C) Statement concerning persona or/and capital connections between the Service Provider and the Ordering Party.
- D) Declaration of compliance with the information obligations provided for in article 13 or article 14 of the GDPR
- E) Basic information about OATD-01 compound and its expected mechanism of action (on request)