



Warsaw, ~~26 NOV 2018~~

14/12/2018

REQUEST FOR PROPOSALS 39/2018 – ARG
Change of the deadline and contact person

I. ORDERING PARTY:

OncoArendi Therapeutics SA	Contact person
Żwirki i Wigury 101 02-089 Warszawa VAT ID 728 27 89 248	Anna Lipińska a.lipinska@oncoarendi.com phone no. +48 573 900 610

II. OBJECT OF THE REQUEST / PROPOSAL:

**Professional consulting service related to drug development and regulatory affairs,
and preparation of regulatory documents**

The order 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 The Public Procurement Law (29/01/2004 i.e. Dz. U. z 2013 r., poz. 907 z późn. zm.).
- 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 winning 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 tenderers 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 an offer for a part of an 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.
- IV.2 The offers may be issued by parties who:
 - have the necessary knowledge, qualifications and necessary human resources to execute the contract,
 - have at least 5 years of experience in providing, to pharma and biotech companies, professional consulting service related to drug development and regulatory affairs, and building EMA and US FDA compliant regulatory strategies for drug candidates,
 - have relevant experience in organizing and supporting scientific advice meetings with regulatory agencies (European Medicines Agencies, European Union – National Competent Authorities, US Food and Drug Administration) for pharma and biotech companies.



- have relevant experience in preparation and maintenance of regulatory documentation required during drug development process like Briefing Books, Investigator's Brochures, Investigational Medicinal Product Dossiers, CTD modules for pharma and biotech companies,
- are in a good economic and financial standing, which assures proper execution of the project in the declared time,

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 Regarding human resources, the Ordering Party requires the Service Provider to engage professional, multi-disciplinary team of experts:

- with thorough understanding of 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*),
- with documented experience in preparation of regulatory documentation required during drug development process like Briefing Books, Investigator's Brochures, Investigational Medicinal Product Dossiers, CTD modules etc.,

Fulfillment of the above conditions will be evaluated on the basis of a) statement of the Service Provider, a model statement is attached as Appendix 2 to the Request for the Offer, b) CVs of expert that would be engaged in the project.

IV.5 Excluded from the proceedings shall be those contractors who are personally or equity related to the Ordering Part by in particular:

- 1) participation in the company, in a civil or limited partnership.
- 2) holding at least 10 % shares or interests.
- 3) serving a function of a member of the supervisory organ, a member of the management organ or proxy.
- 4) 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.

V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:

CPV code: 73200000-4

V.1 General Information

OncoArendi Therapeutics is developing a low-molecular-weight arginase inhibitor OATD-02 as an innovative cancer treatment. The Sponsor intends to apply for the Scientific Advice meeting to one of the European Union National Competent Authority in Q1 2019 and submit the Clinical Trial Applications for the First-in-Human clinical trial in oncology patients to selected European Union National Competent Authorities in H2 2019.

The scope of this order includes:

- gap analysis and assessment of data backlog in OATD-02 research program,
- building EMA and US FDA compliant regulatory strategy for OATD-02 drug candidate,



- preparation and professional assistance during Scientific Advice meeting with representatives of one of the European Union National Competent Authority,
- preparation of the initial Investigational Medicinal Product Dossier for OATD-02 drug candidate
- preparation of the initial Investigator's Brochure for OATD-02 drug candidate

More detail information about the project as well as the order's scope is presented in Appendix No. 6 to this Document. The Appendix No. 6 will be disclosed on the Contractor's demand only after signing the confidentiality agreement available as Appendix No. 5. The scan of filled and signed confidentiality agreement should be sent by email to a.lipinka@oncoarendi.com. The Appendix No. 6 will be provided within 48 hours from receiving a scan of the signed confidentiality agreement.

V.2 Contract period

The contract will be valid until 30/06/2020

VI. EVALUATION OF THE OFFERS:

VI.1 Price – weight: 90% (90 pts.)

In this criterion point will be calculated according to the formula below:

Points received $P_c = C_{min} / C_{evaluated} \times 90$ pts.

where:

P_c – 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 60 or more days from the invoice date

5 points - when the payment deadline is between 30 and 59 days from the invoice date

0 points - when the payment deadline is less than 30 days from the invoice date

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 into consideration (eg.ISO).

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 those 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 The costs of the offer preparation shall be incurred by the offering party.

VII.4 Offers must be submitted no later than: **31/01/2019 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 the 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 (+48 512 974 496) no later than **18/01/2019** ~~14 DEC 2018~~ **16:00 (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 **18/01/2019** ~~14 DEC 2018~~ **16:00 (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 the Minister of Finance of 28 November 2008 (Journal of Laws of 2008, No. 212, item 1337, as amended).
- VII.13 The offer price should include VAT. The correct determination of VAT is the 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 amended).
- 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 in PLN, EUR, USD or GBP.

VIII. TENDER RESULTS

The winner will be informed via e-mail. Formal results will be also published on the Ordering Party's website (www.oncoarendi.com) and Baza Konkurencyjności.

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:
- 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:
 - the change of the Service Provider cannot be made due to economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of the basic contract,
 - the change of the Service Provider would cause significant inconvenience or substantial cost increase to the Ordering Party,
 - the value of any subsequent changes do not exceed 50% of the basic contract value,
 - the amendment does not lead to a change in the nature of the contract and the following conditions are met:
 - the need for the contract change is brought about by circumstances which the Ordering Party, acting with due diligence, could not foresee,
 - the value of a change does not exceed 50% of the basic contract value,
 - the amendment does not lead to a change in the nature of the contract and the total value of 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.

Appendices:

- The offer form (Appendix 1).
- Statement concerning fulfillment of all the requirements set out in part IV of the Request for offers (Appendix 2).
- Statement concerning personal or/and capital connections between the Service Provider and the Ordering Party (Appendix 3).
- Declaration of compliance with the information obligations provided for in article 13 or article 14 of the GDPR (Appendix 4).



5. Confidentiality Agreement (Appendix 5).