

REQUEST FOR PROPOSAL No. 20/2020 – SARCO**I. ORDERING PARTY**

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II. OBJECT FOR THE REQUEST

Expert advisory services in the field of preclinical studies regarding chronic toxicity studies in rodent (Sprague Dawley rat) and non-rodent (Beagle dog) for OATD-01 chitinase inhibitor

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

„Preclinical and clinical development of drug candidate OATD-01, for the treatment of sarcoidosis patients” (MAZOWSZE/0128/19)

as part of the "Path for Mazovia" competition co-financed by the National Centre for Research and Development from national funds conducted in the mode of request for quotation in accordance with paragraph 10 of the Grant Agreement.

III. THE FORM OF THE ORDER

- III.1 The request is not made under The Act of 29 January 2004 Public Procurement Law (Journal of laws of 2019, item 1843).
- III.2 This order is carried out in accordance with the principle of competitiveness, equal treatment of contractors, openness, economy, impartiality, objectivity and efficiency. The Ordering Party works to ensure that all potential contractors have the same access to information concerning a given public contract and that no contractor is privileged over another and the procedure will be conducted in a transparent manner.
- 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 may 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 any changes by publishing relevant information on its website. Any changes made shall be also provided to all Tenders to which the request was sent or to all Tenders 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 an offer for part of the order. It is not possible to make a variant offer.

IV. THE 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:

- 1) have the necessary qualifications to carry out the described activity:
 - A. have at least 5 years of experience in providing consulting service related to preclinical drug development programs;
 - B. within the last 3 years designed and oversaw for third parties at least 10 development programs from early to late stage, including long-term preclinical safety programs to support Phase II and Phase III clinical trials for NME, new molecular entities;
 - C. within the last 3 years designed and oversaw for third parties at least 5 toxicity programs supporting treatment of chronic conditions including longer-term toxicity studies in rodent and non-rodent species of up to 6 to 9 months in duration, or longer, designed to determine:
 - a) the potential organs of toxicity,
 - b) the reversibility of toxicities observed,
 - c) the NOAEL,
 - d) the potential clinical risk in relation to the anticipated clinical dose following longer-term treatment.
 - D. within the last 3 years performed for third parties at least 10 audits of CRO's research sites conducting preclinical GLP studies.
 - E. within the last 3 years prepared for third parties at least 10 Investigator's Brochures and/or similar regulatory documentation such as CTD modules, Briefing Books etc.
- 2) have the appropriate technical potential to perform the contract;
- 3) are in a good economic and financial standing, which assures proper execution of the project;
- 4) 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. The model statement is attached as Appendix 2 to this request for proposal.

IV.3 Regarding human resources, the Ordering Party requires the Service Provider to engage experts with documented experience in:

- A. designing preclinical drug development strategies in the context of full development program;
- B. designing ICH, EMA & FDA compliant, chronic toxicity studies for innovative medicinal products for

human use; [ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), EMA (European Medicines Agency), FDA (Food and Drug Administration)];

- C. analysis, evaluation, interpretation and positioning of results from chronic toxicity studies;
- D. review, analysis, interpretation of histopathological slides from chronic toxicity studies;
- E. monitoring of studies in preclinical development;
- F. scientific writing of regulatory documents (EU & US): briefing documents for Scientific Advice, Investigational Brochure, CTD modules and Briefing Books etc.;
- G. interactions with Regulatory Authorities.

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 CV's of the above mentioned experts. The model statement is attached as Appendix 2 to this request for proposal.

IV.4 Excluded from the proceedings shall be those contractors who are related to the Ordering Party. The Contractor is considered to be related if it is:

- a) an affiliated, a subsidiary, a jointly controlled or a dominant entity in relation to the Ordering Party in the understanding of the Accountancy Act of 29 September 1994,
- b) remaining with the Ordering Party or its officers by any actual or legal relationship that may give rise to any reasonable doubts as to the impartiality in the selection of the supplier of goods or services, and in particular by the relationship of marriage, consanguinity or affinity up to the second degree, adoption, guardianship or custody, including through membership in the corporate bodies of the supplier of goods or services,
- c) classified as a linked enterprise or a partner enterprise of the Ordering Party in the understanding of the Commission Regulation (EU) No 651/2014,
- d) an entity personally related to the Ordering Party in the understanding of Art. 32 Sec. 2 of the VAT Act of 11 March 2004.

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.5 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 (Research and development consultancy services)

Order description:

Expert advisory services in the field of preclinical studies regarding chronic toxicity studies in rodent (Sprague Dawley rat) and non-rodent (Beagle dog) for OATD-01 chitinase inhibitor

Scope of the order:

- a) designing preclinical drug development strategies in the context of full development program;
- b) designing ICH, EMA & FDA compliant, chronic toxicity studies for innovative medicinal products for human use;
- c) analysis, evaluation, interpretation and positioning of results from chronic toxicity studies in rodent and non-rodent;
- d) review, analysis, interpretation of histopathological slides from chronic toxicity studies;
- e) verification of reports from completed chronic toxicity studies;
- f) monitoring of studies performed by CRO at the request of Ordering Party;
- g) performing an audit of CRO's research site.

The Ordering Party anticipates the demand for expert advisory services in the amount of approx. 725 hours.

The Ordering Party reserves the right not to use the full estimated number of hours indicated above.

The Contractor is not entitled to apply to the Ordering Party with claims for the use of the full estimated number of hours and will receive remuneration only for hours ordered.

Order due date: from signing the contract until 31.12.2021

VI. EVALUATION OF THE OFFERS

VI.1 Price – weight: 80% (80 pts.)

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

$$Pc = \frac{C_{min}}{C_{evaluated}} \times 80$$

Pc – Points received

C_{min} – The lowest Net price

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

80 – weight of the criterion (80%)

VI.2 Payment deadline – weight: 20% (20 pts.)

In the Payment deadline criterion points will be awarded as below:

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

- 15 points – when the payment deadline is set at 25-29 days from the date of delivery of a correctly issued invoice
- 10 points – when the payment deadline is set at 20-24 days from the date of delivery of a correctly issued invoice
- 5 points – when the payment deadline is set at 14-19 days from the date of delivery of a correctly issued invoice
- 0 points – when the payment deadline is 13 or less days from the date of delivery of a correctly issued invoice

20 – weight of the criterion (20 %)

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: **13/05/2020 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: p.dera@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 Paulina Dera (+48 605 532 126) no later than 11/05/2020 15:00 (CET). Contact person is: Paulina Dera.
- VII.9 Any questions concerning the formal issues of the tender should be addressed to k.kazimierczak@oncoarendi.com no later than 11/05/2020 15:00 (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).

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/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 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 concerning connections between the Contractor and 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.