

REQUEST FOR PROPOSAL No. 28/2020 – SARCO**I. ORDERING PARTY**

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II. OBJECT FOR THE REQUEST

Professional advisory services in the field of registration and regulatory matters related to the clinical development of a drug candidate (OATD-01) and preparation of documents required by the Polish, German, Dutch and French regulatory authorities.

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 the changes made by publishing relevant information on its 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 an offer for part of the order.

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:

- A) Have the necessary qualifications (minimum 5 years of experience in providing advisory services related to regulatory activities for clinical development programs of innovative drugs), and:
- o Over the last 5 years, they participated in **10** Scientific Advice meetings, including **2** with representatives of MEB
 - o Over the past 5 years, they have prepared, at the request of third parties, at least **10** Investigator's Brochures and other documentation required by international regulations and local regulations necessary to obtain permission to start and conduct a clinical trial
 - o Over the past 5 years, they have prepared (at the request of third parties) at least **10** Phase II Clinical Trial Protocols approved by regulators
- B) have the appropriate technical potential and personnel capable of performing the contract
- 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. 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 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.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:

73110000-6 - Research services

73200000-4 - Research and development consultancy services

Order description:

In connection with the planned commencement of a new clinical trial (Phase 2a trial) for the first-in-class mammalian acid chitinase inhibitor, OncoArendi Therapeutics (OAT) has started work on the preparation of documentation necessary to obtain a permit to conduct the study. OAT is planning to conduct a multicentre clinical trial in several European countries and plans to apply for the appropriate authorization from the competent national authorities, i.e. German: the Federal Institute for Drugs and Medical Devices (BfArM), the Dutch (Centrale Commissie Mensgebonden Onderzoek, **with the support of / together with College ter Beoordeling van Geneesmiddelen**, MEB), Polish (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) and the French Authority (Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM, France). In addition, before submitting the Clinical Trial Application (CTA), OAT plans to apply for a Scientific Advice consultation meeting with representatives of the Dutch authority: Centrale Commissie Mensgebonden Onderzoek **with the support of/together with College ter Beoordeling van Geneesmiddelen**.

The order includes:

- Gaps analysis concerning the documentation submitted to regulatory authorities and Bioethics Committees from the pre-clinical and clinical trials conducted so far.
- Organization and professional support during a Scientific Advice meeting with representatives of the Dutch regulatory authority, including:
 - preparation and submission of an application for a SA meeting with representatives of MEB (**College ter Beoordeling van Geneesmiddelen**);

- preparing a list of issues (questions) requiring consultation with representatives of the office along with the presentation of the OAT position;
 - Preparation of a presentation including a list of sponsor's questions related to the planned study and other documents required by the regulator using appropriate templates, including the briefing book
 - Payment of the official fee for SA*
 - Participation of an experienced expert (or group of experts) in a meeting with representatives of MEB (College ter Beoordeling van Geneesmiddelen);
 - Prepare a report (minutes) from the meeting which will be submitted to the MEB (College ter Beoordeling van Geneesmiddelen)
- Verification of the Investigational Medicinal Product Dossier (IMPD) for compliance with regulatory requirements (this document will be submitted with the CTA for a clinical trial)
- Update of Investigators Brochure (IB) - this document will be submitted with the CTA for the clinical trial and attached to the documentation prepared for at Scientific Advice
- Preparation of a clinical trial protocol in accordance with applicable regulations and guidelines

*The Contractor will pay the official fee for Scientific Advice on behalf of OAT, and the Ordering Party will reimburse Contractor for it.

The detailed synopsis of planned 2a study is presented in Appendix No. 5 to this Document. The Appendix No. 5 will be disclosed on demand to the Contractors who express their interest in participating in the procedure, ask for it and send electronically a scan of the signed Confidential Disclosure Agreement (CDA). The CDA will be provided electronically at Contractor's request.

The scan of filled and signed CDA should be send by email to k.wozniak@oncoarendi.com .The Appendix No. 5 will be provided within 24 working hours from receiving a scan of filled and signed CDA.

Submitting an application for SA is a critical element and should take place in the second half of November 2020. All documents required for the meeting (e.g. updated ~~researcher's~~ Investigator's brochure) should be ready by then.

Order due date: from the moment of signing the contract until **May 31, 2021.**

VI. EVALUATION OF THE OFFERS

VI.1 **Price** – weight: 80% (80 pts.)

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

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

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.)

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

20 points – when the payment deadline is 23-30 days from the date of delivery of a correctly issued invoice

10 points - when the payment deadline is set between 15-22 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

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: **21/09/2020 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: k.wozniak@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 k.wozniak@oncoarendi.com (+48 573 900 610) no later than 15/09/2020 15:00 (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 15/09/2020 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, 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).

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 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 point 2 of Appendix 1) extends for at least 30 days, the Contractor 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 when execution time is exceeded by at least 60 days. The right of withdrawal can be exercised until December 31, 2021 .

- B) Due to the termination or withdrawal from the Agreement by either Party for reasons caused by the Contractor, the Ordering Party will charge a contractual penalty of 15% of net offer price.
- C) The formal basis for charging contractual penalties will be a debit note the Ordering Party delivers to the Contractor. The Ordering Party shall be entitled to deduct contractual penalties from payments due to the Contractor.
- D) The Ordering Party has the right to claim damages in the amount exceeding contractual penalties based on general principles.
- E) Contractual penalties will be paid within 7 days from the debit note receipt date.
- F) Contractual penalties sum up.

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 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.
- E) Appendix No. 5 Protocol Synopsis of planned 2a study