



Warsaw, 27/08/2018

## REQUEST FOR PROPOSAL No. 51/2018 - SARCO

### I. THE ORDERING PARTY:

<p><b>OncoArendi Therapeutics S. A.</b> ul. Żwirki i Wigury 101 02-089 Warszawa VAT ID: 728 27 89 248</p>	<p><b>Contact person:</b> <b>Anna Cabaj</b> <b>e-mail: a.cabaj@oncoarendi.com</b> <b>Tel. + 48 573 446 723</b></p>
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### II. OBJECT FOR THE REQUEST:

#### **Execution of the developmental and reproductive toxicology studies program for the chitinase inhibitor OATD-01, developed as an innovative treatment for sarcoidosis**

The request for offers is carried out with the reference to the application process for the grant titled:

**SARCO: PRECLINICAL AND CLINICAL DEVELOPMENT OF SMALL MOLECULE OATD-01, A DRUG CANDIDATE FOR THE TREATMENT OF SARCOIDOSIS,**

which would be co-financed by the National and European Union Funds through the sectoral programme InnoNeuroPharm (Call for proposals 3/1.2/2018) 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 pricing proposals submitted in the procedure, the Ordering Party will extend the tender submission deadline. Any changes made will be provided promptly to all parties invited to submit the pricing proposal and to all parties that informed the Ordering Party about being interested in participating in the tender.
- 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 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:

- A) Have the necessary qualifications, experience, background data, appropriate technical capabilities, current GLP processes (approved by the national authority as demonstrated by documented evidence), and necessary human resources for executing the project described in the Request for Proposal No. 51/2018 - SARCO and in the Appendix no. 6.
- B) Guarantee the studies to be performed in a research site located on the territory of OECD countries.
- C) Have at least 10 years of experience in providing service covered by this Request for Proposal and involving execution of GLP DART studies for innovative medicinal products for human use and maintains historical background data for DART studies to aid in interpretation of findings over at least the past 5 years.

To prove the above, the Service Provider will enclose together with the Pricing Proposal the list of studies conducted within the last 5 years (2013 – 2017). The list should include information about the number and type of conducted DART studies, including species, route of administration and exact study type (main GLP or non-GLP dose-range finding studies).

- D) Within last 5 years (2013 - 2017) executed at least 50 GLP DART studies, of which at least 5 were conducted for each study type (Fertility and early embryonic development, embryo-foetal development in rodents and non-rodents, and pre- and postnatal development studies) for innovative medicinal products for human use.
- E) Work under GLP for a least the last 5 years (documented evidence to be provided).
- F) Guarantee that any inspections that were carried out within the last five years didn't reveal any critical findings and provide their regulatory inspection history over the last 5 years.

The Ordering Party reserves the right to enquire copies of selected documents issued by regulatory agencies after inspections which took place between August 2013 and August 2018. If copies of the above documents are not disclosed to the Ordering Party within 24 hours from sending a written request for making them available, the offer will be considered invalid.

- G) Ensure animal welfare in compliance with EU Directive 2010/63/EU and have current AAALAC accreditation (AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care International).
- H) Are in a good economic and financial standing, which assures proper execution of the project in the declared time and guarantees availability of GLP-compliant archiving of study related materials and documentation for at least 15 years.
- I) 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 No. 2 to this request for proposal), copies of GLP certificate and a copy of the AAALAC accreditation letter.



- IV.3 Regarding human resources, the Ordering Party requires the Service Provider to engage:
- A) Project Manager who have at least 2 years of experience in coordinating the research and development projects carried out on behalf of third parties.
  - B) Study Directors who have been trained in the field of DART studies for at least 3 years and who have documented experience over at least the past 5 years as responsible study directors conducting DART studies in rodents and non-rodents, including documented evidence of their ongoing training both from a scientific and a GLP perspective and thorough knowledge of the current, applicable OECD, ICH and national/regional guidelines. The Ordering Party requires an experienced specialist to be assigned as the Study Director of the GLP studies meeting the above requirements.
  - C) Foetal Pathologists who have documented experience in the examination of DART study specimens of rodents and non-rodents over at least the past 10 years, with documented evidence of their ongoing training both from a scientific and a GLP perspective and thorough knowledge of the current, applicable OECD and ICH guidelines. The Ordering Party requires a specialist planned to be assigned as a foetal pathologist responsible for the evaluation of the collected specimen.
  - D) Technical staff undertaking all required activities associated with the study including, but not limited to, animal handling, treatment, in-life observations, blood sampling, sample handling and analysis, necropsies etc. with at least 5 years' experience and documented evidence of their ongoing training both from a scientific and a GLP perspective.
- IV.4 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 No. 3 to this request for proposal.

IV.5 The Ordering Party does not allow to subcontract to a third party any part of the GLP standard service.

IV.6 Issuing the offer represents the full acceptance of the rules set in this Request.

## **V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:**

CPV Code: 73111000-3 (Research laboratory services)

### V.I General Information

The order includes the execution of selected developmental & reproductive toxicology studies (some of them in compliance in GLP) for OATD-01 and ADME studies with <sup>14</sup>C-OATD-01. OATD-01 is the low-molecular weight



organic compound, chitinase inhibitor that is being developed by OncoArendi Therapeutics SA as an innovative treatment of sarcoidosis.

The Ordering Party requires that the research program is carried out in the compliance with the current OECD (*Organisation for Economic Co-operation and Development*), ICH (*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*), EMA (*European Medicines Agency*), US FDA (*Food and Drug Administration*) guidelines, in certified research sites that are located in the OECD country/-ies.

The detailed scope of the research program together with the design of individual studies are 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.cabaj@oncoarendi.com](mailto:a.cabaj@oncoarendi.com). The Appendix No. 6 will be provided within 48 hours from receiving a scan of the signed confidentiality agreement.

#### V.2 The project execution timeline

The Ordering Party expects the project to be executed in no longer than 24 months. The project execution time is defined as time from the signing of the contract to submitting of all audited draft reports.

The Ordering Party expects audited draft reports for each study type to be issued within 3 months from the last day of the experimental phase.

The Ordering Party also requires that the audited draft reports of the embryo-fetal development studies in rats and rabbits and fertility studies to be available not later than Dec-2019.

#### V.3 The Ordering Party will provide

1. Sufficient amount of the test item along with the corresponding analytical report.
2. Sufficient amount the test item standard along with the corresponding analytical report.
3. Sufficient amount of the internal standard along with the corresponding analytical report.
4. Dosing formulation procedure.
5. Bioanalytical method procedure.
6. Material Safety Data Sheet for the test item.

### VI. EVALUATION OF THE OFFERS:

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

A) In this criterion points will be calculated according to the formula below:

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

Pc – Points received

C<sub>min</sub> – The smallest Net price

C<sub>evaluated</sub> – Net price of the offer being evaluated

80 – weight of the criterion (80%)



The total cost of the service is the sum of the prices for individual studies, which have been priced according to the information provided in the Request for Proposal No. 51/2018 – SARCO and Appendix No. 6 to the Request for Proposal.

VI.2 Project initiation – weight: 20% (20 pts.)

For the purpose of this project it is assumed that signed contract is in place by the end of October 2018. In this criteria, points will be awarded according to the formula:

20 points – when the first studies are initiated in less than 2 months from the date of signing the contract.

10 points – when the first studies are initiated between 2 and 4 months from the date of signing the contract.

0 points – when the first studies are initiated in more than 4 months from the date of signing the contract.

20 – weight of the criterion (20 %).

The project execution time is defined as time from the signing of the contract to the date of receiving all audited draft reports.

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: **26/09/2018 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.cabaj@oncoarendi.com](mailto:a.cabaj@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.cabaj@oncoarendi.com](mailto:a.cabaj@oncoarendi.com) (+48 573 446 723) no later than 20/09/2018 15:00 (CET). Contact person is: Anna Cabaj.

VII.9 Any questions concerning the formal issues of the tender should be addressed to [m.skrzek@oncoarendi.com](mailto:m.skrzek@oncoarendi.com) (+48 22 552 67 24) no later than 20/09/2018 15:00 (CET). Contact person is: Michał Skrzek.

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 the offer via email. Formal results will be also published on the Ordering Party's website [www.oncoarendi.com](http://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 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 30 days for reasons attributable to the Service Provider's fault (which includes only gross negligence and willful misconduct), the Service Provider shall pay the Ordering Party a contractual penalty of 1%



of the net offer price for exceeding the time limit, and then another 2% of net offer price for each additional 30 days of delay. Moreover, the Ordering Party will gain a right to withdraw from the contract if the project execution time is exceeded by at least 60 days. The Ordering Party may withdraw from the agreement until 31<sup>st</sup> Dec 2019.

- B) Due to the termination or withdrawal from the Agreement by either Party for reasons attributable to the Service Provider's fault (which includes only gross negligence and willful misconduct), the Ordering Party will charge a contractual penalty of 10% 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 30 days from the debit note receipt date.

IX.4 Due to the nature of the Agreement, the Ordering Party reserves the right to conduct a GLP audit of their research sites with its own resources or using an independent third party at each stage of the Agreement, in particular before it is undertaken by the Supplier. Negative audit findings may be the basis for cancellation of the Agreement by the Ordering Party.

#### **X. APPENDENCIES:**

- A) The offer form (Appendix No. 1).
- B) Statement concerning fulfilment of all the requirements set out in part IV of the Request for offers (Appendix No. 2).
- C) Statement concerning personal or/and capital connections between the Service Provider and the Ordering Party (Appendix No. 3).
- D) Declaration of compliance with the information obligations provided for in Article 13 or Article 14 of the GDPR (Appendix No. 4).
- E) Confidentiality Agreement (Appendix No. 5).
- F) Detailed Scope of Work & Technical Information Package (Appendix No. 6), disclosed only after signing the confidentiality agreement.
- G) The Conditional Contract for the performance of the research services within the scope of the project (Appendix No. 7).