

**REQUEST FOR THE PROPOSAL No 29/2020-IBD**

**I. ORDERING PARTY**

<p><b>OncoArendi Therapeutics S. A.</b> <b>ul. Żwirki i Wigury 101</b> <b>02-089 Warsaw</b> <b>VAT ID: 728 27 89 248</b></p>	<p><b>Contact person:</b> <b>Kinga Woźniak</b> <b>e-mail: k.wozniak@oncoarendi.com</b> <b>Tel. (+48) 573 900 610</b></p>
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**II. OBJECT FOR THE REQUEST**

*A pharmacometric modelling service for selecting of a therapeutic dose based on data from Phase I clinical trials with OATD-01.*

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

- **IBD:** „PRE-CLINICAL AND CLINICAL RESEARCH OF CANDIDATE FOR INNOVATIVE DRUG IN ASTHMA AND INFLAMMATORY BOWEL DISEASES THERAPY” (POIR.01.01.01-00-0168/15)

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 Public Procurement Law (Journal of laws of 2019, item 1843 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 In justified cases, at any time, before the deadline for the submission of tenders, OncoArendi Therapeutics SA reserves the right to 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, on Concurrency database 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 contract.
- III.7 It is **not possible** to make and offer for part of order.

#### **IV. 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 and experience (Contractor should have at least 3 years of experience in pharmacometric modeling and in preparing the final reports attached to the Investigator's Brochure, 10 such reports are a minimum) to carry out the described activity and have the appropriate technical potential and personnel capable of performing the contract;
- B) are in a good economic and financial standing, which assures proper execution of the order;
- C) 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 personally or equity related to the Ordering Party. Equity or personal relationship is understood as relations between the Ordering Party or individuals authorized to take commitments on behalf of the Ordering Party or those acting on behalf of the Ordering Party in order to prepare and implement the Contractor selection procedure and the Contractor, including 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.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: 73000000-2 Research and development services and related consultancy services.

### V.1 Order description:

The object of the tender is development and validation of the population PK/PD model using pharmacometric methods (with justification for model selection). This model is intended to describe the plasma concentration-time profile of OATD-01 and chitinolytic activity after single and multiple dose administration in healthy male and female volunteers. Model will be used for further simulations with different doses regarding chitinolytic activity and the correlation between QT prolongation and plasma concentration of OATD-01. Results of simulations will be the basis for justifying of dose selection for the next stage of clinical development of the drug candidate. Raw data will be available in Excel format.

The detailed synopsis of Phase 1a and 1b study is presented in Appendix No. 5 to this Document. The Appendix No. 5 will be disclosed on the Contractor's demand only after signing the Confidential Disclosure Agreement (CDA). The CDA will be provided electronically at Contractor's request.

The scan of filled and signed CDA should be sent by email to [k.wozniak@oncoarendi.com](mailto:k.wozniak@oncoarendi.com) The Appendix No. 5 will be provided within 24 hours from receiving a scan of the signed CDA.

### V.2 The order includes:

1. Development of a detailed analysis program.
2. Providing the safe electronic transfer of documents.
3. Organizing at least 3 online meetings/teleconferences: opening the project, result presentation with possibility to ask questions and clarifications, and meeting closing the project.
4. Project coordination and communication.
5. Creation and validation of pharmacometric models (including justification for model selection) based on the provided documentation from Phases 1a and 1b, including:
  - establishing the relationship between pharmacodynamic effect (i.e. inhibition of chitinolytic activity in plasma) and OATD-01 concentrations
  - investigating the potential correlation between gender and therapeutic effect (chitinolytic activity in plasma)
  - correlation between body weight and pharmacokinetics of OATD-01
  - correlation between QT prolongation and concentration of OATD-01
  - selection of a therapeutic dose for the next phase of clinical trials with justification; by therapeutic dose we mean inhibition of the chitinolytic activity in plasma (>80%) caused by OATD-01, with sufficient safety margin versus potential QT prolongation effects
  - final report with quality check of results and format that allows its incorporation into Investigators' Brochure
6. Development of the final report of the simulations and analyses according to the guidelines(requirements) in point V.2, V.4

### V.3 Details of the required analyses and simulations:

Population PK/PD analysis plan
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NONMEM dataset generation
Population PK model development
Population PK/PD model development
PK, PK/PD dosing simulations
Population PK/PD report for incorporation into investigators' brochure
Concentration-QT feasibility assessment
Concentration-QT analysis plan
Concentration-QT dataset generation
Concentration-QT model development
Concentration-QT report for incorporation into investigators' brochure
Project coordination and communication
Slides and teleconferences meanwhile to discuss progress of work
Archiving of electronic studies files
Quality control of modelling and simulations work

The price offer should include all costs of the order realization.

**V.4 For the purposes of the contract, the Contractor will provide the Ordering Party:**

1. Presentation of results in Microsoft Power Point format
2. Final report in Microsoft Word and PDF format with a description of the models in line with the ICH/EMA guidelines for submissions for regulatory authorities in clinical trials
3. Data set from analyses and simulations as an electronic file/files in the format of text files separated by commas and separated by spaces

Order due date: **Maximum 12 weeks from the date of confirmation that the Contractor has received the full data package from Phases I clinical trials.**

**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<sub>min</sub> – The lowest Net price

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

80– weight of the criterion (80%)

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

In the criterion "order completion deadline" points will be awarded according to the formula:

20 points - when the order is completed within 8 weeks inclusive from the date of delivery of the data set by the Ordering Party to the date of submission of the final report summarizing the project with a dataset from the analyses.

10 points – when the order is completed over 8 weeks – up to 11 weeks inclusive from the date of delivery of the data set by the Ordering Party to the date of submission of the final report summarizing the project with a dataset from the analyses.

0 points – when the order is completed in more than 11 weeks up to 12 weeks inclusive from the date of delivery of the data set by the Ordering Party to the date of submission of the final report summarizing the project with a dataset from the analyses.

20 – weight of the criterion (20%)

The order completion date is defined as the time from the date of delivery data set by the Ordering Party to the date of submission of the final report summarizing the project with a dataset from the analyses.

- 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: **31/08/2020 23:59 (UTC+01:00)** 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](mailto:k.wozniak@oncoarendi.com)
- VII.6 The date of receiving the email shall be considered as a date of issuing the offer to the e-mail address provided in point VII.5.
- 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 directed to the e-mail address indicated in point I, no later than 27/08/2020 15:00 (UTC+01:00.) Contact person is: Kinga Woźniak
- VII.9 Any questions concerning the formal issues of the tender should be addressed to [k.kosinska@oncoarendi.com](mailto:k.kosinska@oncoarendi.com) or by phone 573-975-784 no later than 27/08/2020 15:00 (UTC+01:00). Contact person is: Karolina Kosinska
- 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](http://www.oncoarendi.com)) and on Concurrency database website.

### **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 declared order execution deadline (as defined in point 3 of Appendix no 1 to the Request for proposal) extends for at least 15 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 execution when execution time is exceeded by at least 60 days. The right of withdrawal can be exercised until 31.12.2020.

- 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 personal and capital 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 Phase 1a and 1b study (will be disclosed on the Contractor's demand only after signing the CDA)