

**REQUEST FOR PROPOSAL 26/2017 - IBD / IPF****I. ORDERING PARTY:**

<b>OncoArendi Therapeutics SA</b> ul. Żwirki i Wigury 101 02-089 Warszawa VAT No. 728 27 89 248	<b>Contact person</b> Barbara Dymek <a href="mailto:b.dymek@oncoarendi.com">b.dymek@oncoarendi.com</a> tel. 798 352 548
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**II. OBJECT OF THE REQUEST / PROPOSAL:**

*Consult and expert analyses in the field of histological assessment of lung tissue, including the assessment of animal lung tissue obtained in in vivo studies of new compounds developed by OncoArendi especially in animal models of asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF)*

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

- **IBD:** Preclinical and Clinical Development of a New Chemical Entity for Asthma and Inflammatory Bowel Disease (POIR.01.01.01 00-0168/15)
  - **IPF:** Development of a first-in-class small molecule drug candidate for treatment of idiopathic pulmonary fibrosis through chitotriosidase inhibition (POIR.01.01.01-00-0551/15)
- co-financed by the National and 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 qualifications to carry out the described activity and have the appropriate technical potential to perform the contract,
- are in a good economic and financial standing, which assures proper execution of the project in the declared time,
- are licensed to carry out the activity in question, if this is required by law,

IV.3 As far as the personnel is concerned the Ordering Party requires the Contractor to engage the person who:

- a) has PhD degree in biological or medical sciences or an equivalent
- b) has at least 10-year experience in working as a histopathologist in academia or in a pharmaceutical company
- f) has a documented experience in the histopathological assessment of both human lung tissue specimens and also animal lung tissue obtained in the studies in mouse models of inflammatory or fibrotic diseases, supported by at least 3 published papers in peer-reviewed journals, in particular in the bleomycin-induced lung fibrosis mouse model.

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 Issuing the offer represent the full acceptance of the rules set in this Request.

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

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

CPV code: 73000000-2 Research and experimental development services and related consultancy services

The subject of the service is the expertise and histopathological assessment, in particular:

- the expert consult in preparing animal tissues for histopathological assessment of inflammation and fibrosis
- the consults and expert analyses of laboratory animals tissue sections and quantification of pathological features according to standardized scoring system, among others: inflammation and immune cells tissue infiltration, pathologic tissue remodeling and fibrosis, epithelial cells hyperplasia and metaplasia, etc.
- the analysis and the assessment of tissues obtained in the laboratories of both OncoArendi Therapeutics and the cooperating academic research units and CRO companies.

The selected Contractor will cooperate not only with R & D personnel and the contracting authority but also with other entities / persons providing research services to the Ordering Party.

Estimated number of person days will be: 24 working days - 8 working hours each.

The Ordering Party reserves the right not to use the full estimated number of person days mentioned above. The Contractor is not entitled to apply to the Orderer with claims to use the full estimated number of person days. The Contractor will be paid only for hours ordered.

Contract completion deadline: 31.12.2018

## VI. EVALUATION OF THE OFFERS:

### VI.1 Price – weight: 70% (70 pts.)

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

$$\text{Points received} = P_c = \frac{C_{\min}}{C_{\text{evaluated}}} \times 70$$

where:

$P_c$  – Points received

$C_{\min}$  – the smallest Net price

$C_{\text{evaluated}}$  – Net price of the offer being evaluated

70 – weight of the criterion (70%)

### VI.2 Delivery time – weight: 30% (30 pts.)

30 points – delivery up to 2 weeks from the work order

20 points – delivery up to 3 weeks from the work order

10 points – delivery up to 4 weeks from the work order

0 points – delivery in more than 4 weeks from the work order

30 – weight of the criterion (30 %)

## 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 Contractor should make the offer in Polish or English.

VII.4. The costs of the offer preparation shall be incurred by the offering party.

VII.5. Offers must be submitted no later than: **01/06/2017, 23:59** and must be written on the form as in Appendix 1 to the request for proposals

VII.6. Offers shall be issued via email to: **b.dymek@oncoarendi.com**

VII.7. Offers that do not meet the deadline will not be taken into consideration.

VII.8. Any questions concerning the Object of the tender should be addressed to k.czyzewska@oncoarendi.com no later than 29/05/2017, 15:00. Contact person is: Karolina Czyżewska

VII.9. The offer should be valid for at least 30 days from its submission.

VII.10. The price should be set in both Net and Gross.

VII.11. The offer shall not be presented in price variants.

## VIII. TENDER RESULTS

The winner will be informed via e-mail address, Formal results will be also published on the Ordering Party's website ([www.oncoarendi.com](http://www.oncoarendi.com)) and on public domain called 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.

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 economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of the 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 a 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 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
- d) If the modification of clinical study plan become a matter of necessity, the order description and the Clinical Study Synopsis will be adjusted. The current study plan will be reviewed and validated after analyzing all preclinical toxicology and safety pharmacology data.
- If the clinical study plan changes, the contract value will be amended. The amendment will be based on fixed unit prices included in the table no. 2 of the Offer Form (the Appendix 1).  
The amendments will not cause introduction of a contract change.
- a) If the severe adverse effect or serious adverse reaction occurs, the contract value will be amended. The amendment will be based on fixed unit prices included in the table no. 3 of the Offer Form (the Appendix 1). The amendments will not cause introduction of a contract change.

Any contract amendment must be done in writing, otherwise will not be valid.

Appendices:

1. The offer form
2. Statement concerning fulfillment of all the requirements set out in part IV of the Request for offers
3. Statement concerning personal or/and capital connections between the Service Provider and the Ordering Party