

REQUEST FOR THE PROPOSAL NR 15/2020-IPF**I. ORDERING PARTY**

OncoArendi Therapeutics S. A. ul. Żwirki i Wigury 101 02-089 Warszawa VAT ID: 728 27 89 248	Contact person: Karolina Kosińska k.kosinska@oncoarendi.com + 48 573-975-784
---	---

II. OBJECT FOR THE REQUEST:

Professional consulting and advice on pharmacology in the context of study design and verification of research strategy of the company at every stage of drug development up to early phase clinical trials in therapeutic areas of lung diseases (including idiopathic pulmonary fibrosis-IPF) and metabolic diseases (including nonalcoholic steatohepatitis-NASH).

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

— **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 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 contracts.

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 to carry out the described activity (The Ordering party requires that the Contractor):

1. has a university degree, PhD or equivalent;
2. has at least 5 years of experience in the pharmaceutical industry in the field of drug discovery;
3. has previously led a research group or research department related to inflammatory diseases and diseases of the airways or cancer;
4. introduced at least 20 compounds to the development phase;
5. was the manager of at least 5 projects, as a result of which potential drugs were introduced into the second (or later) phase of clinical trials;
6. was the manager of at least one project, as a result of which the drug developed in the project was launched on the market;
7. was the author or co-author of at least 10 peer-reviewed scientific papers, including at least 1 international scientific journal
8. was the author of the chapters for textbooks in the field of pharmacology and drug discovery;
9. has documented experience in the field of industry cooperation with research groups in scientific units.

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: 73200000-4 Research and development consultancy services

V.1 The subject of the contract is expertise and research consultancy in the below mentioned areas:

- Professional consulting and expert advice on establishing and validation of in vivo models for autoimmune and inflammatory diseases leading to tissue remodeling and fibrosis, analysis and interpretation of experimental data from studies on discovery and development of new small molecule drugs.
- Expert advice in study design and data analysis of in vitro cell-based assays and in vivo animal model studies, analysis and interpretation of experimental data from studies on development of OncoArendi new small molecule drugs.
- Professional consulting and expert advice on translational studies, i.e. in vivo preclinical efficacy studies of new compounds discovered and developed by OncoArendi in animal models of idiopathic pulmonary fibrosis – IPF and nonalcoholic steatohepatitis– NASH, as well as in-vivo data analysis and interpretation with special focus on their translational potential.
- Professional consulting and expert advice on PK/PD characterization of new compounds developed by OncoArendi in the context of translational prediction of human dose range.

- Professional consulting and advice on pharmacology in the context of study design and verification of research strategy of the company at every stage of drug development up to early phase clinical trials in therapeutic areas of lung diseases (including idiopathic pulmonary fibrosis-IPF) and metabolic diseases (including nonalcoholic steatohepatitis-NASH)
- Professional consulting and expert advice on biological research, including pharmacological studies, in vivo efficacy experiments of new compounds developed by OncoArendi using in vivo models particularly unique humanized mice models that reflect pathophysiology of human idiopathic pulmonary fibrosis-IPF, data analysis and interpretation with regard to translational potential.
- Professional consulting and expert advice on design and data analysis of new compound pharmacokinetics, pharmacodynamics (PK/PD) and metabolic studies in OncoArendi drug discovery and development programs (in rodents and non-rodents) in therapeutic indications of idiopathic pulmonary fibrosis – IPF) and nonalcoholic steatohepatitis– NASH).

The Contractor's responsibilities will also include interpretations of data from various sources and research in terms of both the safety profile, biological activity and mechanisms of action of drug candidates in research projects implemented by the Ordering Party.

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

The estimated number of consultancy will be: 50 man hours

The Ordering Party reserves the right not to use the full number of man hours indicated above. The Contractor is not entitled to apply to the Ordering Party with claims for the use of the full number of man-hours and will receive remuneration only for man-hours ordered by the Ordering Party and performed.

Contract period: from signing the contract until 30/06/2020

VI. EVALUATION OF THE OFFERS:

VI.1 Price – weight: 85% (85 pts.)

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

$$Pc = \frac{C_{min}}{C_{evaluated}} \times 85$$

Pc – Points received

C_{min} – The smallest gross price

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

85 – weight of the criterion (85%)

VI.2 Payment deadline– weight: 15% (15 pts.)

In the payment deadline, points will be awarded according to the formula:

15 points – when the payment deadline is 30 or more days from the correctly issued invoice

10 points – when the payment deadline is between 29 and 20 days from the correctly issued invoice

5 points – when the payment deadline is between 19 and 10 days from the correctly issued invoice

0 points – when the payment deadline is less than 10 days from the correctly issued invoice

15 – weight of the criterion (15 %)

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: **06.04.2020 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.kosinska@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.kosinska@oncoarendi.com (+48 573-975-784) no later than 02/04/2020 15:00 (CET). Contact person is: Karolina Kosińska

VII.9 Any questions concerning the formal issues of the tender should be addressed to k.kosinska@oncoarendi.com (+48 573-975-784) no later than 02/04/2020 15:00 (CET).

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 Gross.

VII.12 The value in the offer (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 shall not be prepared in price variants.

VII.14 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) and 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 the 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 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 personal or/and capital connections between the Service Provider 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.