

REQUEST FOR PROPOSAL 64/2017 - IPF**I. ORDERING PARTY:**

OncoArendi Therapeutics SA Zwirki i Wigury 101 02-089 Warszawa VAT ID 728 27 89 248	Contact person Karolina Czyżewska k.czyzewska@oncoarendi.com tel. +48 798 352 548
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II. OBJECT OF THE REQUEST / PROPOSAL:

In vivo study of chitinase inhibitor efficacy in the mouse model of liver fibrosis

The order carried out as a part of the projects 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)

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 research facility necessary to conduct in vivo studies and biochemical and histochemical analysis of collected biological material,
 - have proven experience in in vivo studies of the new drugs in a mouse model of liver fibrosis
 - are in a good economic and financial standing, which assures proper execution of the project in the declared time,
 - 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).

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 by in particular:

- 1) participation in the company, in a civil or limited partnership.
- 2) holding at least 10 % shares or interests.
- 3) serving a function of a member of the supervisory organ, a member of the management organ or proxy.
- 4) 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.

V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:

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

The contract research service aims to test the therapeutic effects of chitinase inhibitors in a mouse model of liver fibrosis induced by streptozocin administration after birth and high fat diet from week 4. The experiment should consist of minimum 4 groups (appropriate control groups and groups treated with chitinase inhibitor in two doses). Every group should consist of at least 10 mice. Additionally, two control groups should be included in the study that would allow material collection at a day of the start of treatment (minimum of 8 animals per group). The experiment should be conducted in therapeutic scheme of treatment with 4-week-long treatment.

The primary readouts should be as follows:

- Body weight changes through the experiment
- Liver weight
- Body-to-liver weight index
- Plasma ALT
- Plasma AST
- Triglycerides in liver
- Histological analysis of pathological changes in the liver (NAFLD Activity Score on hematoxylin-eosin stained liver)

Secondary analyses (decision about this step would be made after receiving results from primary analyses):

- Plasma cholesterol
- Plasma triglycerides
- Plasma CK-18 level
- Histological analysis of fibrosis area in the liver (Picro Sirius staining and morphometric analysis of fibrosis area)
- Immunohistochemical analysis of macrophages in the liver (F4/80 staining and morphometric analysis of F4/80-positive area)

Plasma, frozen liver, paraffin-embedded liver tissue and histological slides will be transferred to Ordering Party laboratories after study final at contract research organisation's own expense.

The detailed study plan and study timelines will be agreed with the Ordering Party before signing an agreement.

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 Payment deadline – weight: 30% (30 pts.)

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

30 points - when the payment deadline is over 30 days of the invoice date

25 points - when the payment deadline is from 22 to 30 days of the invoice date

10 points - when the payment deadline is 15 to 21 days of the invoice date

5 points - when the payment deadline is from 8 to 14 days of the invoice date

0 points - when the payment deadline is up to 7 days from the invoice date

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 into consideration (eg.ISO).

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

VII.4 Offers must be submitted no later than: **06/12/2017 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.czyzewska@oncoarendi.com**

VII.6 The date of receiving the email shall be considered as the 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 b.dymek@oncoarendi.com (+48 798 352 548) no later than 04/12/2017 23:59 (CET). Contact person is: Barbara Dymek

VII.9 Any questions concerning the formal issues of the tender should be addressed to m.skrzek@oncoarendi.com (+48 22 552 67 24) no later than 04/12/2017 23:59 (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 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 the Minister of Finance of 28 November 2008 (Journal of Laws of 2008, No. 212, item 1337, as amended).
- VII.13 The offer price should include VAT. The correct determination of VAT is the 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 amended).
- 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 in PLN, EUR, USD or GBP.

VIII. TENDER RESULTS

The winner will be informed via e-mail. Formal results will be also published on the Ordering Party's website (www.oncoarendi.com) and 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 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 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

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

IX.4 Information regarding contractual penalties:

- a) if the offered project execution time (as defined in the offer) extends for at least 15 days, the Service Provider 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 if the project execution time is exceeded by at least 60 days. The Ordering Party may withdraw from the agreement until 31st Dec 2018.
- b) Due to the termination or withdrawal from the Agreement by either Party for reasons caused by the Service Provider, the Ordering Party will charge a contractual penalty of 25% of net offer price.
- c) The formal basis for charging contractual penalties will be a debit note the Ordering Party delivers to the Service Provider. The Ordering Party shall be entitled to deduct contractual penalties from payments due to the Service Provider.

- 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 form the debit note receipt date.

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.