

Warsaw, 26.11.2021

REQUEST FOR PROPOSAL NO. 40/2021

We invite all Professionals meeting the conditions specified below to submit offers to expert advisory services in the field of preclinical development of innovative medicinal products for human use.

The procurement carried out in accordance with the principle of competitiveness as defined in the Guidelines for the eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for 2014-2020, version of 21 December 2020.

The tender is carried out:

- in connection with the implementation by the Ordering Party of the project entitled “Use of matrix metalloproteinase inhibitor to develop an innovative therapy of preventing the development of post-traumatic and post-stroke epilepsy” /POIR.01.01.01-00-0235/20-00/ within Measure 1.1. R&D projects of enterprises, Submeasure 1.1.1 Industrial research and development work implemented by enterprises, co-financed by the European Regional Development Fund.
- in accordance with the principle of competitiveness and is not a subject of public procurement regulated by the Public Procurement Law of 11 September 2019.

I. THE ORDERING PARTY

PIKRALIDA sp. z o. o.
ul. Bukowska 70, apt. B424
60-812 Poznań,

Contact:
Joanna Lipner
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tel. +48 608 711 071

II. DESCRIPTION OF THE SUBJECT MATTER OF THE ORDER

- a) The procurement order is for the provision of an expert advisory services in the field of preclinical development of innovative medicinal products for human use, concerning in particular:
- i. designing preclinical drug development strategy for the drug candidate PKL-021 in the context of full development program,
 - ii. designing ICH, EMA & FDA compliant, First-in-Man enabling preclinical studies for innovative medicinal products for human use (drug candidate PKL-021), including, but not limited to, toxicology studies, safety pharmacology studies, genotoxicity studies,
 - iii. analysis, evaluation, interpretation and positioning of results from performed preclinical studies,
 - iv. verification of reports from completed studies,
 - v. monitoring of studies performed by CRO at the request of Ordering Party,
 - vi. performing an audit of CRO's research site at the request of Ordering Party,
 - vii. preparing sections of regulatory documents (briefing book, IB) summarizing preclinical data.
- b) The Ordering Party anticipates the demand for expert advisory services in the amount of approx. 400 hours

Please note that:

- The Ordering Party reserves the right not to use the full estimated number of hours indicated above.
 - The Contractor is not entitled to apply to the Ordering Party with claims for the use of the full estimated number of hours and will receive remuneration only for hours ordered.
- c) Common Procurement Vocabulary (CPV): 73200000-4 (research and development consultancy services)
- d) Contract schedule:
- i. The Ordering Party intends to sign the consultancy agreement in December 2021
 - ii. Contract duration: 18 months from signing the agreement
- e) Under this Request for proposal, the Ordering Party does not allow the submission of partial bids.

III. THE CONDITIONS OF PARTICIPATION IN THE COMPETITION AND THE DESCRIPTION OF THE ASSESSMENT OF THE FULFILMENT THEREOF

- a) The Request for proposal is directed to Professionals (Contractors) conducting activities matching the description of the subject matter of the order.
- b) The procurement contract may be awarded to professionals who:
- i. offer a service matching the subject matter of the order,
 - ii. have the necessary qualifications to fulfil the contract:
 - a. knowledge of current ICH, EMA and FDA guidelines for First-in-Man enabling preclinical studies for innovative medicinal products for human use, including, but not limited to, toxicology studies, safety pharmacology studies, genotoxicity studies,
 - b. knowledge of current requirements of EMA and FDA that a small molecule drug candidates has to meet to enter Phase I clinical studies (in terms of data availability and acceptable safety profile),
 - c. documented experience in designing and overseeing preclinical programs for innovative medicinal products for human use, including, but not limited to, toxicology studies, safety pharmacology studies, genotoxicity studies,
 - d. documented experience in providing consulting service related to preclinical drug development programs,
 - e. documented experience in preparing sections of regulatory documents (briefing book, IB) summarizing preclinical data.
 - iii. are in an economic and financial situation which allows them to duly execute the order;

Fulfilment of the conditions as above shall be evaluated based on the declaration included in the tender form filled out and signed by the Contractor (appendix No. 1).

- c) The following shall not be eligible:
- i. Contractor having personal or capital relations with the Ordering Party. The term “capital or personal relations” refers to mutual relations between the Ordering Party or persons authorised to incur liabilities on behalf of the Ordering Party or persons involved in the preparation and execution of the Contractor selection procedure on behalf of the Ordering Party, and the Contractor, involving in particular the following:
 - participation in the company as a partner in a civil partnership or partnership;
 - ownership of at least 10 % of shares;
 - acting as a member of the supervisory or managing board, proxy, plenipotentiary;

- being married, in a direct or secondary relationship of kinship or affinity or in a relationship involving adoption, custody or guardianship.

In order to document lack of grounds for exclusion, the Contractor shall attach to its bid a Declaration on lack of grounds for exclusion from the procedure due to personal or capital relations (Appendix No. 2).

- ii. entities who, as a result of deliberate action or gross negligence, misled the Ordering Party when presenting the information that they are not subject to exclusion or who concealed such information or are unable to produce the documents required;
 - iii. entities who, as a result of carelessness or negligence misrepresented information, misleading the Ordering Party, which could have a significant impact on decisions taken by the Ordering Party in the procurement award procedure;
 - iv. entities which entered into an agreement with other bidders aimed at manipulating competition between bidders in the contract award procedure, which the Ordering Party is able to prove by demonstrating relevant evidence;
 - v. entities that have culpably committed a substantial breach of professional duties compromising its integrity, in particular where the entity failed to perform or misperformed the contract as a result of a deliberate action or gross negligence, which the Ordering Party is able to prove by demonstrating relevant evidence.
- d) The bid of an excluded entity shall be deemed to be rejected.
- e) The Ordering Party may exclude an entity at any stage of the procurement award procedure.
- f) Submitting a bid is tantamount to accepting, without reservation, the content of this Request for proposal.

IV. BID EVALUATION CRITERIA

- a) Price – Weight: 90% (90 points)

In the “Price” criterion, points shall be awarded (to two decimal places) according to the following formula:

$$P_c = C_{\min} / C_{\text{cons}} \times 90$$

P_c – points for price criterion

C_{\min} – the lowest price

C_{cons} – price of the bid under consideration

90 – criterion weight (90%)

- b) Payment deadline – Weight: 10% (10 points)

For the criterion “Payment deadline”, points shall be awarded according to the following formula:

10 points – when the payment deadline is 30 days from the date of delivery of a correctly issued invoice,

5 points – when the payment deadline is 14 days from the date of delivery of a correctly issued invoice,

0 points – when the payment deadline is 7 days from the date of delivery of a correctly issued invoice.

If there are two or more bids with equal score awarded, the Ordering Party shall call upon the Contractors that submitted equally scored bids to submit additional bids by the date and time specified by the Ordering Party. Contractors submitting additional bids may not offer prices higher than those offered in the previously submitted bids.

V. DEADLINE AND MODE FOR SUBMITTING BIDS

- a) Bids should be delivered to the Ordering Party in line with the template provided as Appendix No. 1 to this Request for proposal.
- b) The bids should include the following:
 - i. CV of the Professional
The CV shall include information about the expert education, present the professional experience in the field of preclinical development of innovative medicinal products for human use, certificates held etc.
- c) The offer should be signed physically on the document or electronically by a duly authorised representative of the Contractor.
- d) Bids should be submitted electronically to the following e-mail address: pricing_offers@pikralida.eu or via the competitiveness database as a response hereto, wither personally or by post (the date of receipt shall be considered binding) to the address of the Ordering Party.
- e) The bids must be submitted by the 3rd of December 2021 until: 11:59 pm.
- f) The date of submission of a bid shall be the date of its receipt by the Ordering Party.
- g) Any bids received after the deadline, to the wrong e-mail address, on the wrong form as well as incomplete bids shall not be evaluated.
- h) Bids shall include a terms therefor (at least 30 days from the date designated for submission of bids).
- i) A Contractor may submit only one bid per Request for proposal.
- j) All costs associated with the preparation of the bid shall be borne by the Contractor.
- k) Any inquiries regarding the subject matter of the order should be sent via the Competitiveness Database by the 2nd of December 2021 until: 15:00. The authorised contact person is: Joanna Lipner.
- l) **The price (the hourly rate and the contract value) should be provided as the gross amount, including any taxes.**
If the Ordering Party is obligated to calculate and pay to the competent office an advance tax instead of the Contractor, payment of the remuneration will be reduced by such an advance tax.
- m) The values specified in the bid (gross amount) shall be rounded to two decimal places, following the mathematical rule for rounding numbers.
- n) The Ordering Party does not allow for a bid price to be submitted in several variants.
- o) The bidder may change or withdraw its bid before the bid submission deadline.

VI. NOTICE OF AWARD

The bidder shall be notified that his bid was awarded via e-mail. The results of the procedure, in accordance with the principle of competitiveness, shall be made public using the same notification mode as for the Request for proposal.

VII. MATERIAL PROVISIONS OF THE AGREEMENT AND THE CONDITIONS FOR AMENDING THE SAME

- a) The Contractor shall be obliged to conclude an agreement in line with the conditions included herein and in the tender.
- b) No substantial amendments to the provisions of the agreement concluded as regards the contents of the bid constituting the basis for selecting contractor shall be made, unless:
 - i. such amendments relate to implementation of additional services or supplies from the existing Contractor, not included in the basic contract, if they have become necessary, and the following conditions are jointly met:
 - the Contractor may not be changed due to economic or technical reasons, in particular regarding interchangeability or interoperability of equipment, services or installations, ordered under the basic contract,

- changing the Contractor would cause considerable inconvenience or increase the costs for the Ordering Party,
 - the value of each subsequent amendment does not exceed 50% of the contract value initially specified in the agreement,
- ii. the amendment does not change the nature of the agreement, and the following conditions are jointly met:
- the need to amend the agreement is caused by a force majeure understood as an event or combination of events or circumstances beyond the control of the Parties, which substantially hinder or prevent the performance of particular Party's obligations under the agreement, which could not have been foreseen, prevented or overcome had that Party acted with due diligence,
 - restrictions are introduced due to an epidemic emergency state being declared on the territory of the Republic of Poland,
 - the value of the amendment does not exceed 50% of the contract value initially specified in the agreement,
- iii. the amendment does not change the character of the agreement, and the total value of the amendment is lower than the amounts specified in provisions issued pursuant to Article 11 section 8 of the Public Procurement Law that are behind the obligation to notify the Publications Office of the European Union, while being lower than 10% of the order value originally indicated in the contract.

Any amendments to the agreement to be concluded as a result of the procedure must be made in writing in order to be valid.

VIII. OTHER

- a) The Ordering Party reserves the right to cancel the procedure at any stage, without giving reasons therefor.
- b) The issuance of this Request for proposal does not oblige the Ordering Party to accept a particular bid, in whole or in part, and does not oblige it to provide explanations or reasons for accepting or rejecting a particular bid.
- c) The Ordering Party reserves the right to request additional information, documents or clarifications.
- d) In justified cases, at any time before the deadline for submission of bids, Pikralida sp. z o.o. may modify or supplement the content of the Request for proposal. The Ordering Party shall inform about the changes made using the same mode as for notifying the public about the Request for proposal.
- e) This Request for proposal does not oblige Pikralida sp. z o.o. to enter into an agreement.
- f) The Ordering Party shall not be responsible for any costs or expenses incurred by bidders in connection with preparation and submission of the bid.
- g) The Ordering Party reserves the right to reject an abnormally low bid.¹

IX. APPENDICES TO THE REQUEST FOR PROPOSAL

1. Tender form template;
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¹ An abnormally low bid shall mean a bid with a total price (including the applicable VAT) lower than 70% of the price of all bids submitted under the procedure.

2. Declaration of personal and capital relations with the Ordering Party;
3. Statement regarding the fulfilment of the information obligation provided for in Article 13 or Article 14 of the GDPR.
4. The template of the agreement