

Warsaw, 21 February, 2024

REQUEST FOR PROPOSAL NO. 9/2024

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

The procurement procedure is carried out:

- in connection with the Ordering Party's application for co-financing of the project "Development of an intravenous formulation of an innovative drug with neuroprotective activity intended for stroke patients" as part of the call for proposals in the SMART path competition financed under the program: European Funds for a Modern Economy (SMART Path – Projects implemented in consortiums (no. FENG.01.01-IP.01-005/23)) by the National Centre for Research and Development (NCBR) ("Project"),
- in accordance with the principle of competitiveness as set out in the Guidelines for the eligibility of expenditure for 2021-2027 of 18 November 2022.

This procurement procedure shall not be governed by the Public Procurement Act of 11 September 2019 (Journal of Laws of 2023, item 412, as amended).

The contract with the winning tenderer will be concluded on the condition precedent that the Ordering Party obtains funding for the Project under the abovementioned calls for proposals and that the Ordering Party concludes a funding agreement with NCBR.

I. THE ORDERING PARTY

PIKRALIDA sp. z o. o.
ul. Uniwersytetu Poznańskiego 10
61-614 Poznań

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II. DESCRIPTION OF THE SUBJECT MATTER OF THE CONTRACT

- a) The subject of the order is expert advisory services in the field of preclinical studies of a medicinal product administered as an intravenous formulation for patients after stroke, mainly in the toxicological area. The clinical candidate was selected by applying a repositioning strategy. The Ordering Party is in possession of the results of preclinical studies supporting the conduct of a phase 1 clinical trial on a population of healthy volunteers after oral administration.

The expert advisory service should cover in particular:

- i. designing a preclinical research program, with emphasis on toxicological studies, to support the conduct of a phase 1 clinical trial on a population of patients after stroke, the preclinical research program must comply with the ICH, EMA and FDA guidelines,
 - ii. designing individual studies and verification of study protocols,
 - iii. analysis, evaluation, interpretation of results from performed preclinical studies,
 - iv. verification of study reports,
 - v. monitoring of studies performed by CRO,
 - vi. preparation of summaries of the results of preclinical studies,
 - vii. preparation of relevant sections of regulatory documents (Briefing Books, Researcher's Brochure),
 - viii. performing an audit of CRO's research site at the request of Ordering Party,
- 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.
- c) 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.
- d) Common Procurement Vocabulary (CPV):
- 73200000-4: research and development consultancy services
- e) Deadlines:
- i. Deadline for bid submission: 28 February , 2024
 - ii. Planned date for signing the conditional contract: the first week of March 2024
 - iii. Duration of contract: 1 September, 2024 to 31 March, 2028
- f) Under this Request for Proposal, the Ordering Party does not allow the submission of partial bids.

III. CONDITIONS OF PARTICIPATION IN THE COMPETITION AND ASSESSMENT OF THEIR FULFILMENT

- a) This Request for Proposal is addressed to potential Contractors carrying out activities matching the description of the subject matter of the contract and having the respective PKD entry in the relevant business register.
- b) The procurement contract may be awarded to Contractors 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 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)
 - b. documented experience in designing and overseeing comprehensive preclinical research programs for low-molecular drug candidates intended for humans, including toxicology and safety studies
 - c. documented experience in providing consulting service related to preclinical drug development programs,
 - d. 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 contract may not be awarded to:
 - a. 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 a company as a partner in a civil partnership or a general partnership;
 - holding at least 10% of shares or stocks;
 - acting as a member of a supervisory or management board, commercial proxy (*prokurent*) or attorney-in-fact;
 - being married, or in a relationship of direct, secondary or collateral kinship, or in a relationship of adoption, custody or guardianship, or in cohabitation,
 - being in such a legal or factual relationship that there is reasonable doubt as to their impartiality or independence in relation to the procurement procedure.

In order to document the absence of grounds for exclusion, the Contractor shall attach to the bid a Statement on the absence of grounds for exclusion from the procedure due to personal or capital relations (Appendix 2).

- b. an entity to which the following circumstances apply:
 - i. the circumstances outlined in Article 7(1) of the Act of 13 April 2022 on special solutions to prevent support for aggression against Ukraine and to protect national security;
 - ii. the circumstances outlined in Article 5k of Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's destabilising actions in Ukraine.

In order to document the absence of grounds for exclusion, the Contractor shall attach to the bid a Statement on the absence of grounds for exclusion from the procedure due to personal or capital relations (Appendix 2).

- c. an entity who, as a result of deliberate action or gross negligence, misled the Ordering Party when providing information that it is not subject to exclusion, or who withheld such information or is not capable of producing the required documents;
 - d. an entity which as a result of recklessness or negligence provided information that was misleading to the Ordering Party, which could have a significant impact on the decisions taken by the Ordering Party in the contract award procedure;
 - e. an entity which entered into an agreement with other bidders aimed at distorting competition between bidders in the contract award procedure, which the Ordering Party is able to prove by means of appropriate evidence;
 - f. an entity that has culpably committed a grave breach of professional duties, which compromises its integrity, in particular when the entity, as a result of a deliberate action or gross negligence, has not performed the contract or has performed it improperly, which the Ordering Party is able to prove by demonstrating appropriate evidence.
- b) The bid of an excluded entity shall be deemed to be rejected.
 - c) The Ordering Party may exclude an entity at any stage of the contract award procedure.
 - d) 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)

For the criterion "Price", points will be awarded (to two decimal places) according to the following formula:

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

P_c – points for the price criterion

C_{\min} – lowest net price

C_{cons} – net price of the bid under consideration

90 – criterion date (90%)

- b) Invoice payment deadline – Weight: 10% (10 points)

- 10 points – when the payment date of the invoice is 30 days from the invoice receipt date,
- 5 points – when the payment date of the invoice is 14 days from the invoice receipt date,
- 0 points – when the payment date of the invoice is 7 days from the invoice receipt date.

In the case of two or more bids with an equal number of points awarded, the Ordering Party shall call upon the Contractors who submitted equally evaluated bids to submit additional bids by a deadline specified by the Ordering Party. The Contractors submitting additional tenders may not offer prices higher than those offered in their bids.

V. DEADLINE AND PROCEDURE FOR BID SUBMISSION

- a) Bids should be delivered to the Ordering Party in line with the template provided as Appendix 1 to this Request for Proposal.
- b) The bid should include:
 - 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. If the offer is submitted by an entity employing a specialist or cooperating with a specialist, the specialist's CV should be attached.

- c) The bid shall be signed by a duly authorised representative of the Contractor, by hand or by a qualified electronic signature.
- d) **Bids must be submitted via the Competitiveness Database as a response to this Request for Proposal.**
- e) **Bids must be submitted by (date) 28 February, 2024 until 23:59 .**
- f) The bid submission date shall be the day of its entry into the Competitive Database.
- g) Bids received after the deadline or submitted by email or in hard copy at the office of the Ordering Party or submitted using an incorrect form or incomplete bids shall not be evaluated.
- h) The Ordering Party shall reject any bid that does not comply with the provisions of the Request for Proposal or with the essential terms of the contract or if it is unacceptable for other reasons, as well as if a Bidder does not agree to an extension of the bid validity period or to the selection of its bid after the expiry of this period..
- i) **The bid validity period shall be 60 days** from the deadline for bid submission.
- j) A Contractor may submit only one bid per one Request for Proposal.
- k) All costs associated with the preparation of the bid shall be borne by the Contractor.
- l) **Inquiries regarding the subject matter of the contract should be sent via the Competitiveness Database by 26 February, 2024 until: 15:00 hours. The authorised contact person is Karolina Stępień.**
- m) Prices should be quoted in net values (not including VAT) and in gross values.
- n) The values quoted in the bid (net and gross amounts) should be rounded to two decimal places, observing the mathematical rule of rounding numbers.
- o) The bid price should include the VAT due, if applicable. The correct determination of VAT is the responsibility of the Contractor. In the event that VAT is incorrectly determined, the bid price considered in the evaluation shall be the net value.
- p) If the Bidder submits an offer in a foreign currency, it is assumed that the basis for the conversion of the bid value containing the price in a currency other than PLN shall be the average exchange rate of PLN in relation to the respective currency **as of the date of the Request for Proposal**, announced by the National Bank of Poland.
- q) The Ordering Party does not allow the bid price to be presented in several options.
- r) The bidder may amend or withdraw its bid before the deadline for submission of bids.

VI. NOTICE OF CONTRACT AWARD

The Contractor will be notified of the award of contract by email. The results of the procedure, in accordance with the principle of competitiveness, will be made public in the same way as the Request for Proposal.

VII. MATERIAL PROVISIONS OF THE CONTRACT AND THE TERMS OF THEIR AMENDMENT

- a) The Contractor shall be obliged to conclude a conditional contract on the terms set out in this RFP and the bid. The condition for the contract entry into force is that the Ordering Party obtains co-financing for the Project and signs a co-financing agreement for the Project with NCBR.
- b) The Ordering Party reserves the right to award a supplementary contract to the Contractor selected as a result of the completed procurement procedure, in an amount not exceeding 50% of the value of the basic contract. The subject matter of the supplementary contract will be consistent with the subject matter of the main contract.

- c) No substantial amendments to the provisions of the contract concluded can be made versus the contents of the bid serving as the basis for selecting contractor, unless:
- i. amendments concern the performance of additional services, supplies from the existing Contractor, not covered by the basic contract, if they have become necessary and all the following conditions have been jointly met:
 - change of the Contractor is not possible due to economic or technical reasons, in particular concerning interchangeability or interoperability of equipment, services or installations, ordered within the framework of the basic contract,
 - change of the Contractor would cause substantial inconvenience or significant increase of costs for the Ordering Party,
 - the value of each subsequent amendment does not exceed 50% of the contract value originally stated in the contract,
 - ii. the amendment does not change the nature of the contract, and the following conditions are jointly met:
 - the need to amend the contract 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 a given 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 originally stated in the contract,
 - iii. the amendment does not change the nature of the contract, and the total value of the amendment is lower than the amounts specified in provisions issued pursuant to Article 11(8) of the Public Procurement Law, on which the notification requirement to the Publications Office of the European Union is conditional, and at the same time is lower than 10% of the contract value as originally set out in the contract.

No amendments to the contract to be concluded as a result of the procurement procedure shall be valid unless made in writing.

- d) Information on contractual penalties:
- i. For termination or withdrawal from the Contract by either Party for reasons attributable to the Contractor, the Ordering Party shall charge a contractual penalty of 5% of the Contract value.
 - ii. The documentary evidence serving as the basis for the calculation of the contractual penalties shall be a debit note of the Ordering Party delivered to the Contractor by email sent to the address specified in the bid/contract.
 - iii. The Ordering Party shall have the right to deduct the contractual penalties from the Contractor's remuneration.
 - iv. The Ordering Party shall have the right to claim damages in excess of the amount of contractual penalties specified in the Contract on generally applicable terms.
 - v. The contractual penalties shall be payable within 7 days from the date of delivery of the debit note to the Contractor by the Ordering Party.
 - vi. The contractual penalties shall be cumulative.

VIII. OTHER INFORMATION

- a) The Ordering Party reserves the right to cancel the procedure at any stage without giving reasons. The Ordering Party does not provide for legal appeal remedies for participants in the

proceedings against the decisions of the Ordering Party made in the course of the contract award procedure.

- b) All costs and expenses incurred by the bidders in connection with the preparation and delivery of the bids shall be borne by the bidders.
- c) The Contractor shall not be entitled to any claims against the Ordering Party in connection with the Request for Proposal and the conducted proceedings, including for costs and damages incurred, in particular in the event of cancellation of the proceedings by the Ordering Party or selection of another Contractor.
- d) The publication of this Request for Proposal does not oblige the Ordering Party to accept any bid, in whole or in part, and does not oblige the Ordering Party to provide explanations or reasons for accepting or rejecting a bid.
- e) This Request for Proposal does not oblige the Ordering Party to conclude a contract.
- f) During the examination and evaluation of bids, the Ordering Party may request clarifications from Contractors regarding the content of submitted bids or the content of enclosed statements or documents, as well as request amendment of statements or documents if the statements or documents are incomplete, contain errors or raise doubts pointed out by the Ordering Party. The Ordering Party shall call for their submission, supplementation, correction or clarification within an indicated time limit, unless despite their submission, supplementation, correction or clarification, the Contractor's tender shall be rejected or invalidation of the procurement procedure would be necessary. The Ordering Party may supplement the missing statements or documents on its own, if it has them in its possession or can obtain them from free and generally accessible databases, in particular from public registers.
- g) In justified cases, at any time before the deadline for submission of bids, the Ordering Party may modify or supplement the contents of the Request for Proposal.
The Ordering Party will inform about such modification in the same way as it made the Request for Proposal public.
- h) The Ordering Party reserves the right to reject a bid containing an abnormally low price in relation to the subject matter of the contract, subject to the provision that if the bid price or the bid cost seems abnormally low in relation to the subject matter of the contract i.e., if it differs by more than 30% from the arithmetic mean of the prices of all valid bids which are not subject to rejection, or if it gives rise to doubts of the Ordering Party as to the capability to perform the subject matter of the contract in accordance with the requirements specified in the Request for Proposal or resulting from other provisions, the Ordering Party shall demand from the Contractor to submit explanations, including evidence, concerning the calculation of the price or cost within the set deadline. The Ordering Party shall evaluate such explanations in consultation with the Contractor and may reject that bid only if the explanations submitted, together with evidence, do not justify the price or cost quoted in the bid.
- i) The Ordering Party shall not disclose information constituting a business secret within the meaning of the provisions of the Act of 16 April 1993 on counteracting unfair competition (consolidated text: Journal of Laws of 2022, item 1233, as amended), if the Contractor, along with the submission of such information, reserves that it may not be disclosed and demonstrates that the classified information constitutes a business secret. If a bid containing a business secret is submitted, it should be submitted in two parts described as the "non-confidential part of the bid" and the "confidential part of the bid". A bid submitted without division into open and secret parts shall be an open bid. The Contractor may not classify the information about the names and places of business or places of residence of the contractors, prices or costs contained in the bids.
- j) By submitting a bid, the bidder is deemed to have accepted the contents of this Request for Proposal without qualification.

IX. APPENDICES TO THE REQUEST FOR PROPOSAL

- a) Appendix 1: Bid form template;
- b) Appendix 2: Statement on personal and capital relations with the Ordering Party
- c) Appendix 3: Statement on the fulfilment of information obligations pursuant to Article 13 and Article 14 of the GDPR
- d) Appendix 4: Statement on the absence of relations with sanctioned entities.