

## Request for Bids No. 01/WPD101/2020

### Project Title:

“Development of a new drug used in the therapy of glioblastoma multiforme”.

Project implemented under the contract No. POIR.01.01.01-00-0912/17-00, co-financed by the European Union under the Smart Growth Operational Program 2014-2020, Priority I: Support for Research and Development work by Small and Medium Enterprises, Measure: Research and Development Projects by Enterprises, Sub-Measure: Industrial Research and Development work by Enterprises

### Status:

Active

### Contract object:

Research service, involving process and analytical development, non-GMP and GMP manufacture of drug substance for consistent generation of the biopharmaceutical recombinant-protein product.

### Bid submission term:

**13<sup>th</sup> March 2020, 5pm CET**

### Bid submission place and method:

1. Bid submission method:
  - a) by recorded delivery letter, through a messenger or in person at the registered office of the Awarding Entity (address: WPD Pharmaceuticals sp. z o. o., ul. Żwirki i Wigury 101, 02-089 Warsaw, Poland),
  - b) by email to the Awarding Entity's address:  
[oferty@wpdpharmaceuticals.com](mailto:oferty@wpdpharmaceuticals.com)
2. Bids submitted by recorded delivery letter, in person or through a messenger should be submitted in a sealed envelope with the note “Request for Bids No. 01/WPD101/2020”.

### Contact e-mail for submitting the Bids:

[oferty@wpdpharmaceuticals.com](mailto:oferty@wpdpharmaceuticals.com)

### Announcement category:

Research services

**Place of the order implementation:**

Mazowieckie

**City:**

Warszawa

**Contact object description:**

Aim of the order:

Implementation of the research tasks under the project No. POIR.01.01.01-00-0912/17-00

**Contact object:**

- 1) The contract object is a research service, involving process and analytical development, non-GMP and GMP manufacture of drug substance for consistent generation of the biopharmaceutical recombinant-protein product.
- 2) The service will be performed for the purpose of research and developmental work conducted by the Awarding Entity as a part of the project No. POIR.01.01.01-00-0912/17-00.
- 3) The scope of the contract object will include implementation of the research work under the following Stages:

**Stage I - Cell banking, in particular:**

- Host-cell line generation
- Research cell bank (RCB) manufacturing
- RCB QC testing
- Master cell bank (MCB) manufacturing and storage in compliance with GMP
- MCB QC testing and release
- EPCB manufacturing
- EPCB testing

**Stage II - Manufacturing process development, in particular:**

- Upstream Process Development
- Downstream Process Development
- Manufacture and testing of a demo batch of DS

- Viral clearance validation studies

**Stage III - Analytical methods development and validation**, in particular:

- Analytical methods development and validation for RCB, MCB and EPCB
- Analytical methods development and validation for the DS
- Characterization studies of the DS
- Establishment of reference standards

**Stage IV - Non-GMP DS manufacture and stability studies**, in particular:

- Non-GMP DS manufacturing
- Non-GMP DS QC testing and release
- Stress testing studies
- Non-GMP DS stability studies

**Stage V - GMP manufacture and stability studies**, in particular:

- GMP DS manufacturing
- GMP DS QC testing and release
- GMP DS stability studies

**NOTE:** *The above-mentioned activities within each Stage are minimal and not exhaustive and may be extended by the Contractor in order to achieve the assumed research goal. The extension referred to above may not result in the Contractor's claim additional remuneration for the implementation of the order.*

- 4) Detailed description of the contract object (further: OPZ) is indicated in Appendix 8 to the Request for Bids. The Contractor is obligated to sign the Non-Disclosure Agreement (NDA), which constitutes Appendix 6 to the Request for Bids to obtain detailed OPZ. NDA partially executed by the Contractor should be sent within the time limit provided for the submitting applications and inquires for this contract award procedure, in accordance with the principles indicated in Section XIII, paragraph 2.
  - 5) The Contractor undertakes that the scope of work carried out by him and the results presented in submitted reports, as well as developed documentation will be prepared in accordance with the relevant ICH guidelines, EMA regulatory requirements and GMP requirements (when indicated) and will be suitable for submitting a registration application for a new medical product.
1. The Awarding Entity requires Contractors to organize teleconferences or meetings on regular basis throughout the service implementation for a total duration of at least 10



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hours, including one at project initiation and one after delivery of the final report and all documentation performed during the service.

2. The Awarding Entity accepts to prepare of all documentation developed as part of the service only in English language.
3. The Awarding Entity does not allow to submit partial bids for organizational, technical, economic and teleological reasons.
4. Submission of variant-based bids shall not be accepted.

#### CPV Code:

73110000-6

#### CPV Code Name:

Research service

#### Order delivery date:

1. The term for the delivery of the order shall remain valid for 18 months from the date of signing the contract.
2. The service will be implemented in stages in accordance with the work schedule agreed with the selected Contractor after signing the contract.
3. The contract object shall be deemed fully completed after the Awarding Entity acceptance each of the Stage, which shall be confirmed by signing delivery and acceptance protocol with no objections as to the performance of the Contract.

#### Deadline and manner of contract execution:

- 1) The Awarding Entity plans to sign the contact with the selected Contractor within a maximum of 60 days from the date of the submission of the bids. This deadline may change in the event of the extension of the period of being bound by the bid.
- 2) The deadline for contract execution shall start on the day of signing the contract and expire upon delivery of final reports and all necessary documentation indicated in detailed description of the contract object which constitutes Appendix 8 and after final approval of the delivery and acceptance protocol and with no objections as to the performance of the Contract.
- 3) The Awarding Entity shall pay for each stage, after confirmation by the Awarding Entity with the delivery and acceptance protocol, within 30 days from the date of receipt of the correct invoice. The value of the invoice submitted for payment will correspond to the value in the contract.
- 4) The invoice will be submitted after approval and signing the delivery and acceptance protocol, which confirms the correct implementation of each stage of the contract by the Awarding Entity.

## Appendices:

Request for Bids No. 01/WPD101/2020

Appendix No. 1. Bid Form

Appendix No. 2. Declaration of the Contractor

Appendix No. 3. Declaration of no capital or personal links

Appendix No. 4. List of services

Appendix No. 5. List of persons dedicated to the service performance with CV

Appendix No. 6. Non-Disclosure Agreement - template

Appendix No. 7. Important provisions of the contract – template

**Full text of the Request for Bids including Appendices is available in the Competitiveness Base of European Funds:**

<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/publication/view/1230344>

## Participation terms:

### Contract amendment terms:

The Awarding Entity reserves the right to amend the provisions of the contract signed with the selected Contractor in the following cases:

- 1) changes to generally applicable legal regulations, in particular changes to tax law (e.g. the rates of goods and services tax), provided that the change has a direct impact on the performance of the contract object and may lead to the modification of only those contractual provisions it refers to;
- 2) changes to regulations concerning the implementation of the project covered by co-financing application no. POIR.01.01.01-00-0912/17 as regards the manner of implementation or financing of tasks included in the Request for Bids, which have a direct impact on the performance of the contract with the Contractor and which may lead to the modification of those provisions of the contract that they refer to;
- 3) the opportunity to use more modern technical solutions which are more beneficial to the Awarding Entity than those which existed at the time of signing the contract, provided that they do not increase the amount of the fee due to the Contractor;
- 4) changes concerning the execution of additional deliveries or services by the Contractor which were not included in the basic order, provided that they became



essential for the delivery of the order and that the following conditions have been jointly met:

- a) the Contractor must not be replaced for economic or technical reasons, in particular ones which concern the interchangeability or interoperability of equipment, services or installations ordered as part of the basic order,
  - b) a change of the Contractor would cause significant inconvenience or would drive up the cost for the Awarding Entity,
  - c) the value of each subsequent change does not exceed 50% of the value of the order specified originally in the contract;
- 5) the change does not alter the nature of the contract and the following conditions are jointly met:
- a) the need to amend the contract is due to circumstances which the Awarding Entity, acting with due diligence, could not have foreseen and
  - b) the value of the change does not exceed 50% of the value of the order specified originally in the contract;
- 6) The Contractor who was awarded the contract by the Awarding Entity is to be replaced by a new contractor:
- a) on the basis of contractual obligations, provided that they do not alter the nature of the contract,
  - b) as a result of a merger, division, transformation, bankruptcy, restructuring or acquisition of the existing contractor or its enterprise, provided that the new contractor meets the conditions for participation in the procedure, there are no grounds for its exclusion from the procedure and that the change does not entail any other significant amendments to the contract,
  - c) as a result of the Awarding Entity taking over the Contractor's obligations towards its subcontractors;
  - d) the change does not alter the nature of the contract and the total value of the change is less than the amounts specified in the provisions issued under Art. 11 paragraph 8 Polish Public Procurement Law, on which depends the obligation to submit notices to the Publication Office of the European Union, and at the same time it is less than 10% of the value of the order specified in the original contract,
- 7) there are discrepancies or ambiguities in the contract which cannot be eliminated in any different manner and the change will make it possible to eliminate such discrepancies and make the contract more precise in order to ensure its unambiguous interpretation by the parties,



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- 8) the occurrence of a force majeure event,
- 9) changing the deadline of the contract execution in the event of external causes beyond the control of the Awarding Entity resulting the inability to meet the original deadlines indicated in the contract,
- 10) reducing the amount of remuneration due to the Contractor limitation or exclusion of execution by the Awarding Entity a part of the contract,
- 11) extension of the deadline for implementation of the Subject of the contract in the event of extension of the registration procedure or other procedures in the relevant offices and institutions;
- 12) changing the date of the Agreement in the event of changes in the term of the Project, under which the contract is executed;
- 13) changes of the persons responsible for contacts and supervision over the completion of the Subject of the contract;
- 14) changes in the name of the company, the seat of the Parties, bank account numbers and other identification data.

Change of the work schedule established with the Contractor after signing the contract does not constitute an amendment to the Contract.

#### **List of documents/declarations required from the Contractor:**

Appendix No. 1. Power of attorney to represent the Contractor (if applicable)

Appendix No. 2. Declaration of the Contractor

Appendix No. 3. Declaration of no capital or personal links

Appendix No. 4. List of services

Appendix No. 5. List of persons dedicated to the service performance with CV

Appendix No 6. Certificate of European GMP standard or other equivalent documents recognized by the European Union

Appendix No. 7. Any other documents required by law, such as, actual authorization of the appropriate office for production of recombinant protein, or equivalent, confirming compliance with the requirements described in the Section VI of the Request for Bids No. 01/WPD101/2020.

#### **Bid evaluation criteria and method:**

1. In selection the best offer the Awarding Entity shall evaluate the "Gross total price" criterion for the total gross prices of the Contract Object described in Section III(3) on the basis of the information supplied by the Contractor in the Bid Form.

2. The score for this criterion shall be calculated as follows:

$$\text{Score granted to the evaluated offer} = \frac{\text{Lowest bid price}}{\text{Evaluated bid price}} \times 100$$

3. The score will be expressed with the accuracy of up to two decimal places.
4. As a result of the evaluation, according to the criterion indicated in the clause 1 above, the bid may receive the score of maximum 100 points.
5. The most economic and best quality bid shall be the one which has not been excluded from the procedure and which receives the highest score during the evaluation.
6. The price shall be given in Polish zlotys (PLN) or any currency other than PLN.
7. The price must be expressed numerically with the accuracy of up to two decimal places and in words.
8. The price must include all the costs of the contract including all fees and taxes (including goods and services).
9. Any other costs which have been incurred by the Contractor while completing the order and have not been included in the bid price will not be additionally covered by the Awarding Entity.
10. Bids submitted by the foreign Contractors participating in the contract award procedure, who under other regulations are not obligated to pay VAT in Poland, contain prices without VAT (0% VAT). Tax liability in the situation of acquiring goods or services from foreign entities rests with the Awarding Entity, in accordance with the provisions of the Value Added Tax Act. For the purpose of comparing the bids Awarding Entity will add to the bid price submitted by the foreign Contractors, the amount of VAT and custom duty (if applicable, for Contractors from outside the European Union), which are charged to the Awarding Entity for the performance of the contract.
11. For the purpose of comparing the bids the bid price in a foreign currency will be converted into PLN using the average exchange rate given by the National Bank of Poland (NBP) valid for the day of the request for bids publication in the Competitiveness Base. Average exchange rate is available at the NBP official web site: <http://www.nbp.pl>.
12. The prices stated in the bid shall remain valid throughout the entire period of its validity and shall be binding for the signed contract.
13. When two or more bids receive the same score, the Awarding Entity will select the best offer by the criterion of positive environmental impact. Positive environmental impact may be demonstrated by, for example:





- the use of solutions that reduce energy consumption during service performance or during the operation of the object of the contract,
- the use of solutions that reduce or eliminate the amount of waste generated during the service performance or during the operation of the object of the contract,
- the use of solutions that reduce the consumption of consumables during the service performance or during the operation of the object of the contract,
- other.

The Contractor may indicate and describe any number of solutions having a positive impact on the environment, indicating technical parameters that allow verification of the declared impact in comparison with standard solutions.

The bid may receive (1) one point for each solution indicated regarding positive environmental impact. If no solution is indicated or solution is indicated but without technical parameters allowing verification of the declared environmental impact in comparison with standard solutions, the bid will not receive a point.

14. The Awarding Entity shall award the contract to the Contractor whose bid received the highest score during the evaluation process.

#### **Contract award procedure participation terms:**

1. In the contract award procedure may participate Contractors who:
  - 1) have the necessary knowledge and experience and have technical potential and people capable to perform the object of the order or present a written commitment of other entities to provide technical potential and persons capable to perform the object of the order, such as:
    - a) Have at least 2 years of documented experience in the provision of services in generation or maintenance or characteristics of the microbial cell banks used for production of the recombinant proteins or other biological products with the use of microbial protein expression system. To confirm the above, the Contractor have to demonstrate at least (2) two orders duly completed, in particular consisting of generation and maintenance and analysis of microbial cell banks (master cell bank (MCB) and working cell bank (WCB)) and manufacturing of recombinant protein products in compliance with GMP standard;
    - b) In terms of staff potential, the Awarding Entity requires Contractors to have and engage to perform the contract persons with appropriate qualification and experience, including at least (2) persons with a specialized education (in pharmacy, chemistry, biotechnology or related fields, i.e. medicine, biological sciences), experienced in recombinant protein production with the use of microbial cell expression systems in compliance with GMP, process

optimization and characterization of the expression systems as well as analytical method development and validation;

- c) In terms of technical potential, the Awarding Entity requires that the Contractor have appropriate technical facility and optimal equipment dedicated to the production, maintenance and testing of microbial cell expressions systems/banks, as well as manufacturing, maintenance and testing of the recombinant protein products obtained with the use of microbial cell expression systems in compliance with GMP and have certificate of the GMP standards for the production of the above-mentioned as API or have other required by law documents for the production, testing and storage of cell banks and protein based APIs, such as valid authorization for API manufacturing for the purpose of clinical trials, issued by the Main Pharmaceutical Inspectorate or other office appropriate for the country of residence of the Contractor, recognized by the European Union.
- 2) are in financial and economic situation that will allow the contract object to be performed;
  - 3) are not excluded from the contract award procedure.
2. Contractors, in order to confirm the fulfillment of the condition for participation in the contract award procedure described in the paragraph 1 above, shall submit the declarations and documents indicated below:
- 1) The “Bid Form” completed in accordance with the specimen and signed by the Contractor, which constitutes Appendix 1 to the Request for Bids;
  - 2) Declaration of compliance with the requirements indicated in Section VI, paragraph 1 of the Request for Bids, which constitutes Appendix 2 to the Request for Bids;
  - 3) Declaration of no capital or personal links, which constitutes Appendix 3 to the Request for Bids: “Declaration of no capital or personal links;
  - 4) List of services provided in accordance with the specimen indicated in paragraph 1, point 1) a, which includes:
    - Contract object (i.e. type of the compound, the amount produced, types of documents prepared),
    - Names of the entities for which the orders have been completed (or the country of origin, if providing name of the entity is not possible),
    - Order delivery date,
    - Order value,(which constitutes Appendix 4 to the Request for Bids: “List of the services”);



- 5) In the scope of the possibility of involving people capable to perform the object of the order, in accordance with the requirements specified by the Awarding Entity, the Contractor shall present a list of persons dedicated to perform the service, which constitutes Appendix 5 to the Request for Bids: "List of Persons", with documentation confirming qualifications and the experience, e.g. valid CV;
  - 6) Documents (or certified true copies) confirming that the Contractor has an EU GMP certificate for production of proteins with the use of microbial cell expression systems or banking of the microbial expression strains, or other equivalent documents, recognized by the European Union;
  - 7) Other documents required by law (or certified true copies) related in particular to the production and maintenance of microbial cell banks for expression strains or production of proteins based on such expression systems, including actual manufacturing authorization issued by the Main Pharmaceutical Inspectorate (for Poland) or other office, appropriate for the country of residence of the Contractor, recognized by the European Union, allowing confirmation of compliance with the requirements specified by the Awarding Entity in the description of the object of the order.
3. Submitted statements and documents should confirm that the conditions for the participation in the contract award procedure have been met for the date on the day of the deadline for the bid submission.
  4. Assessment of compliance with the above conditions will be made in accordance with the formula "meets - does not meet", based on information contained in the documents listed in clause 2 above. The content of the attached documents must clearly show that the abovementioned conditions are met by the Contractor.
  5. Failure to complete at least one of the above conditions will result in exclusion of the Contractor from the contract award procedure.
  6. The bid of the excluded Contractor shall be considered rejected. Awarding Entity shall notify the Contractor about the exclusion, stating the justification for the exclusion.

The Awarding Entity reserves the right to verify the proper performance of the services referred in paragraph 2 point 4) above by calling the selected Contractor to present at the stage of signing the contract documents confirming the proper performance of the services indicated in the bid. As a proof that the order has been duly completed, the Awarding Entity shall consider references of other documents issued by the entity, for which the order has been completed, and in the event of objective reasons that such documents cannot be obtained, a statement of the Contractor.

#### **Grounds for exclusion from the contract award procedure:**

1. Excluded from the contract award procedure shall be Contractors who:



- a) do not meet the conditions listed in Section VI;
  - b) performed activities directly related to the preparation of the contract award procedure or used to prepare the bid with persons participating in these activities, unless the participation of these contractors does not hinder the fair competition;
  - c) submitted false information affecting the outcome of the contract award procedure.
2. Contractors who have capital or personal links to the Awarding Entity shall also be excluded from participation in the contract award procedure; capital or personal links shall be understood as mutual ties between the Contractor and the Awarding Entity or persons authorized to incur obligations on behalf of the Awarding Entity, or persons performing any activities related to the contractor selection procedure on behalf of the Awarding Entity; such links shall in particular include:
- a) participation in the company in the capacity of a partner in a civil law company or partnership;
  - b) ownership of at least 10% of shares or stock, provided that a lower threshold is not mandated under legal regulations or rules concerning the principles of implementation of the project covered by the Request for Bids,
  - c) holding the function of a member of a supervisory or management body, a commercial representative or an attorney;
  - d) being married to or having lineal consanguinity or direct affinity, collateral consanguinity or affinity to the second degree to, or being adopted by, or being under the guard or custody of such persons,
- or any other relationships which may result in the conflict of interests while awarding the contract and in the violation of the competition principle. Should any capital or personal links be revealed between the Contractor and the Awarding Entity, the contract shall not be awarded to the Contractor.
3. In order to demonstrate the absence of premises referred to in the paragraph 2, being the basis for excluding the Contractor from participation in the contract award procedure, the Contractor is obligated to submit together with the Bid Form, completed in accordance with the specimen, which constitutes Appendix 1 to the Request for Bids, declaration of no capital or personal links, according to the specimen, which constitutes Appendix 3 to the Request for Bids: "Declaration of no capital or personal links".
4. Failure to submit the declaration referred to in paragraph 3 will exclude the Contractor from the contract award procedure. Excluding the Contractor from the contract award procedure means rejection of the Bid submitted by the Contractor.
5. The Awarding Entity may exclude the Contractor from the contract award procedure at any stage.



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**Awarding Entity Name:**

WPD Pharmaceuticals

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