

Projects entitled „Development of therapy based on immunoligands recruiting the immune system to fight cancer”, Action 1.2 Sectoral Program InnoNeuroPharm, European Regional Development Fund through Operational Programme Smart Growth 2014 – 2020

Wroclaw, 28.04.2023

Request for Tender within the framework of the project entitled: “Development of therapy based on immunoligands recruiting the immune system to fight cancer”, Action 1.2 Sectoral Program InnoNeuroPharm, European Regional Development Fund through National’s Centre for Research and Development (POLAND) Operational Programme Smart Growth 2014 – 2020.

Number: PB003/34/2023

Order title:

“Service to conduct safety, tolerability and potency studies on an animal model for lead molecule PB003.”

SECTION I: ORDERING PARTY

I.1. Name and address of the Ordering Party

Pure Biologics S.A.
ul. Duńska 11
54-427 Wrocław
VAT NUMBER 8943003192

I.2. CPV code for the order

CPV code: 73100000-3 Research, experimental and development services .

SECTION II: SUBJECT OF THE ORDER

II.1. Mode of proceeding

This procedure is granted in the form of an inquiry, with the principle of competition. The basis for initiating these proceedings are the applicable Guidelines on the eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for 2014-2020 of 21 December 2020.

II.2. Definition of the subject of the order:

The subject of the order is to conduct preclinical assessment of the safety, tolerability and potency of biologically active anticancer compound PB003 using humanized mouse models bearing xenogeneic transplants.

II.2.1. Name of the order:

Service to conduct safety, tolerability and potency studies on an animal model for lead molecule PB003.

Project title: „Development of therapy based on immunoligands recruiting the immune system to fight cancer”, no of co-financing agreement: POIR.01.02.00-00-0086/18-00.

II.2.2. Description and basic conditions of the subject of the contract:

1. The subject of the contract is safety study of biologically active anticancer compound using systematic treatments on CD34+humanized NCG-hIL15 mice with human tumor cells, as detailed in Attachment
2. The subject of the order also includes the preparation and delivery to the Ordering Party of reports on this study.
2. The maximum deadline for the performance of the service cannot exceed 15 weeks from the date of order.

II.2.3. Conditions

1. Partial bids are not allowed.
2. Submission of a variant offer is not allowed.
3. The validity period of the offer is: 60 days from the date specified in II.4.4. p.1.

II.3. Requirements for the Bidders :

1. The Ordering Party reserves that tender may only be submitted by the Bidders who:
 - a) have the necessary knowledge and experience, including documented experience in oncology studies in mice of the hNCG-hIL15 genotypes - at least 40 studies conducted in the last 24 months;
 - b) dedicate mice with hNCG-hIL15 genotypes for research, confirmed by appropriate certificates;
 - c) dedicate a principal investigator to the project who has at least 5 years of experience in conducting research in the field of in vivo pharmacology in the field of immuno-oncology;
 - d) are accredited by AAALAC to conduct animal testing as part of the pharmacology of active substances. and experience in conducting animal studies in accordance with internal SOPs (i.e. non-GLP standards).
 - e) have the technical potential to perform the contract, including: an animal facility with a confirmed SPF standard, the ability to conduct tests on at least 86 mice simultaneously;
 - f) have personnel qualified to perform the contract, including personnel authorized to work with animals, including euthanasia of animals, and with documented experience in working with CD34+ humanized mice with hNCG-hIL15 genotype.
 - g) have the HT-29 cell line and have a documented track-record of HT-29 in subcutaneous inoculation of huHSC-NCG-hIL15 mice for tumor implantation.
2. Bidders who are personally or financially related to the Ordering Party are excluded from the procurement procedure. Equity or personal links are understood as mutual links between the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party or persons performing activities on behalf of the Ordering Party related to the preparation and conduct of the Contractor selection procedure and the Bidder, consisting in particular in:
 - a) participating in the company as a partner in a civil law partnership or partnership,
 - b) holding at least 10% of shares or shares,
 - c) acting as a member of the supervisory or management body, proxy, attorney,
 - d) being married, in a relationship of consanguinity or affiliation the direct line, in a second-degree relationship or in a second-degree affinity relationship in the collateral line, or in a relationship of adoption, guardianship or guardianship.
3. The Ordering Party shall consider the above conditions to be met if the Bidder submits a statement on the fulfillment of the above conditions together with the offer. conditions for participation in the procedure.

The assessment of the fulfillment of the above conditions will be made on a meet/do not meet basis.

Offers that do not meet at least one of the conditions described in point II.3 will be excluded from the procedure.

II.4. Submission of the tenders:

II.4.1. Basic requirements

1. Each Bidder may submit only one tender.
2. The tender should be prepared strictly in accordance with the requirements set out in this specification.
3. The offer must be signed by the person(s) authorized to represent the Bidder.
4. The authorization of the persons signing the offer to sign it must result directly from the documents attached to the offer.
5. The documents attached to the offer should be completed and signed by the Bidder.
6. The cost of preparing and delivering the offer is covered by the Bidder.

II.4.2. Form of the tender

1. The offer must be made in Polish or English, in writing.
2. The entire offer should be submitted in a form that prevents its accidental incompleteness.
3. Any deletions and changes made by the Tenderer to the text previously entered by him must be initialed by the person(s) signing the offer and dated.
4. Documents may be presented in the form of originals or copies certified by the Bidder as true copies. Declarations made on the basis of the templates attached to this specification should be submitted in the original form.
5. Documents can be signed manually (sent electronically in the form of scans) or signed electronically.

II.4.3. Content of the tender

1. The offer have to be submitted by an authorized person/persons.
2. The offer should contain attachments signed by authorized persons, at least:
 - a) a document authorizing/authorization for the person submitting the offer,
 - a) Attachment No. 1 – completed tender form together with statements concerning the Bidder,
 - b) Attachment No. 3 - statement on the lack of relations between cooperating entities.

II.4.4. Place, date and manner of submitting the tender

1. The tender have to be submitted by 29.05.2023 CET inclusive.
2. The tender should be submitted directly to the European Funds Competitiveness Database (<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>) as an offer for the procedure in question.
3. It is also possible to submit an offer by e-mail to the following address: oferty@purebiologics.com. The offer should be sent as a scanned signed attachment/attachments to the message. In the title the news belongs include information:

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"Offer in procedure No. PB003/34/2023 "Service to conduct safety, tolerability and potency studies on an animal model for lead molecule PB003"". Do not open until 29.05.2023 inclusive.

4. Offers received after the deadline will be returned to the Bidders without their evaluation as invalid.

II.5. Mode of evaluating the tenders:

1. The Ordering Party commission will examine whether the tenders meet the formal conditions. Tenders that do not meet the formal conditions will be rejected and will not be evaluated.
2. The Ordering Party commission evaluates tenders that have not been rejected for formal reasons. Tenders will be analyzed by the Ordering Party within 2 working days from the date of the deadline for submission of the tenders, with the proviso that in the event of requesting additional clarifications or supplements to the Bidders, the deadline for evaluating the offers shall be extended by the deadline indicated for the Bidder's response specified in point II. 5.3.
3. The time for the explanation of the tender are 2 working days from the date of delivery by the Ordering Party the inquiry / request for clarification.
4. After analyzing the offers and considering - in accordance with the principle of competitiveness - the submitted tenders, the Ordering Party will publish the results in the European Funds Competitiveness Database (<https://bazaaktywosci.fundusze Europejskie.gov.pl/>)

II.6. Rejection of the tender, exclusion of the Bidder

1. The Ordering Party rejects the tender if:
 - a) its content does not correspond to the content of this inquiry or is incomplete,
 - b) its submission constitutes an act of unfair competition within the meaning of the provisions on unfair competition,
 - c) The Bidder did not submit explanations regarding the content of the submitted bid at the request of the Employer, was submitted by a Bidder who does not meet the criteria of this procedure or by an excluded Bidder,
 - d) is invalid under separate regulations.
2. Bidders are excluded from the procedure, if:
 - a) directly performed activities related to the preparation of the procedure or used persons participating in these activities to prepare the tender, unless the participation of these contractors in the procedure does not impede fair competition,
 - b) they did not agree to extend the period of validity of the offer,
 - c) submitted false information affecting or likely to affect the outcome of the proceedings,
 - d) did not meet the conditions for participation in the procedure,
 - e) are personally or financially related to the Ordering Party.
3. The tender of the excluded Bidder shall be deemed rejected.

II.7. Criteria for tenders evaluation :

1. Formal assessment - will be made on the basis of attachments, documents and statements on meeting the conditions for participation in the procedure specified in point II.3. Tenders that do not meet at least one of the conditions described in point II.3. will be rejected.
2. The Ordering Party will evaluate tenders that are not subject to rejection, submitted by Bidders who are not subject to exclusion from the procedure, according to the following criteria:

Criterion - Price - weight 100 points

The number of points for the price criterion will be calculated taking into account valid (not rejected) offers submitted by Bidders not excluded from the procedure according to the following formula (counting to two decimal places):

$$\text{Number of points} = (C_{\min} / C_{\text{offer}}) * 100 \text{ points}$$

Where:

C_{\min} - the lowest price from all submitted offers

C_{offer} - the price of the examined offer

3. To evaluate the price criterion, the total net prices of the offer will be taken into account. The net offer price in Polish zloty (PLN) will be assessed. In the case of offers submitted in a currency other than Polish zloty, the average exchange rate of the National Bank of Poland on the date of submission of offers will be used for currency conversion specified in II.4.4. p.1, accurate to 4 decimal places.
4. The most advantageous offer will be the offer meeting the conditions specified in point II.2.3, II.3, II.4, which will receive the highest number of points determined with an accuracy of 2 decimal places.

II.8. Terms of settlement

1. The Ordering Party provides for settlements based on an invoice, payment method - bank transfer.
2. Payment deadline 30 days from the delivery of a correctly issued invoice. The Ordering Party allows the invoice to be delivered electronically to the address indicated in the contract.
3. The basis for issuing an invoice settling the performance of the subject of the order will be the test report approved by the Ordering Party.
4. The Ordering Party allows for the possibility of making an advance payment before the commencement of the tests.

SECTION III: ADDITIONAL INFORMATION

III.1. Project financing:

The Ordering Party informs that it intends to implement the project with the use of European Union funds under the European Regional Development Fund - Smart Growth Operational Program for 2014-2020, Action 1.2 - "Sectoral program InnoNeuroPharm".

III.2. Forms of communication

1. The Ordering Party is not obliged to conduct the procedure according to the Public Procurement Act.
2. The content of the inquiry is available in the European Funds Competitiveness Database <https://bazaaktywosci.fundusze Europejskie.gov.pl/> as well as in the Ordering Party's Project Office: ul. Legnicka 48 E, 54-202 Wrocław,
3. Questions regarding the request for quotation should be sent directly through the Competitiveness Database or to pmo@purebiologics.com
4. The Ordering Party will answer the questions directly via the Competitiveness Database or by e-mail, respectively, within 2 business days of receiving the inquiry, provided that the questions are received no later than 3 business days before the date of submission of tenders.
5. If the question concerns confidential information resulting from the specificity of the subject of this Inquiry, the answer to such question will be provided individually after signing the Confidentiality Obligation by the Party submitting such a question. In this case, the Ordering Party will respond within 2 business days of receiving a signed copy of the Confidentiality Obligation.
6. If the answers to questions or reported problems involve a change in the terms of the order, they will be made available in the European Funds Competitiveness Database and the Ordering Party's Project Office. In such a situation, the Purchaser may extend the deadline for submission of tenders.

III.3. Important to both parties provisions of the contract

1. After the completion and publication of the results of the tender procedure, the Ordering Party and the Contractor will sign an appropriate cooperation agreement. The contract will be prepared jointly by the Employer and the Contractor based on the provisions in this request for proposals.
2. The Contract may be terminated at any time with the consent of both Parties.
3. The Ordering Party may withdraw from the contract in the event of a significant change in circumstances that could not have been foreseen at the time of concluding the contract or in the event of the Intermediate Body withholding the project co-financing.
4. Termination and withdrawal from the contract requires a written form to be effective under pain of nullity.
5. The contract expires after the time for which it was concluded or when circumstances occur for which the parties are not responsible and which prevent its further performance.
6. The Contracting Authority allows for a change to the contract in the form of an annex in the case of:
 - a) when the Intermediate Body needs to change the method of performance of the contract by the Contractor,
 - b) when the deadlines for completing the stages of the project under which the contract is implemented change,
 - c) significant changes in the scope of the subject and manner of performance of the Contract not caused by the action or omission of any of the Parties to the Contract,
 - d) occurrence of force majeure, which makes it impossible to perform the subject of the contract in accordance with the specification of the order.
 - e) changes in the implementation of the project affecting the term of the contract.

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Attachment No. 1 - Offer form

Offer form (Model)

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.....

.....

(place and date)

.....

.....

(name and address of the Bidder)

Offer in the procurement procedure conducted in the form of a request for proposals, with the principle of competitiveness, in accordance with the Guidelines on the eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for 2014-2020 of December 21, 2020, to the documentation Action 1.2 Sectoral Program InnoNeuroPharm under the Smart Growth Operational Program 2014-2020 co-financed by the European Regional Development Fund.

Number: **PB003/34/2023**

Order Name:

" Service to conduct safety, tolerability and potency studies on an animal model for lead molecule PB003."

Project title: „Development of therapy based on immunoligands recruiting the immune system to fight cancer”, no of co-financing agreement: POIR.01.02.00-00-0086/18-00.

- 1. WE SUBMIT AN OFFER** for the performance of the subject of the order and we declare that we will perform it under the conditions set out in the request for proposals No. PB003/34/2023 with attachments.

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2. WE OFFER :

It. No.	STAGE	Price net (PLN/EUR/USD) *	Price gross (PLN/EUR/USD) *
1.	Stage A		
2.	Stage B		
	SUM		

- a) Total net price*
- (in words :)
- b) Gross price TOTAL*
- (in words :)
- *- provide the correct currency for the tender

The above price includes all costs (including an option of additional mice that may be needed) related to the performance of the order, in accordance with the requirements set out in the Inquiry No. PB003/34/2023.

3. WE DECLARE that:

- we will perform the subject of the order, including reports, in accordance with its description and the conditions indicated in the inquiry tender No. PB003/34/2023 with attachments within the maximum period of 15 weeks from the date of order,
- we have read the content of Attachment 2 and that all its provisions are understandable to us and fully acceptable,
- we have the necessary knowledge and experience, including documented experience in conducting research in the field of oncology in mice with hNCG-hIL15 genotypes, we have performed at least 40 tests on these models in the last 24 months,
- we dedicate mice with the hNCG-hIL15 genotypes for research, which will have the appropriate certificates,
- we dedicate a principal investigator with at least 5 years of experience to the research in conducting research in the field of in vivo pharmacology in the field of oncoimmunology,
- we dedicate a pathologist with at least 5 years of experience to the IHC assessment
- we are AAALAC accredited to conduct animal testing under pharmacological research of active substances and have experience in conducting studies under internal SOPs.
- we have the technical potential to perform the order, including: an animal facility with a confirmed SPF standard, the possibility of conducting research on at least 86 mice simultaneously, the possibility of conducting
- we have staff with qualifications that allow us to perform the order, including personnel authorized to work with animals, including animal euthanasia and with a proven track record of working with CD34+ humanized mice with NCG-hIL15 genotype,
- we have the HT-29 cell line and have a track-proven record of HT-29 with subcutaneous inoculation in huHSC-NCG-hIL15 mice for tumor implantation,

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k) at the request of the Ordering Party, before signing the contract, we will present the relevant ones documents confirming the fulfillment of the requirements for Bidders,

l) this offer is public, except for the information contained on the pages, which constitute a company secret within the meaning of the Act on Combating unfair competition and as such cannot be made publicly available.

Forewarned of liability for making a false statement or concealing the truth, we hereby declare that the above-mentioned the data is true.

4. **WE CONSIDER ourselves** bound by this offer for a period of 60 days from the expiry of the deadline for submitting offers - point II.4.4.p.1 of the Request for Proposals No. PB003/34/2023.

5. **ANY CORRESPONDENCE** regarding this proceeding should be addressed to:

First name and last name

Address:

Telephone:

E-mail adress:

6. **OFFER** on _____ consecutively numbered pages and attach the following statements and documents to it:

1).....

2).....

3)...

(place and date)

(signature of the Bidder)

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Attachment No. 3

.....
.....
.....
.....

(name and address of the Bidder)

.....
(place and date)

Declaration of no relationship between cooperating entities

I declare that the Bidder submitting the offer is not personally or financially related to the Ordering Party. Equity or personal links are understood as mutual links between the Bidder and the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party or persons performing on behalf of the Ordering Party activities related to the preparation and conduct of the procedure for selecting the contractor in the procedure no.: **PB003/34/2023 entitled: “Service to conduct safety, tolerability and potency studies on an animal model for lead molecule PB003”**, consisting in particular of:

- a) participating in the company as a partner in a civil law partnership or partnership,
- b) holding at least 10% of shares or shares,
- c) acting as a member of the supervisory or management body, proxy, attorey,
- d) being married, in a relationship of consanguinity or affiliation in the direct line, in a second-degree relationship or in a second-degree affinity relationship in the collateral line, or in a relationship of adoption, custody or guardianship.

There are no links between the Ordering Party and the Bidder mentioned above.

(date and signature of the Bidder)