



Republic
of Poland



MEDICAL
RESEARCH
AGENCY

Wrocław, 10.11.2023

Request for tender no. ABM/23/2023/ZF

Name of Order:

“Determination of the pharmacokinetic profile in animal models”

Project:

“Design and clinical development of the first-in-class small-molecule drug candidate in colorectal cancer therapy, based on the immune cells stimulation to enhanced anti-cancer activity through induced protein degradation.”

Order co-financed by the state budget from the Medical Research Agency



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SECTION I: ORDERING ENTITY

I.1 Name and address of the ordering entity

Captor Therapeutics S.A.
ul. Duńska 11
54-427 Wrocław

NIP 8943071259

I.2. Mode of proceeding

This procedure is awarded on the basis of market discernment.

The contracting authority is not obliged to conduct the proceedings in accordance with the Public Procurement Act.

I.3. Information about the project

The project is co-financed from the state budget from the Medical Research Agency under the Competition no. ABM/2022/6 entitled. "Development of targeted or personalized medicine based on therapy with nucleic acids or small-molecule compounds, KWAS".

Contract No. 2022/ABM/06/00001 - 00.

SECTION II: SUBJECT MATTER OF THE CONTRACT

II.1 Definition of the subject matter of the contract

The subject of the order is to determine the pharmacokinetic profile in animal models. Order implemented for the project:

"Design and clinical development of the first-in-class small-molecule drug candidate in colorectal cancer therapy, based on the immune cells stimulation to enhanced anti-cancer activity through induced protein degradation."

CPV code:

73111000-3 - Research laboratory services



II.2.1. Defining the subject of the order:

- a) The scope of work includes determination of parameters for PK values in animal models. The Bidder shall perform in vivo PK tests (for selected routes of administration per compound) on animal model (healthy mice and rats) for compounds received from the Ordering Party, develop an analytical method for quantitative detection of compounds in animal tissues/ body fluids.

b) General conditions:

Estimated number of compounds:	2 - 10
Test standard:	Non-GLP
Duration of service:	From the day of contract's signing and no longer than 31 October, 2025.
Animal species*:	Healthy mice (the Bidder must have one of these species available: CD-1 or C57Bl/6 or Balb/C), healthy rats (the Bidder must have one of these species available: SD or Wistar)
Route of administration (per a given compound)*:	Intravenous (i.v.)/ oral (p.o.)/Intraperitoneal (i.p)
Method of compound analysis:	LC/MS/MS
*The Ordering party reserves the rights to choose the animal species and route of administration depending on the needs of the Ordering party.	

Planned scope of studies*		
1.	Formulation screening	Solution/Suspension with the stability confirmation in a given formulation with LC/MS method
2.	PK study in mice	(Healthy mice; the Bidder must have one of these species available: CD-1 or C57Bl/6 or Balb/C) including body fluids analysis method development (LC/MS/MS); routes: i.v., p.o., i.p.; Min N=3 per route/dose; price per route/dose, min. 8 time points; including the analysis of a compound concentration in plasma
3.	PK study in rats	(Healthy rats; the Bidder must have one of these species available: SD or Wistar) including body fluids analysis method development (LC/MS/MS); routes: i.v., p.o., i.p.; Min N=3 per route/dose; Min 8 time points; price per route/dose; including the analysis of a compound concentration in plasma
*The Bidder must have a full panel of tests in all variants listed by the Ordering Party. The Ordering party reserves the rights to choose the scope of research individually for each compound. The selection of studies depends on the results from the research work.		



The Bidder will prepare a research schedule and propose experimental conditions: sex, weight, age, number of animals, measurement time, collected blood amount, blood collection method, formulation and submit them for approval by the Ordering party. The research schedule together with a description of the proposed conditions will be sent in writing (it may be sent electronically).

c) Dose and route of administration

Test in dose/s for each of the selected routes of administration, depending on the needs of the Ordering party.

d) Bioassays

The Bidder will develop an analytical method for quantitative detection of a given compound in animal body fluids. The method, together with its description, proposed conditions and parameters will be sent in writing at the request of Ordering party (it may be sent electronically) for formal approval. The quantitative procedure will allow to determine the selectivity, calibration model, stability, precision, detection limit as well as repeatability and accuracy.

II.2.2. Order approval

1. The Ordering party will approve the given order for execution after the mutual determining of the experiment terms and conditions (PK panel).
2. The Ordering Party is planning to sign the contract in November 2023.
3. The Ordering Party reserves the right to implement the subject of the Order in parts, depending on the current demand in the project throughout the term of the contract. The selected panel of tests for a given compound will be consulted with the Bidder each time and will be submitted in the form of an Order ("Order"). The execution of each Order will begin upon mutual acceptance of the terms and conditions of the experiment.
4. The Bidder is obliged to submit technical reports in electronic form on the progress of the work by a person designated to keep in touch with the Ordering Party, the reports should include (at a minimum): a detailed description of the method and results of each experiment/task in Excel form with raw experimental data, as well as in a compiled version and statistical analysis. The bidder shall provide technical reports after the completion of each experiment/task resulting from a given order or once a week (depending on the parties' arrangements).

Note: The Contracting Authority will not incur additional costs associated with the development and submission of the above reports; the costs are included in the cost of the service.



5. The Ordering Party allows the possibility of delay in the order execution as a result the force majeure¹, whose consequences could not have been avoided. In a justified situation where the timely (due to the "Order form" or Agreement) execution of the order is not possible, Contractor shall inform the Ordering party about any delays.

Note: The cost of the service includes all costs related to the execution of the subject matter of the contract, including but not limited to reagents, equipment, salaries, supplies.

II.3 Conditions

1. Partial bids are not allowed.
2. Variant bids are not allowed.
3. The binding period with the bid: : minimum 60 days from the deadline for submission of tenders, with the first day of the tender period being the day on which the deadline for submission of tenders expires.
4. The Ordering Party reserves the right to cancel the request for tender without giving reasons, and may do so at any time without liability to Bidders who submitted bids.

II.4 Requirements for Bidders:

The Contracting Authority stipulates that taking part in the tender process can only Bidder who:

1. Has the permission to perform specific activities if the law imposes an obligation to hold them to perform the activity covered by the Order.
2. Declares that has the technical and professional capacity to perform the contract i.e. it will have at its disposal at the stage of contract execution a team of specialists with the necessary knowledge, appropriate education and experience required for the service, including experts and consultants in the field of PK studies on selected animal model (mouse, rat), have the animal lab with high level of cleanliness (SPF standard) and equipped with Individually Ventilated Cage (IVC) system.
3. Confirms that it has completed at least two projects in the field of PK studies for pharmaceutical industry partners within the last 3 years.
4. Undertakes to humane treatment of laboratory animals used for scientific purposes in accordance with applicable legal requirements.
5. Submit a statement on the lack of relation between cooperating entities (Attachment No. 2).

¹ „force majeure” is understood by both sides to mean as an event beyond the control of (i) the Parties which (ii) prevents proper execution of one or more contractual obligations in spite of proper adherence to the due diligence RFP, (iii) The event (iv) is external and irresistible, unforeseeable with due diligence; whose consequences are irreversible and could not have been avoided. When described conditions can be considered to be fulfilled, the „Force majeure” involved include in particular:

a) exceptional disturbances in collective life (including: wars (also on the territory of others country when its causes has impact on Poland (i.e. sanctions); state of emergency; military operations; invasions; mobilizations; requisitions; terrorism), pandemics, epidemics.

b) the occurrence of radioactive radiation and radiation contamination

c) natural disasters such as earthquakes, floods or other events considered as a disaster in accordance with applicable regulations of affected country.



From the contractor selection procedure are excluded bidders who are personally or financially related to the ordering entity. Financial or personal ties are understood as the relationship between the bidder and the ordering entity or the persons authorized to incur liabilities on behalf of the ordering entity or persons performing on behalf of the ordering party activities related to the preparation and conduction of contractor selection procedure, consisting particularly of:

- A) participating in the company as a partner in a civil law partnership or partnership,
- B) holding at least 10% of shares,
- C) acting as a member of the supervisory or management body, proxy, attorney,
- D) marriage, kinship or affinity in a straight line, second degree affinity or second degree affinity in a sideline or adoption, care or guardianship.

Evaluation of the fulfillment of the aforementioned conditions will be made on the basis of fulfillment / non-fulfillment.

Bidders that do not meet the conditions described in Section II.3 will be excluded from the proceeding

II.5 Submission of bids:

II.5.1. Basic requirements

1. Each Bidder may submit only one bid.
2. The bid and its appendices must be signed by persons authorized to represent the Bidder. If the authority of the signatory does not result from the document stating the legal status (e.g. KRS), the offer must be accompanied by appropriate authorization.
3. The bid and its attachments should be sent electronically.
4. The contracting authority allows the submission of a bid:
 - in the form of a scan of the offer previously bearing his or her handwritten signature,
 - in document form (as referred to in Article 77³ of the Civil Code - electronic document form), i.e. signed files especially with the qualified electronic signature, trusted electronic signature, personal electronic signature, DocuSign, deSignatures, digital representation are recognized as the original
5. The Ordering Party recommends that the bid and the attachments to the tender be prepared on the basis of the templates attached to this request for proposals. If the Contractor plans to submit a bid on its own form, it should include in the content of the documents the statements and requirements specified in the model documents attached to the request for proposal.
6. The bid shall be drawn up in Polish or English. Documents or statements drawn up in a foreign language should be submitted with a translation into Polish or English.
7. The cost of preparing and delivering the bid is covered by the Bidder.



II.5.2 Contents of the offer

The bid should include annexes signed by authorized persons:

- a) appendix no. 1 - the completed offer form with the declarations concerning the Bidder
- b) appendix no. 2 - statement on the lack of relations between cooperating entities.

II.5.3 Place, term and manner of submitting the bid:

1. Tenders should be submitted electronically to 22.11.2023 by 11:00 a.m.
2. Please send your offer to: pmo@captortherapeutics.com. In the title of the email, please write: "The bid in the proceeding no. **ABM/23/2023/ZF**"
3. Tenders received after the deadline will not be evaluated.

II.6 Evaluation of tenders:

1. The Ordering Party shall carry out formal and substantial evaluation of submitted tenders in accordance with the requirements specified in the Request for Tender and according to the evaluation criteria specified in item II.7.1.
2. **Evaluation by criteria** - in accordance with the evaluation criteria set out in section II.7.1, the Contracting Authority will calculate the number of points for each tender.
3. **Substantive evaluation** - The offer, which obtained the highest number of points (according to II.7.1), is subject to substantive analysis in order to verify the compliance of the offered products with the technical specification presented in Annex No. 1. During the offer analysis, the Ordering Party may ask the Bidder for additional explanations or supplements, if the information contained in the offer does not allow for objective evaluation of the offer. The Ordering Party shall reject the offer of the Bidder who has not submitted explanations within the set deadline (min. 2 days) or if the evaluation of the explanations confirms that the offer does not comply with the technical specification. In this situation, the Ordering Party shall evaluate the next bid in order according to the score obtained according to item II.7.1. The Ordering Party reserves the right to extend the time for submitting supplements/clarifications.
4. **Formal evaluation** - the Ordering Party shall examine whether the offer which obtained the highest number of points and passed the substantive evaluation satisfies the formal conditions specified in the Request for Tender. The Ordering Party may call upon the Bidder to supplement formal deficiencies of the offer or to submit explanations regarding formal issues. The Ordering Party shall reject the offer of the Bidder who did not submit supplements within the set deadline (min. 2 days) or if the received response confirms that the offer does not meet formal conditions. The Ordering party reserves the right to extend the time for the submission of supplements/clarifications.
5. The bid which obtains the highest number of points and which is in line with the content and meets the formal requirements will be deemed the most advantageous.
6. Following the evaluation of the bids, the Ordering Party will inform the Bidders by e-mail of the selection of the most advantageous bid



7. The Ordering Party rejects a tender if:
- its content does not correspond to the content of this request for proposals or is incomplete,
 - its submission constitutes an act of unfair competition within the meaning of the rules on unfair competition,
 - The bidder did not submit clarifications/additions to the Ordering Party request regarding the content of the submitted bid,
 - was submitted by a Bidder who does not meet the criteria for this procedure or by a Bidder who is excluded,
 - is invalid under separate provisions.
8. from the contractor selection procedure are excluded Bidders who:
- were directly involved in the preparation of the procedure or used persons involved in the preparation of the tender, unless the participation of those economic operators in the procedure does not hinder fair competition,
 - have submitted false information affecting or likely to affect the outcome of the proceedings,
 - have failed to demonstrate that they meet the conditions for participation in the procedure,
 - have a personal or capital relationship with the Ordering Party.

The bid of an excluded Bidder shall be considered as rejected.

II.7. Criteria for bids evaluation The Contracting Authority will evaluate the submitted tenders according to the following criteria:

1. Criterion - Price - weight 100 points.

The number of points for the price criterion will be calculated according to the following formula (counting to two decimal places), maximum score: 100 pts.

$$\text{Number of points.} = \frac{\text{minimum bid price PLN net}}{\text{price of the tested offer PLN net}} \times 100 \text{ pts.}$$

- The evaluation will be based on the net bid price in the Polish zloty (PLN). In the case of bids submitted in a currency other than the Polish zloty, the average exchange rate of the National Bank of Poland as of the last day for the submission of bids with an accuracy of 4 decimal places will be used for currency conversion.
- The most advantageous bid will be the one that meets the conditions specified in



in points. II.2., II.3, II.6 , which will obtain the highest number of points.

SECTION III: ADDITIONAL INFORMATION

III.1 Forms of communication

1. All correspondence related to the preparation of tenders, including formal and substantive questions, should be sent by e-mail to Diana Zarębska at e-mail address:
d.zarebska@captortherapeutics.com
2. The Ordering Party will answer questions up to 3 working days from receipt of the enquiry if questions are received no later than 2 working days before the date of submission of tenders (the period of 3 days does not include the day of submission of tenders). When calculating the deadline from the date of the question, please note that the day on which the question is received is not included - the first day of the deadline is the next working day after receipt of the question. The deadline ends on the last working day. Answers will be provided by the Ordering Party by e-mail.
3. The Ordering Party reserves the right to extend the response time and the possibility of extending the deadline if the answers to the questions or issues raised involve a change to the terms of the Order.

III.2. Project financing

The ordering entity informs that is going to implement the project with the use of European Union funds under the European Regional Development Fund – Operational Programme smart Growth 2014-2020.

III.3 Important to both parties provisions of the agreement

1. Once the results of the enquiry have been finalized and made public, the Ordering Party and the Bidder will sign the relevant contract. The selected Bidder shall be obliged to sign the contract within the deadline set by the Ordering Party. If the Bidder, whose bid was selected as the most advantageous, refuses to sign the contract, the Ordering Party may select the next most advantageous bid from among the remaining bids.
2. The contracting authority stipulates that the contract will specify contractual penalties for non-performance or improper performance of the subject matter of the contract.
3. The Ordering Party reserves the right to amend the contract concluded with the Tenderer selected in the course of the procedure in the event of the occurrence of one or more of the circumstances listed below, subject to the conditions specified for their introduction:
 - 3.1 The completion date of the contract may change in the following situations:
 - a) the occurrence of force majeure², preventing the timely performance of the subject of the Contract, whereby the Bidder shall be obliged to inform the Ordering Party and specify the

²By "force majeure" is understood by both sides to mean as an event beyond the control of (i) the Parties which (ii) prevents proper execution of one or more contractual obligations in spite of proper adherence to the due diligence RFP, (iii) The event (iv) is external and irresistible, unforeseeable with due diligence; whose consequences are irreversible and could not have been avoided. When described conditions can be considered to be fulfilled, the „Force majeure” involved include in particular:



force majeure causing the impossibility of timely performance of the contract and indicate the impact that this event has had on the course of performance of the contract

- b) the occurrence of extraordinary circumstances, other than force majeure, preventing the timely performance of the subject of the Agreement, which the Parties, exercising due diligence, did not foresee at the conclusion of the Agreement and are not at fault of the Parties;
- c) suspension of the execution of the contract by the Ordering Party due to the occurrence of technical or organizational reasons which make it impossible to continue the execution of the subject matter of the Contract, by the time of suspension. Ordering Party shall notify the Bidder of the suspension of the contract execution, indicating the reason for the suspension;
- d) the occurrence of changes in the project timetable.

The aforementioned changes may not constitute grounds for an increase in remuneration. Any of the above changes may be associated with a reduction in remuneration.

3.2 The Ordering Party shall allow for the possibility of introducing changes to the subject matter of the Agreement or for the Ordering Party to abandon the execution of a part of the subject matter of the Contract in the event of:

- a) Where, for reasons of extreme urgency and after analysing the test results the Ordering Party decided to change the method (for example purity; amount of final product), In such cases Parties may add it to the contracts. All changes mentioned in the preceding sentence may constitute grounds for increasing the remuneration and explanation with proper calculations which directly indicate the amount, term and scope of change.
- b) the occurrence of force majeure, preventing the execution of the subject of the Contract, whereby the Bidder shall be obliged to inform the Ordering Party and specify the force majeure causing the inability to execute the contract on time, as well as indicate the impact that this event has had on the course of the contract execution
- c) the occurrence of circumstances, other than force majeure, preventing the execution of the subject of the Agreement, which the Parties, exercising due diligence, did not foresee at the conclusion of the Agreement and are not at fault of the Parties, e.g. the occurrence of changes in the Ordering Party's research process, occurrence of changes in the project assumptions,
- d) a change in the applicable legislation affecting the subject matter and terms of the contract and a change in the legal or factual situation of the Bidder and/or the Ordering Party resulting in an inability to perform the subject matter of the contract.

a) exceptional disturbances in collective life (including: wars (also on the territory of others country when its causes has impact on Poland (i.e. sanctions); state of emergency; military operations; invasions; mobilizations; requisitions; terrorism), pandemics, epidemics.

b) the occurrence of radioactive radiation and radiation contamination

c) natural disasters such as earthquakes, floods or other events considered as a disaster in accordance with applicable regulations of affected country.



- e) changes in the applicable laws, affecting the modification in realization the subject matter where the new technical or material changes are necessary.

The above-mentioned changes may constitute grounds for increasing the remuneration. In the event of such conditions, the Bidder is obligated to present the explanation with proper calculations which directly indicate the amount and scope of change.

3.3 If in the course of execution of the project carried out by the Ordering Party, the relevant Institution makes any recommendations concerning any changes to the Project affecting the scope of the Agreement, the Agreement may be amended to the extent corresponding to the changes in the Project. The aforementioned changes may not constitute grounds for an increase in remuneration. Any of the above changes may be associated with a reduction in remuneration.

3.4 Form of amendments:

1. Initiation of amendments – at a written request of the Ordering Party and/or Bidder (letter with information).
2. Annex to the Agreement with the Bidder in writing, otherwise being null and void.

Appendices:

Appendix no. 1 - Bid form

Appendix no. 2 - Statement on the lack of relation between cooperating entities



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Appendix no. 2

.....
(place and date)

.....
(name and address of the tenderer)

Statement on the lack of relation between cooperating entities

I declare that the Bidder submitting the bid is not related personally or financially with the ordering party. Financial or personal ties are understood as the relationship between the bidder and the ordering party or the 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 conduction of contractor selection procedure, in the procedure: ABM/23/2023/ZF entitled: **“Determination of the pharmacokinetic profile in animal models”** consisting in particular of:

- a) participating in a company as a partner in a civil partnership or a partnership,
- b) owning at least 10 % of the shares,
- c) acting as a member of a supervisory or management body, proxy or attorney,
- d) marriage, kinship or affinity in a straight line, second degree affinity or second degree affinity in a sideline or adoption, care or guardianship

In addition, I declare that the Bidder is not a related party to the Ordering Party, within the meaning of Commission Regulation (EC) No. 1126/2008 of November 3, 2008 adopting certain international accounting standards in accordance with Regulation (EC) No. 1606/2002 of the European Parliament and of the Council.

There are no mentioned above relations between ordering entity and the bidder.

.....
(Stamp, date and signature of the bidder)