







WROCŁAW, 27.04.2023

Invitation to submit a bid within the framework of the project entitled "Inducing apoptosis with small molecules as therapeutic intervention in multiple severe malignancies", European Regional Development Fund through National's Centre for Research and Development (POLAND)

Operational Programme Smart Growth 2014 – 2020

ORDER NO: CT2/2/23

Name of order:

"API manufacture - GMP campaign"











SECTION I: ORDERING ENTITY

I.1. Name and address of the ordering entity

Captor Therapeutics Inc. Dunska 11 street 54-427 Wroclaw, POLAND VAT NUMBER 8943071259

I.2. CPV code for the order subject

CPV: 73111000-3 - Research laboratory service

SECTION II: SUBJECT OF THE ORDER

List of abbreviations:

For the purposes of this tender request, abbreviations are used in the description of the subject matter of the contract:

- 1. API (Active Pharmaceutical Ingredient)
- 2. GMP (Good Manufacturing Practice)
- 3. (rac)- racemate
- 4. ((rac)-CT Cmpd 2 or (rac)-CT Cmpd 3 or (rac)-CT Cmpd 4) the names of the compounds restricted details of the compounds will be made available upon signature of a confidentiality agreement
- 5. BB Building Block
- 6. RSM Regulatory Starting Material
- 7. IPC In-Process Control
- 8. ICH International Council for Harmonisation
- 9. EMA European Medicines Agency
- 10. FDA Food and Drug Administration

II.1. Mode of proceeding

This procedure is conducted in the mode of invitation to submit a bid, according to the principle of competitiveness.

The basis for initiating said action are guidelines for eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for the years 2014-2020.

II.2. Defining the subject of the order

The subject of the order is a manufacture of active pharmaceutical ingredient (API) in large scale under GMP conditions - for the purpose of project's implementation.











II.2.1. Name of the order:

"API manufacture - GMP campaign".

Title of the project: "Inducing apoptosis with small molecules as therapeutic intervention in multiple severe malignancies", European Regional Development Fund through National's Centre for Research and Development (POLAND) Operational Programme Smart Growth 2014 – 2020. POIR.01.01-00-0956/17. "The project".

II.2.2. Detailed description of the subject of the order

- 1. The Ordering Party stipulates that disclosure of the full details concerning the subject of the tender will be made or provided after signing the confidentiality agreement (in case of Bidders with whom such agreement have not yet been concluded) according to Appendix No. 3.
- 2. The Subject of the tender refers to manufacture of the active pharmaceutical ingredient (AP) called (rac)-CT Cmpd 2 or (rac)-CT Cmpd 3 or (rac)-CT Cmpd 4 on a scale of (2 Kg or 3 Kg or 5 Kg)* under GMP standards.
- 3. The activities within the above subject's tender will cover the following two stages divided into a main order and an optional order:

STAGE 1 (the main order)

- a. The Bidder will produce or purchase the BB1 (Building Block 1) in the amount reliable to secure production of the defined amount of API* till the **end of September 2023.**
- b. The Bidder will produce the BB2 (Building Block 2) in the amount reliable to secure production of the defined amount of API*, where the last chemical transformation leading to the BB2 will be performed in GMP regulated manufacturing environment in order to be classified as RSM (Regulatory Starting Material), till the **end of September 2023.**
- c. The Bidder will perform at least the first 2-3 chemical transformations (for the main synthesis pathway), leading to cmpd C on the scale intended to produce defined amount of API*, till the end of September 2023.

The Ordering Party obliges to provide the selected Bidder, with technical documentation on the synthetic methods (verified, adapted and reproducible) developed for the production process for the demo and/or non-GMP batches at the scale of 1KG (rac)-CT Cmpd 2.

STAGE 2 (the optional order)

- a. The Bidder will establish a process and documentation for GMP manufacture of the nominated API on the scale and phase intended based onthe process developed for non-GMP production, (details of which will be provided to the Bidder, after signing the confidentiality agreement).
- b. The Bidder will establish specification, validation and to perform analytical method development for release of the final product (API), release of the RSMs (Regulatory Starting Materials) and analysis of the intermediates formed during the production process using validated











IPC (In-Process Control) analytical methods complying with GMP protocols. Analytical method development required for releasing the API should comply with ICH guidance and include the following parameters: appearance, identity, purity, determination and identification of impurities (side-products), hygroscopicity, residual water, residual solvents, elemental analysis (if required), determination of counter-ion (for a salt form), residual metals, physical form determination of the final product and particle size distribution in the final batch of the product.

- c. The Bidder will oblige to manufacture on the scale of 2KG or 3KG or 5KG* of the nominated API ((rac)-CT Cmpd 2 or (rac)-CT Cmpd 3 or (rac)-CT Cmpd 4)* under GMP conditions using verified, applicable and reproducible synthetic methods developed on demo and 1KG scale of non-GMP (rac)-CT Cmpd 2. The Ordering Party will provide the relevant technical documentation.
- d. The Bidder will produce the API complying with relevant acceptance criteria including agreed purity profile of the API and its appropriate physical form (to be determined by Ordering Party in details prior to initiation of the GMP manufacturing campaign).
- e. The Ordering Party stipulates that the API will be manufactured under GMP condition for the last 3-4 chemical transformations (accordingly to the main synthetic pathway) and the API will be delivered to the Ordering party.

*Note: The tenderer will be obliged to price the manufacture of the active pharmaceutical ingredient (API) substance ((rac)-CT Cmpd 2 or (rac)-CT Cmpd 3 or (rac)-CT Cmpd 4) on a scale of (2 Kg or 3 Kg or 5 Kg) in GMP standards.

The Ordering Party divided, considering the 3 different API active pharmaceutical compounds and the 3 different production quantities of the substance, into 9 variants detailed in Annex 1 Tender Form to the request for proposal.

The Ordering Party requires the Bidder to submit a bid for all variants that are listed in Annex 1 of the Request for Proposal.

The Ordering Party shall, on the based on the results of the research and development work, select one variant by the end of the 15 Juny 2023 at the latest, of which it shall inform the selected Bidder immediately ("Selected Variant"). The Bidder will be obliged to perform the service only with regard to the Selected Variant.

- 4. The Ordering Party provides for the possibility of applying the right of option to this contractapplies to Stage 2 of the tender.
- 5. The Ordering Party allows for the possibility of "Supplementary contracts" within the meaning of point 6.5.7 g) from Guidelines on the eligibility of expenditures under the European Regional Development Plan. The Plan consist on the repetition of similar services i.e. "API manufacture GMP campaign". As "Similar services" The Ordering Party defines: Synthesis and manufacture of API in large scale under GMP for selected batches.
 - Supplementary contract may be concluded within 3 years from the date of signing agreement to a core project.
 - In order to carry out the supplementary contracts' services The Ordering Party shall invite the Bidder to the new contract negotiations where the detailed scope of work remuneration, terms and conditions will be determined.
- 6. The Ordering party is expecting to sign the cooperation agreement with the selected Tenderer in Q2 of 2023, by 30.06.2023, and to commence the service no later than July 2023, which should be carried out in accordance with the provision of point. III. 3 of the Tender Request.











- 7. Cost of the service includes all costs related to the execution of the order like cost of reagents, equipment, salaries, shipments and also costs of reports.
- 8. The Bidder will additionally deliver to the Ordering party:
- a) Representative samples of all intermediates and final product.
- b) The results of analytical measurements taken during the production process, for isolated intermediates as well for the final product, in the form of reports.
- 9. The Bidder will be obligated to provide following reports (in an electronic form) by a person assigned for contacts with the Ordering party:
- a) Technical reports (written in an electronic form) and work progress updates (via teleconference) (weekly).
- b) Summary reports with regard to each completed stage.
- c) Final reports for final product including description of a synthesis pathway under GMP regulations, the detailed GMP production protocols (with detailed reaction conditions, reaction yields, information about potentially formed side-products, detailed qualitative and/or quantitative analysis for used for this particular process with detailed description of the execution sequence) in the case of Stage 2.
- 10. For every delivered batch of manufactured final compound (API), the Bidder is obligated to provide certificates of analysis and certificates of quality control or other documents confirming product purity and quality. The exact details of responsibilities to guarantee the quality of GMP (including the required quality parameters and the responsibility of the parties for meeting these) will be defined in a quality contract. The quality contract will be concluded at the latest at the time of the Purchaser's decision on the implementation of stage 2.
- 11. The Ordering Party allows the possibility of delay in the order execution as a result the force majeure¹, which consequences of could not have been avoided. In justified situation where the timely (due to the bid) execution of order is not possible, Bidder shall inform the Ordering party about any delays.

II.2.3. Conditions

- 1. Possibility of submitting a partial bid is not admissible. The Ordering party treats the bid as a one continuous process.
- The Ordering Party shall accept the possibility of submitting a variant bid. The Ordering Party shall specify nine variants, which the Tenderer is obliged to specify in his tender, in accordance with Appendix No. 1 Tender Form. The Ordering Party based on the outcome of research and development works will select one variant by the end of May 2023 and will inform the Bidder

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



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









immediately ("Selected Variant"). The Bidder will be obliged to performe services only in relation to the Selected Variant.

- 3. The Ordering Party provides for the possibility of applying the right of option to this contract. The contract covered by the right of option refers to the scope presented in Stage 2. The right of option is an entitlement of the Ordering Party, which may, but does not have to, be exercised in the performance of this contract. If the Ordering Party does not exercise its right of option, the Contractor shall not be entitled to any claims on this account.
 - The Ordering Party may exercise the right of option within 3 months from the date of conclusion of the contract and shall inform the Bidder by e-mail.
 - The Ordering Party shall decide on the implementation of Stage 2 depending on the available possibilities of further project financing.
- 4. The binding period with the bid: 90 days from the last day of submitting the offers, which is counted as the first day of its validity.
- 5. The Ordering party reserves the right to cancel the request of tender anytime and without giving the reason and with no consequences relative to the Bidders.

II.3. Requirements for the Bidders:

The Ordering party reserves that offers may be submitted only by the Bidders which:

- 1. have the rights/necessary permits (approved by legal authority) to perform a requested activity including activities related to API production with unknown biological activity, if such permits are required by the law to perform the activities covered by the contract.
- 2. The Bidder has the technical and professional capacity to perform the contract, i.e. the Contracting Authority requires the Tenderer to demonstrate that:
 - (a) will have at its disposition during the order execution phase expert(s) and consultant(s) in the field of synthetic organic chemistry and/or in the field of research and development, with the possibility of using their competences for the execution of the order.
 - (b) will declares that carried out at least 2 services related to the synthesis of at least: 1 KG of an active pharmaceutical ingredient (API) under GMP standard in the last 3 years.
 - (c) will have on its premises capability for integrated processes/operations (solid state characterization, ability to generate and/or collect the required physicochemical data which are essential for developing pre-clinical formulation of the API) during the execution of the order.
 - d)) will possess capability to manufacture of the requested API being the subject of the order, have a large-scale flow reactors, continues stirred tank reactors (CSTR) and possibility to conduct deuteration reaction.
- The Bidder will be capable for technology transfer of established, developed and evaluated chemical production processes of API from non-GMP to GMP production under EMA and/or FDA regulations.
 - The Bidder is obliged to provide the Purchaser with a copy of the current GMP certificate issued by the EMA or FDA.
- 4. The Bidder will agree for the audit of manufacturing site and analytical laboratories which can be conducted by Ordering Party or other entity authorized by Ordering Party. The cost of the audit will be covered by the Ordering Party.











5. The bidder should submit the statement on the lack of relation between cooperating entities (Attachment 2).

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.

- 6. In order to prove the fulfilment of the conditions of participation in the proceedings (as specified in item II.3 from 1 to 4), the Bidder is obliged to submit a declaration, the contents of which are contained in item 4 of the Bid Form, constituting Appendix No. 1 to the Request for Tender.
- 7. Bidders that do not meet the conditions described in Section II.3 will be excluded from the proceeding.

II.4. Submission of the bids:

II.4.1. Basic requirements

- 1. Each Bidder may submit only one bid.
- 2. The bid must be prepared strictly in accordance with the requirements specified in this invitation.
- 3. The bid must be signed by person(s) authorized to represent the bidder.
- 4. The authorization to represent the bidder should be indicated in the submitted documents. If the authorization does not result directly from the registration documents (extracts from KRS or CEiDG; or other document which is issued in the Bidder's country and state the legal status of the Company), it is necessary to attach the original of power of attorney or certified copy signed by authorized person. Documents send via electronic way as a scan or other documentary form (with the meaning of the Article 77³ of the Civil Code) i.e. signed files especially with the qualified electronic signature, trusted electronic signature, personal electronic signature, DocuSign, digital representation are recognized as the original.
- 5. It is highly recommended that the bid and attachments are prepared in accordance with the templates (attached to the RFP). Bidder may submit the offer on its own form only if the content of documents/statements/requirements complies with the templates.
- 6. The cost of preparation and delivery of the bid is covered by the bidder.











II.4.2. Form of the bid

- 1. The bid must be made in Polish or English on the Bid form (Attachment no. 1). Bidder may submit the offer on its own form only if the content of documents/statements/requirements complies with the templates.
- 2. The documents shall be presented in the original or in copy certified by the person/persons authorized to represent the Bidder who are indicated in the Bidder's registration document or the Power of Attorney. Statements attached to the bid should be signed and presented in the original. All copies of the supporting documents shall be certified as true copies by the authorizing person/persons in accordance to company's legal status.
- 3. The Ordering party accepts documents signed in manuscript by the Bidder, as a scan of the signed bid together with appendices (attachments), documentary form, (with the meaning of the Article 77³ of the Civil Code) i.e. signed files especially with the qualified electronic signature, trusted electronic signature, personal electronic signature, DocuSign, digital representation.
- 4. If Documents are sent electronically The Ordering Party shall consider it as the original.
- 5. The Ordering Party may request the submission of an original or a notarially certified copy of a document only if the copy of the document submitted by the Bidder is illegible or raises reasonable doubts as to its authenticity, and the Tenderer cannot verify its authenticity in any other way.

II. 4.3. Content of the bid

The bid should include at least:

- 1. If the documents are signed by the person(s) representing the bidder other than indicated in the bidder's registration document, the power of attorney should be attached to the bid to: represent the bidder in the procurement procedure and sign the contract. It is also possible to submit a copy of the power of attorney. The allowed forms of documents are indicated in the II.4.1. point 4.
- 2. The current extract from the relevant register or from the central business information register, issued not earlier than 6 months before the deadline for the bids submission (the original or a copy certified by the person authorized to represent the bidder). It is allowed to submit a document in the form of a printout from the website. When the extract comes from commonly available database (www.ms.ekrs.gov.pl, www.ceidg.gov.pl), The Bidder may not attach it to the Offer. The Ordering party shall download the documents directly from the website.
- 3. A copy of a current GMP certificate issued by EMA or FDA.
- 4. Initialized and signed by persons authorized attachments:
- A) Appendix No. 1 completed bid form together with statements concerning the Bidder,
- B) Appendix No. 2 statement on the lack of relation between cooperating entities.
- C) Appendix No. 3 Confidentiality Agreement (applies, if the Bidder has not previously signed the document).

II.4.4. Place, term and manner of submitting the bid

- 1. The bids must be submitted by May 30, 2023 till 11 a.m. CET.
- 2. The bid must be submitted by choosing one of the following:











| a) | in | person. | . by th | e courier | or traditional | bost |
|----|-----|---------|----------|-------------|----------------|------|
| uj | 111 | person, | , Dy Lii | c countries | or traditional | P |

| at the Project Office of the Ordering party at Dunska 11 street, 54-427 Wroclaw, POLAND. The |
|--|
| Project Office is open from Monday till Friday from 9:00 am to 3:00 pm. |
| in a hard copy, in a non-transparent, sealed envelope, which should be described as follows: |
| Name of the Bidder: |
| Bidder's address: |
| Contact person (name, surname, email address): |
| The bid in the in proceeding No. CT2/2/23 ""API manufacture - GMP campaign" |
| Do not open before: May 30, 2023 till 11 a.m. CET |

- b) electronically via website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/, in accordance with the requirements set out in point II.4.2
- c) <u>electronically via e-mail</u>, to the address: <u>pmo@captortherapeutics.com</u>, in accordance with the requirements set out in point II.4.2

The message containing the tender should be titled:

"Request for tender No. CT2/2/23. DO NOT OPEN before May 30,2023 till 11 a.m. CET".

3. The bids received after the deadline will not be considered.

II.5. Mode of evaluating the bids

- 1. The Ordering party will examine all the bids according to the requirements described in the point II.4.4., according to the criteria for the evaluation set out in point II.7.1.
- 2. The substantive analysis would be conducted for the offer with the highest score of points regarding the Selected Variant (according to II.7.1.). The ordering party examine whether offer complies with the specification according to II 2.2. During the examination procedure, The Ordering party may ask about additional explanations or to complement previously submitted documentation if it is essential for the proper evaluation. If the bidder will not make an explanation in the specific time or the explanation indicates non-compliance the offer would be rejected. In this case, the Ordering party will examine the next offer (with the second point score regarding the Selected Variant) according to the II.7.1.
- 3. The Ordering Part shall examine whether the bid which has received the highest score as per item II.7.1 and has passed the substantive evaluation (as per item II.7.2) fulfils the formal conditions. The Ordering Party may request the Bidder to complete formal deficiencies of the offer, such as: power of attorney, statement about the lack of connections between cooperating entities, lack of company registry documents, unless the extract from the registry can be obtained by the Ordering Party from publicly available databases (www.ms.ekrs.gov.pl, www.ceidg.gov.pl), the Bidder shall not be obliged to attach the extract from the registry to the offer, the Ordering Party shall download the appropriate document from the website, etc. The Ordering Party shall reject the offer of the Bidder which has been evaluated according to the point II.7.1. The Contracting Authority shall reject the offer of the Tenderer who did not submit supplements within the designated time limit or if the response received confirms that the offer does not meet formal











requirements. An offer which does not meet at least one of the conditions described in points II 2.3, II.4. shall be rejected or the Bidder shall be excluded, and the Ordering Part shall examine the next highest evaluated offer (with the second score for the Selected Variant).

- 4. In the event that the Tenderer is called upon by the Contracting Authority to respond, relating to the clarification or supplementation of the tender, the Tenderer shall be given a reasonable period of time to supplement or clarify the documents, but not less than 2 working days from the date of delivery by the Contracting Authority of the question/request for clarification or supplementation.
- 5. After analyzing the bids and considering in accordance with the principle of competitiveness the submitted bids, the ordering party will inform the bidders about the selection of the most advantageous bid and will publish the results in the Competitiveness Center of European Funds (https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/) and by email.

II.6. Rejection of the bid, exclusion of the bidder

- 1. The ordering party rejects the bid if:
 - a) its content does not correspond to the content of this inquiry or is incomplete,
 - b) its submission constitutes as an act of unfair competition within the meaning of the provisions about unfair competition.
 - c) did not submit to the ordering party's request for explanations concerning the content of the submitted bid,
 - d) was submitted by the bidder not meeting the criteria of this procedure or by the bidder excluded,
 - e) is invalid on the basis of separate regulations.
- 2. Bidders are excluded from the procedure, if:
 - a) they were directly involved in the preparation of the proceedings or used to prepare the bid to the participants, unless the participation of these contractors in the proceedings does not impede fair competition,
 - b) have submitted untrue information affecting or likely to affect the outcome of the proceedings,
 - c) have not demonstrated that they meet the conditions for participation in the procedure,
 - d) are personally or financially related to the ordering entity.

The bid of excluded bidder is considered to be rejected.

3. The bidder reserves the right to cancel the tender without assigning any reason at any time and without liability to the bidders who submitted a bid.

II.7. Criteria for bids evaluation:

- 1. The Ordering entity will evaluate bids regarding the Selected Variant according to the following criterion:
 - a) Criterion Net price weight 100 pts.

The criterion "Net price" will be evaluated on a point scale. After taking into account the weighting of the criterion, the lowest bid will score 100 points, the others proportionally less.











The number of points for the price criterion will be calculated in the following formula (counting to two decimal places):

Number of points =
$$\frac{\text{min. price offered net } [PLN]}{\text{price of the bid net } [PLN]} \times 100 \text{ pts.}$$

where,

The net price will be calculated as the sum of Stage 1 (the main contract) and Stage 2 (optional order) for the Selected Variant.

An offer regarding the Selected Variant can receive a maximum of 100 points.

- 2. The most economically advantageous tender will be the one which obtains the highest number of points in the criterion of Net Price for the Selected Variant.
- 3. The evaluation will be based on the net bid price for the Selected Variant in the Polish zloty (PLN). In the case of offers submitted in a currency other than Polish zloty, the average exchange rate of the National Bank of Poland of the day preceding the day of submitting the offers with 4 decimal places will be used for currency conversion.
- 4. The Ordering Party accepts the submission of a tender in PLN/EUR/USD. If an offer is submitted in a currency other than PLN/EUR/USD the offer shall be rejected
- 5. **The substantive analysis** The Ordering entity examine whether the offer with the highest score regarding the Selected Variant (II.7.1.) complies with the requirements according to II.2.2.
- 6. **The formal assessment –** The Ordering entity examine whether the offer and the Bidder meet the requirements (II 2.3, II.3., II.4.)
- 7. An Offer with the highest point score regarding the Selected Variant which meets all the substantive and formal requirements (described in II.2.3, II.3, II.4) shall be considered as the most advantageous.

SECTION III: ADDITIONAL INFORMATION

III.1. 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.2. Forms of communication

Any correspondence related to the preparation of bids or answering inquiries must be delivered
in writing to the project office at: Dunska 11 street, 54-427 Wroclaw, POLAND or by e-mail to
a.karczmarz@captortherapeutics.com via the Competitiveness Center of European Funds at
https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/. For questions the ordering party will
respond by the Competitiveness Center of European Funds at
https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/











submitted via email) within 5 working day of receipt of the inquiry, provided that the questions will be received no later than 5 working days before the date of submission of bids. The time for answering for Bidders questions is counted from the first business day after submitting question. The term ends with the last (5th) working day.

- 2. The ordering entity is not obliged to conduct proceedings under the Public Procurement Act.
- 3. The content of the inquiry is available at the registered office of the ordering entity: Dunska 11 street, 54-427 Wroclaw, POLAND as well as in the European Funds Competitiveness Base https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/
- 4. If the answers to the questions or reported problems are associated with a change in the terms of the contract, all Bidders will be notified of the changes by the European Funds Competitiveness Base.

III.3. Term of contract execution

Contract completion date:

- 1) The main order until 30 September 2023,
- 2) The optional order until 30 November 2023,

The Ordering Party will allow the date of the optional order to be changed, depending on the financing and timetable for the project.

Expected date of signing the Cooperation agreement: II quarter of 2023, until 30.06.2023 r.

III.4. Important to both parties provisions of the agreement

- 1. Upon completion and publication of the results of the tender procedure, the Ordering party and the Bidder who submitted the most advantageous bid, will sign the Cooperation agreement.
- 2. Prior to signing a contract with the selected Bidder, the Ordering Party may require a current tax residency certificate (if applicable) in justified cases.
- 3. If the Contractor demands signing any additional document (license agreement, SOW etc.), it must comply with the provisions of tender CT2/2/23.
- 4. The Ordering party may charge the contractor with contractual penalties on the terms specified in the agreement.
- 5. The Tenderer shall provide the Purchaser with a copy of a current GMP certificate issued by the EMA or FDA, valid for the duration of the contract.
- 6. Due to the nature of the subject of Tender, The Ordering Party allows the possibility of prepayment and partial payments before and during the service implementation of the service. Details shall be determined when negotiate the Agreement.
- 7. The Ordering Party reserves the right to amend the Agreement concluded with the Bidder selected in the course of the proceedings, if at least one of the circumstances listed below occurs, taking into account the indicated conditions for introduction thereof:
 - 7.1 Deadline for completion of the order can change in the following situations:
 - a) occurrence of a force majeure event (in the meaning of the point pkt II.2.2. RFP), making it impossible to timely perform the subject matter of the Agreement, whereas the Bidder is obliged to inform the Ordering Party thereof and specify the force majeure event











preventing it from executing the order on time, and to specify the impact that such event had on the execution of the order

- b) occurrence of extraordinary circumstances other than force majeure, making it impossible to timely perform the subject matter of the Agreement, which were not predicted by the Parties, despite exercising due diligence, at the time of execution of the Agreement and are not due to the Parties' fault;
- c) suspension of the execution of the order by the Ordering Party for technical or organizational reasons making it impossible to continue the performance of the subject matter of the Agreement, for the duration of such suspension. The Ordering Party will notify the Bidder of the suspension of the order and indicate the reason of suspension;
- d) any changes in the time schedule of execution of the Project, for which the agreement of NCBiR isessential by extending the period for completion of the subject matter of the Order beyond November 30, 2023 by the time necessary for proper completion of the subject matter of the Order. The Ordering Party, in each case after negotiations with the Contractor, shall determine the date by which the period for the execution of the Order should be extended.
- e) If the Project's research process changes force to change the timeline for performance of the subject matter of the Agreement. Due to the experimental character of the research, there may be a need to extend the time for each stage in project for the duration of such the performance of all tasks.

In the event of any conditions above (a-b), The Bidder is obligated to demonstrate the effects on the performance of the subject of contract reasoned. The timeline in Agreement may be extended for the duration of the obstacles as well the time needed to remove the effects.

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.

- 7.2 The Ordering Party allows for the possibility to make changes in the subject matter of the Agreement or to choose not to carry out a certain part of the subject matter of the Agreement 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, number of chemists dedicated for the project), 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) occurrence of a force majeure event (in the meaning of the point pkt II.2.2. RFP) making it impossible to timely perform the subject matter of the Agreement, whereas the Bidder is obliged to inform the Ordering Party thereof and specify the force majeure event preventing it from executing the order on time, and to specify the impact that such event had on the execution of the order.
 - c) occurrence of extraordinary circumstances other than force majeure, making it impossible to timely perform the subject matter of the Agreement, which were not











predicted by the Parties, despite exercising due diligence, at the time of execution of the Agreement and are not due to the Parties' fault, including e.g. any changes to the Ordering Party's research process, changes in the project assumptions,

- d) changes in the applicable laws, affecting the subject matter and the terms of the Agreement and any change of the legal or factual situation of the Bidder and/or the Ordering Party resulting in the impossibility to perform the subject matter of the Agreement
- 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, the Bidder is obligated to present the explanation with proper calculations which directly indicate the amount and scope of change.

7.3 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.

7.4 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.











| _ | | | | _ |
|----|-----|------|----|---|
| ЯD | per | าdix | no | 2 |

| (p | lace and date) |
|----|----------------|

(name and address of the bidder)

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: CT2/2/23 entitled:

"API manufacture - GMP campaign"

- "" 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.

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

(stamp, date and signature of the Bidder)











Appendix no 3

Confidentiality Agreement

between

| Captor Therapeutics S.A., a company organized and existing under Polish law, with its registered office at | : ul. |
|--|-------|
| Duńska 11, 54-427 Wrocław, Poland entered into commercial register under KRS number: 0000756383, sh | are |
| capital: PLN 420,914.90, NIP: PL8943071259, represented by: | |

| hereinafter referred to as "Captor" | | | |
|-------------------------------------|---|--|--|
| and | | | |
| | hereinafter referred to as the "Partner". | | |

Captor and Partner are referred to herein collectively as the "Parties" and each individually as a "Party" Whereas:

- the Parties intend to _____ ("Cooperation"),
- in order to discuss the possibility of the Cooperation, and in case of establishment of such Cooperation, also in order to enable such Cooperation ("Purpose") it is anticipated that each Party may disclose (in each case such Party being referred to as "Disclosing Party") to the other Party (in each case such Party being referred to as "Receiving Party") certain Confidential Information (as defined hereunder),
- the Receiving Party may use the Confidential Information only for the Purpose and subject to the terms and conditions agreed herein.

NOW THEREFORE in consideration of the premises and mutual obligations hereinafter described, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby covenant and agree as follows:

1. CONFIDENTIAL INFORMATION

- 1.1 The Receiving Party acknowledges the confidential and proprietary nature of the Confidential Information, as defined herein, and agrees to hold and keep secret and confidential as provided in this Agreement, and agrees to each and every restriction and obligation set out in this Agreement.
- 1.2 "Confidential Information" shall mean all confidential or proprietary materials or information of the Disclosing Party disclosed to the Receiving Party, either directly or indirectly. Confidential Information includes, without limitation, information that falls within the types of information which has been designated as confidential by either Party or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including without limitation information which relates to the business, affairs, properties, assets, trading practices,











goods/services, developments, trade secrets, Intellectual Property rights, know-how, personnel, customers and suppliers of either Party, all personal data and sensitive personal data within the meaning of the applicable privacy laws and the commercially sensitive information.

Confidential Information shall be understood in particular (but not limited to) any information regarding: any projects or research, research results, research and development, experiments and tests, methods, formulae, components, chemical structures, sequence, weight, compositions, specifications, molecules, structure, doses, processes, experience, discoveries, know-how, inventions, intellectual property, patent applications, ideas, conceptions, plans, models, algorithms, analytical methods, products and planned products, use of the products, manufacturing technology, synthetic procedures or other information or material, including test and study data of any kind (including pharmacological, pharmaceutical, physical, biological, chemical, biochemical, study designs, protocols and procedures), trade secrets, contracts, clients, suppliers and other business partners, distribution, financial data, business plans, marketing strategies, development strategies, registration strategies, employment etc.

Confidential Information shall also include all discoveries, experimental results, research, formulations, reports, papers, notebook entries, descriptions, excerpts, samples, any notes, memoranda and the like, or other work product developed by the Receiving Party comprising or incorporating, in whole or in part, Disclosing Party's Confidential Information, or derived from or based on Disclosing Party's Confidential Information.

The fact that conversations between the Parties related to the Purpose are occurring, the content and terms of any offer or proposal and the terms of this Agreement shall be treated as Confidential Information.

2. UNDERTAKING OF THE RECEIVING PARTY

- 2.1. The Receiving Party hereby undertakes to use Confidential Information, only in the necessary extent, solely and exclusively for the Purpose. In particular Receiving Party undertakes not to use Confidential Information for any other purpose whatsoever, including but not limited to: (i) conducting research or experiments, (ii) performance of any services for third parties, (iii) development, manufacture, marketing, sale or licensing of any process, services or products or any other commercial purpose anywhere in the world.
- 2.2. The Receiving Party hereby undertakes to maintain the confidentiality of Confidential Information and not to disclose it directly or indirectly to any third party, organization, individual, the Receiving Party's employees (subject to point 5 below), or otherwise, in particular not to publish Confidential Information or any part thereof, without the prior written consent of the Disclosing Party.
- 2.3. The Receiving Party hereby undertakes to keep the Confidential Information safe in a secure place and properly protected against theft, damage, accidental or other loss, negligent disclosure, or unauthorized access (including, but not limited to, access by electronic means) and, without prejudice to the foregoing, to take all reasonable due precautions and steps and to exercise reasonable skill and due degree of care to protect its confidentiality. In each case such precautions, skills and degree of care shall be no less than the precautions, skills and degree of care the Receiving Party applies to its own confidential information but in any event no less than reasonable care.











- 2.4. The Receiving Party may reproduce the Confidential Information only to the extent necessary for the Purpose, with all such reproductions being considered Confidential Information.
- 2.5. The Receiving Party is obliged to notify the Disclosing Party promptly of any misuse, misappropriation or unauthorized disclosure of Confidential Information, or any threat thereof, which may come to the Receiving Party's attention.

3. EXCLUDED INFORMATION

- 3.1 Confidential Information does not include any information that Receiving Party can establish by competent evidence:
 - 3.1.1 is now or later made known to the public through no wrongful act or default of the Receiving Party; or
 - 3.1.2 is lawfully received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party and being in lawful possession of such information; or
 - 3.1.3 is independently developed by the Receiving Party without reference to or reliance upon Disclosing Party's Confidential Information; or
 - 3.1.4 is disclosed by the Receiving Party after receipt of written permission from the Disclosing Party in accordance with the provisions of such written permission; or
 - 3.1.5 is in the Receiving Party's possession at the time of disclosure other than as a result of a prior confidential disclosure by the Disclosing Party or another party or the Receiving Party's breach of any legal obligation hereunder.
- 3.2 If disclosure of Confidential Information is required under binding law prior to such disclosure the Receiving Party will give if permitted by the applicable law the Disclosing Party a prompt written notice of the information to be disclosed and will take into account any reasonable comments of the Disclosing Party it may have in relation to the content, timing and manner of dispatch of the disclosure and take such steps which are reasonably required to enable the Disclosing Party to mitigate the extent of or avoid the requirement of any such disclosure. The Receiving Party may disclose only the minimum amount of Information consistent with satisfying obligations and shall use reasonable efforts to protect the Confidential Information in connection with such disclosure; provided that any Confidential Information so disclosed shall maintain its confidentiality protection for all purposes other than such legally compelled disclosure.

4 PUBLIC TRADING

4.1 Partner acknowledges that it is aware of the fact that Captor is an issuer of financial instruments admitted to public trading on a regulated market operated by Warsaw Stock Exchange and hence certain Confidential Information disclosed to Partner may constitute inside information within











the meaning of the Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse ("Market Abuse Regulation"). Partner acknowledges that it is aware of the legal consequences arising from such fact, in particular, that (i) Partner shall not a) engage or attempt to engage in insider dealing, b) recommend that another person engage in insider dealing or induce another person to engage in insider dealing, c) unlawfully disclose inside information, (ii) Partner shall maintain a list of persons having access to inside information, and (iii) there are administrative and criminal sanctions for breach of the above obligations. Captor will inform Partner separately of providing the Receiving Party with inside information (if any).

4.2 The Parties confirm that provisions of this Agreement shall not restrict or prohibit Captor from proper fulfilment of its disclosure obligations or obligations towards regulatory authorities, in particular fulfilment of obligations stemming from Market Abuse Regulation, and fulfilment of such obligations shall not be treated as breach of this Agreement.

5. PERMITTED DISCLOSURE

The Receiving Party shall only disclose Confidential Information, in the necessary extent, to its employees who need to know the Confidential Information in order to advise the Receiving Party for the Purpose, provided that the Receiving Party shall procure that prior to such disclosure each of those employees to whom Confidential Information is to be disclosed is made aware of the confidentiality, non-use and other obligations contained herein and are bound by obligations of confidentiality and restrictions on use and non-disclosure that cover such Confidential Information and are at least as stringent as those set forth in this Agreement. Any breach of the obligations contained in this Agreement by such employees shall be treated as a breach of such obligations by the Receiving Party. The Receiving Party is liable for any acts or omissions of such employees as for its own acts or omissions.

6. RETURN OF CONFIDENTIAL INFORMATION

Promptly after receipt of the written request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party any documents, data carriers or other tangible materials containing or representing the Confidential Information received from the Disclosing Party and all copies thereof, and shall destroy permanently any documents, notes, memoranda or other materials created by the Receiving Party or its employees which contain the Confidential Information, and shall delete any Confidential Information contained in any electronic or other data carriers or media. Such obligation does not include the copy of this Agreement. At the written request of the Disclosing Party, the Receiving Party shall promptly confirm to the Disclosing Party such destruction and deletion in writing. The provisions of this Section do not exclude nor limit the obligation of the Receiving Party to observe obligations set forth in this Agreement.

7. INJUNCTIVE RELIEF

- 7.1 In case of any breach of any provisions of this Agreement the Receiving Party is liable, to the fullest extent possible under the law, for damages suffered by the Disclosing Party.
- 7.2 Because Disclosing Party can not be adequately compensated by money damages in the event of breach of any of the provisions of this Agreement, Disclosing Party shall be entitled, in addition











to any other right or available remedy at law or in equity, to an injunction restraining such breach or any threatened breach and to specific performance of any provision hereof and, in either case, no bond or other security shall be required in connection with such injunction.

8. NO GRANT OF RIGHTS

- 8.1 No rights or obligations in Confidential Information are granted other than as expressly provided under this Agreement.
- 8.2 Any Confidential Information disclosed by Disclosing Party and all patent, copyright, trademark and other intellectual property rights therein are and shall remain the sole property of Disclosing Party, and Receiving Party shall assert no patent, copyright or other claim on such Confidential Information. Nothing herein nor the delivery of any Confidential Information hereunder shall be deemed to constitute by implication or otherwise the grant of any license or intellectual property right to or interest under any present or future invention, trade secret, trademark, copyright, or patent, now or hereafter owned or controlled by either Party.
- 8.3 Receiving Party shall not reverse engineer, chemically analyse, disassemble, modify, decompile or create derivative works based on any Confidential Information provided under this Agreement.
- 8.4 Partner acknowledges that Captor and/or any of its Affiliates own and control certain rights, title and/or interest in intellectual property (including without limitation know-how, patents and patent applications) both existent on the Effective Date as well as coming into existence during the term of this Agreement ("Captor IP"). Nothing contained herein shall be construed to grant the Receiving Party any immunity, intellectual property right or license under the Captor IP. Any intellectual property invented, conceived, discovered, developed or otherwise made or generated by Partner on basis of Captor IP and/or Confidential Information shall be owned solely by Captor or its Affiliates respectively.

9. ANNOUNCEMENTS

The Parties shall not originate any publicity, press releases or other public announcement relating to this Agreement or performance hereunder, without the other Party's prior written consent.

10. DURATION

- 10.1 This Agreement enters into force on the Effective Date and shall expire fifteen (15) years after the Effective Date.
- 10.2 Notwithstanding the foregoing, the Receiving Party's obligations set herein concerning Confidential Information constituting a trade secret of the Disclosing Party shall remain in effect for so long as trade secret protection applies (but in no event less than fifteen (15) years after the Effective Date).
- 10.3 The Receiving Party shall perform this Agreement regardless of whether the Parties establish the Cooperation.











10.4 The provisions of this paragraph shall survive expiration or termination of the Cooperation or any agreement between the Parties.

11. LAW AND JURISDICTION

- 11.1 This Agreement, as well as any claims relating to or arising out of this Agreement or the breach thereof, shall be governed by and construed in accordance with the laws of the Republic of Poland.
- 11.2 All disputes arising out of or in connection with this Agreement or its performance shall be settled by the court competent for the Captor's place of business.

12. GENERAL PROVISIONS

- 12.1 This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein superseding all prior oral or written understandings or communications between the Parties.
- 12.2 For the purpose of this Agreement, an "Affiliate" of Captor means any person, whether individual or entity, directly or indirectly controlling, controlled by, or under common control with Captor; provided that, for the purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies, whether through the ownership of equity interests or shares or voting rights, by contract or otherwise, in particular (but not limited to) the following companies: Captor Therapeutics S.A.
- 12.3 Captor appoints the following person responsible for contacts with Partner:

| Name and surname: | |
|--|---|
| e-mail: | |
| phone number: | |
| Partner appoints the following person re | sponsible for contacts with the Captor: |
| Name and surname: | |
| e-mail: | |
| phone number: | |

These persons are not authorized to make any changes or modifications to this Agreement, unless such authorization stems from a separate power of attorney/laws. Any changes of or to the above mentioned persons or to their contact details do not require any amendment to this Agreement, a notification in this regard by e-mail or in written form is deemed to be sufficient.

12.4 Nothing in this Agreement shall be construed to obligate either Party to negotiate or enter into any business arrangement with the other Party or to obligate either Party to disclose or otherwise make available any information to the other Party. Confidential Information is provided by Disclosing Party "as is". Disclosing Party makes no representation or warranty, express, implied











or otherwise, regarding the accuracy, completeness or performance of Confidential Information disclosed under this agreement except that it has the right to disclose such Confidential Information.

- 12.5 This Agreement sets forth the entire agreement between the Parties, and supersedes all prior agreements, written or oral, between the Parties relating to the subject matter of this Agreement. Any modification, amendment, or waiver to the terms of this Agreement must be made by written agreement of both Parties otherwise being null and void. No failure or delay by any Party in requiring performance of any provision hereof shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further the right of such Party at a later time to enforce such provision or any other provision of this Agreement hereunder.
- 12.6 If this Agreement requires any act or action to be in writing, any such act or action performed without observance of the written form shall be null and void.
- 12.7 This Agreement will be binding upon and inure to the benefit of the Parties and their respective heirs, successors and assigns; provided, however the rights and obligations of one Party cannot be assigned or transferred to any third party without prior written and express consent of the other Party.
- 12.8 If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable, that provision shall be stricken and the remainder of this Agreement shall continue in full force and effect. The Parties shall renegotiate an acceptable replacement for the invalid, illegal or unenforceable provision so as to accomplish, as nearly as possible, the original intent of the Parties.
- 12.9 This Agreement is effective on the date of the signature of a latter Party ("Effective Date").
- 12.10 This Agreement has been prepared in two conforming copies, one copy for each Party. This Agreement may be executed in writing or in electronic form (such as an electronic file which contains a scan of the wet ink signature or signed by Skribble, DocuSign or AdobeSign or a similar tool) and be delivered by electronic mail or another transmission method; the counterpart so executed and delivered shall be deemed to have been duly executed and validly delivered and be valid and effective for all purposes.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the last date set forth below.

| By Captor: | By Partner |
|------------|------------|
| | |

Date:

