

INVITATION TO TENDER

Case number: APP1/15/NCN31/2022

CONTRACTING AUTHORITY

<p>Medical University of Warsaw ul. Żwirki i Wigury 61 02-091 Warszawa statistical number (REGON) 000288917 Tax identification number (NIP): 525-00-05-828</p>	<p>Person authorized to contact the Contractors: 1WB2 – lek. Emil Bik e-mail: emil.bik@uckwum.pl Department of Hepatology and Internal Diseases, Central Clinical Hospital of UCK, Medical University of Warsaw ul. Banacha 1A; 02-097 Warszawa</p> <p>1WB2 – prof. dr hab. Piotr Milkiewicz e-mail: piotr.milkiewicz@wum.edu.pl Department of Hepatology and Internal Diseases, Central Clinical Hospital of UCK, Medical University of Warsaw; ul. Banacha 1A; 02-097 Warszawa</p> <p>APP1 – Dorota Orłowska, tel. (+48 22) 57 20 480 e-mail: dorota.orłowska@wum.edu.pl;</p> <p>Karolina Mich, tel. (+48 22) 57 20 202 e-mail: karolina.mich@wum.edu.pl Scientific Projects Department ul. Żwirki i Wigury 81, 02-091 Warszawa</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

I. GENERAL INFORMATION, CONTRACT AWARD PROCEDURE

The procurement procedure is conducted on the basis of the Public Procurement Regulations without applying the provisions of the Public Procurement Law at the Medical University of Warsaw, introduced by the Chancellor's Order No. 1/2021 of 18/01/2021, applicable in cases where pursuant to Art. 2 section 1 point 1 of the Act of September 11, 2019, Public Procurement Law, the provisions of the above-mentioned the act does not apply. Orders with a net value exceeding PLN 50,000.00 to PLN 130,000.00.

II. SUBJECT MATTER OF THE CONTRACT

1. Type of order: supply.
2. Order name and code according to the Common Procurement Vocabulary (CPV): 3360000-6 Pharmaceutical products.
3. The subject matter of the contract is the supply of S-adenosylmethionine 200 mg supplement and the supply of placebo for the above mentioned supplement within the framework of the research project financed from the funds of the National Science Centre entitled: "Clinical effects and molecular mechanisms of S-adenosylmethionine action in patients with primary sclerosing cholangitis (PSC)", implemented under the co-financing agreement No. UMO-2020/39/O/NZ5/03594, and in particular:

The subject of the contract should meet the following requirements in relation to the manufacture and form of packaging of the supplement:

1. Packaging - S-adenosylmethionine 200mg (S-adenosyl-L-methionine disulphate Tosylate 400 mg) - 4,320 blister packs of 10 tablets in an enteric coating (total 43,200 tablets) - blister packs in cardboard boxes printed with the batch number.
2. Manufacturing - in accordance with the Good Manufacturing Practice (GMP) standard in accordance with the Regulation of the Minister of Health on the requirements of Good Manufacturing Practice (Journal of Laws of 2015, item 1979, as amended). Microbiological analysis of the supplied supplement required. Tablets may be coated to give an appearance identical to that of the placebo.
3. Creating a list of serial numbers enabling the identification of the supplement.

The subject of the contract should meet the following requirements in relation to the manufacture and form of packaging of the placebo:

1. Placebo pack for S-adenosylmethionine - 4,320 blister packs of 10 tablets (total 43,200 tablets) - blister packs in cardboard boxes with printed batch number.
2. Manufacturing of a placebo with an appearance, taste and smell identical to the supplement - in accordance with the Good Manufacturing Practice (GMP) standard in accordance with the Regulation of the Minister of Health on the requirements of Good Manufacturing Practice (Journal of Laws of 2015, item 1979, as amended). Tablets may be coated to give an appearance identical to that of the supplement.
3. Creating a list of serial numbers enabling the identification of the placebo.

The subject of the order does not include the collection of unused placebo and supplement packs from the place of delivery and their disposal.

The subject of the order should have a shelf life of at least 18 months at the time of delivery.

III. ORDER COMPLETION DATE

The Ordering Party requires that the Contractor performs the subject matter of the Order, taking into account the following deadlines: delivery of the subject matter of the Order to the Clinic of Hepatology and Internal Diseases at the Central Clinical Hospital UCK WUM - within 3 months from the date of conclusion of the Contract.

IV. CONTRACT FOR PARTICIPATION IN THE PROCEDURE. LIST OF DECLARATIONS AND DOCUMENTS TO BE PROVIDED IN ORDER TO CONFIRM THE FULFILMENT OF CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

Contractors who jointly meet the following conditions may apply for the award of the contract:

- 1) They will declare in the tender form that their legal, economic and financial situation allows them to fulfill the contract.
- 2) They will declare in the tender form that they do not have any capital or personal ties with the Ordering Party.
- 3) They are not subject to exclusion on the basis of Article 7(1) of the Act of 13 April 2022 on special solutions to prevent support for aggression against Ukraine and to protect national security (Journal of Laws item 835)."

V. CRITERIA AND METHOD OF EVALUATION OF OFFERS

- 1) Criteria for evaluating offers and their importance: price 100%.
- 2) The bid with the lowest total gross price will be selected as the most advantageous bid.
- 3) The most advantageous offer (with the lowest price) shall be awarded 100 points, each subsequent offer shall be awarded a number of points proportionally lower, calculated according to the formula:

Number of points in the tested offer = lowest price / tested price x 100 points.

- 4) If the most advantageous offer cannot be selected due to the fact that the submitted offers received the same number of points, the Ordering Party shall call the Contractors who submitted these offers to submit additional offers within the time limit specified by it. Contractors submitting additional bids may not offer higher prices than those offered in the bids submitted.

The Ordering Party shall correct in the offer obvious typing and accounting errors as well as other errors consisting in the non-compliance of the offer with the content of the Invitation, which do not cause significant changes to the content of the offer.

VI. Tender validity period

- 1) Tender validity period is 60 days The period begins with the deadline for submission of offers.
- 2) The offer submitted in the procedure shall cease to be binding in the event of selecting another offer or closing the procedure without selecting the Contractor.

VII. PLACE OF DELIVERY OF THE SUBJECT MATTER OF THE CONTRACT

Department of Hepatology and Internal Diseases
Central Clinical Hospital - UCK Warsaw Medical University
ul. Banacha 1a, 02-097 Warszawa

VIII. DESCRIPTION OF THE PREPARATION OF THE OFFER:

- 1) A contractor may submit only one tender in response to the APP1/15/NCN31/2022 tender competition.
- 2) The tender should be drawn up in accordance with the provisions of this invitation.
- 3) The tender should be drawn up in Polish and/or in the official language of the European Union.
- 4) The offer should be written legibly according to the template constituting Appendix No. 1 to the Invitation to Tender.
- 5) The offer should be signed by persons authorized to sign the offers, and the authorization to sign the offer should be attached to the offer, unless it results from other documents attached to the offer.
- 6) If the Contractor attached a copy of the document as an attachment to the offer, the Ordering Party may request the original or a notarized copy of the document only if the photocopy of the document presented by the Contractor is illegible or raises doubts as to its authenticity, and the Ordering Party cannot verify its authenticity in a different way.
- 7) The Contracting Authority does not allow partial bids.
- 8) Due to the obligation to make the offers submitted in the procedure available for inspection by participants in the procedure - with the exception of part of the information constituting a business secret within the meaning of the provisions of the Act of 16 April 1993 on combating unfair competition in the currently applicable version - the Contractor is obliged to clearly mark this part of the offer which is a trade secret. Lack of an appropriate objection will be treated as consent to the disclosure of all documents under the terms of the Act. Company secrets may not constitute public information on the basis of the Act and other applicable laws.
- 9) A complete tender, including annexes, should have its pages numbered and initialled. It is recommended that all pages of the offer are stapled /sewn together/ in the correct order, in a manner that prevents the offer from being disassembled (applies to offers sent in accordance with the provisions of Part. IX, item 2a).
- 10) The bid must be marked with the case mark, i.e.: APP1/15/NCN31/2022.

IX. DATE AND METHOD OF SUBMITTING OFFERS

1. Tenders must be submitted no later than November the 29th, 2022 by 11.45 p.m.
2. Tenders may be submitted:

- a) In hard copy bearing a personal signature to the address: Warszawski Uniwersytet Medyczny, Dział Projektów Naukowych, 02-091 Warszawa, ul. Żwirki i Wigury 81. Please mark the offer on the envelope with the case number APP1/15/NCN31/2022.
 - b) The Contracting Authority allows tenders to be sent by e-mail in the form of an electronic document and bearing a qualified electronic signature, or an electronic copy of a document drawn up in paper form and bearing a personal signature in a file protected against editing, e.g. pdf, to the e-mail addresses of persons authorised to contact the Contractors, listed in this Invitation to Tender in the table entitled Contracting Authority. Please mark the offer in the subject of the message: APP1/15/NCN31/2022.
 - c) If the Contractor chooses to deliver in the form of an electronic copy of a document prepared in paper form and bearing a personal signature, the Contracting Authority may require the original of the tender to be delivered no later than the date of delivery.
3. The Contractor before the deadline for submission of tenders has the right to:
- a) withdraw the offer - the notification of withdrawal must be introduced according to the same rules as the offer submitted and marked with the note WITHDRAWAL,
 - b) change the offer - notification about the introduction of changes must be introduced according to the same rules as the offer submitted and marked with the annotation "CHANGE".

X. DESCRIPTION OF THE CALCULATION OF THE OFFER PRICE

- 1) For the purpose of these proceedings, the Bidder, on the basis of the Tender Form constituting Appendix No. 1 to this Invitation, is obliged to provide the net price, the amount of VAT and the price with VAT for each of the price elements listed in the Tender Form separately and the total net bid price, the amount of VAT and the total price with VAT for all the elements together, as well as indicate the unit price for the delivery of 1 package of the supplement and 1 package of the placebo.
- 2) The gross total price is the final price including all costs and price components related to the implementation of the subject of the contract. The Contractor shall be obliged to include in the offer price all costs necessary for proper, full and timely execution of the subject matter of the order, resulting from the conditions and obligations specified in the Request for Quotation, as well as his own knowledge and experience.
- 3) There can be only one price for the offered subject of the contract, price variants are not allowed.
- 4) For the purpose of bid comparison, the gross bid price in PLN shall be taken into consideration. If an Contractor specifies a price in a currency other than PLN, the Contracting Authority shall adopt as currency conversion rate the average exchange rate of the National Bank of Poland (NBP), which is available at www.nbp.pl published on the day of publishing this Request for Quotation on the Contracting Authority's website
- 5) If a bid is submitted, the selection of which would lead to a tax obligation of the Contracting Authority - pursuant to the provisions of the Act of 11 March 2004 on tax on goods and services in the currently binding version regarding intra-Community acquisition of goods - the Contracting Authority, in order to evaluate such a bid, will add the tax on goods and services which it would be obliged to pay pursuant to the binding regulations to the price presented in it.
- 6) The offer price should be provided net and gross including value added tax (VAT). The total gross price (i.e. including VAT) for all elements specified in the Tender Form will be taken into account for comparison of the offers.
- 7) The prices set by the Contractor shall be fixed for the period of validity of the contract and shall not be subject to change, subject to the provisions contained in the contract.
- 8) In order to determine whether a tender contains an abnormally low price in relation to the subject matter of the contract, the Contracting Authority shall ask the Bidder to provide, within a defined time limit, explanations regarding the elements of the tender which influence the price.
- 9) During the examination and evaluation of tenders, the Contracting Authority may demand explanations from bidders concerning the contents of their tenders.
- 10) The Contracting Authority shall reject the tender of the Bidder who failed to submit explanations or if the evaluation of the explanations confirms that the tender contains an abnormally low price in relation to the subject matter of the contract.
- 11) If the contractor whose offer has been selected refrains from concluding a public procurement contract or performing an order, the Ordering Party may select the most advantageous offer from among the remaining offers without re-examining and evaluating them.

XI. SELECTION OF THE CONTRACTOR AND METHOD OF NOTIFICATION

- 1) The Contracting Authority will select the tender which receives the highest number of points, based on the tender evaluation criteria set out in this Invitation.
- 2) The Contracting Authority shall inform all Contractors who submitted tenders about the selection.
- 3) The information referred to in point 1-2, the Contracting Authority will post on the website www.pnitt.wum.edu.pl.
- 4) If the contractor whose offer has been selected refrains from concluding a public procurement contract or performing an order, the Ordering Party may select the most advantageous offer from among the remaining offers without re-examining and evaluating them.

XII. CANCELLATION OR CLOSURE OF THE PROCEDURE

- 1) The Contracting Authority reserves the right to cancel or close the procurement procedure at any stage without giving any reason.
- 2) At the same time, the Contracting Authority will notify all Contractors of the cancellation or closure of the procedure in electronic form - by e-mail or will publish information about the failure to award the contract on the website at the place of publication of the invitation (www.pnitt.wum.edu.pl).

XIII. ESSENTIAL CONTRACT PROVISIONS

- 1) Information on the time and manner of delivery: strictly according to the indications listed in par. 2 para. 2 of the Agreement of the responsible persons: dr. Emil Bik and/or prof. dr hab. Piotr Milkiewicz
- 2) The receipt of goods will take place under the supervision of the responsible person named in para. 2 para. 2 of the Agreement. Delivery of the goods will be confirmed by an Acceptance Protocol according to the model specified in Annex 2 to the Contract.
- 3) Method of payment: settlement with the Contractor will take place according to the following schedule:
 - a. the amount of 30% of the remuneration - payable as an advance payment within 14 days of receipt of the advance invoice by the Contracting Authority;
 - b. payment of the remaining part of the remuneration taking into account the advance payment on the basis of a VAT invoice issued by the Contractor and an Acceptance Protocol signed by both Parties, referred to in par. 7 item 2 of the Agreement to the bank account indicated on the invoice. Payment shall be made within 30 days of:
- 4) In order to properly perform the subject matter of the contract, the Contracting Authority provides for the possibility of amending its provisions, including a change in the date and scope of performance of the subject matter, in particular in the event of the fulfilment of one of the following conditions:
 - a) force majeure (force majeure does not include e.g. atmospheric conditions appropriate to the climatic zone of the place of investment, strikes, changes in prices of raw materials and materials, etc.);
 - b) changes to the date, scope and/or manner of the contract due to reasons attributable to the Contracting Authority connected with the conduct of the study, including in particular difficulties in recruiting patients, the need to introduce changes to the scope and/or manner of conducting the study, including those resulting from the SARS - CoV - 2 virus epidemic state introduced on the territory of Poland;
 - c) changes after the conclusion of the contract of legal provisions or the introduction of new legal provisions or the change or introduction of a new mandatory standard causing the need to change, modify or deviate in relation to the subject of the contract;
- 5) In the event that it is not possible to supply the subject of the agreement in accordance with the submitted offer for objective reasons, such as withdrawal of a given product by the manufacturer, withholding or withdrawal of the product from the market, the Contractor, upon approval by the Contracting Authority, shall supply an identical product in its place, with properties no worse than those indicated in the offer. The price of the goods originally specified in the offer shall remain unchanged in this respect. The occurrence of any of the circumstances listed in paragraph 1 shall not constitute an absolute obligation on the part of the Contracting Authority to make such changes, nor shall it constitute grounds for claims by the Contractor to make such changes.

- 6) Any possible modification of the contract shall take into account the impact of the occurrence of the circumstance justifying the modification on the existing contractual obligation.

XIV. LIST OF DOCUMENTS REQUIRED TO BE SUBMITTED WITH A TENDER IN ORDER TO CONFIRM THE FULFILMENT OF THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

The bid consists of a completed and signed Tender Form according to the model constituting Annex No. 1 to the Invitation to Tender.

XV. INFORMATION CONCERNING THE PROCESSING OF PERSONAL DATA

Information addressed to natural persons directly disclosed in connection with the conduct of this procurement procedure.

The Ordering Party informs that in case of:

- natural persons,
- natural persons engaged in sole proprietorship,
- plenipotentiary of the Contractor being a natural person,
- a member of the management body of the Contractor who is a natural person,
- an individual directed to the preparation and execution of this procedure,

will process personal data that he obtained directly in the course of the proceedings.

In connection with the above, pursuant to art. 13 para. 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 / EC (general regulation on data protection) L 119, 04/05/2016, p. 1), hereinafter "General Data Protection Regulation",

The Ordering Party informs you that:

- 1) The administrator of your personal data is:

Medical University of Warsaw

ul. Żwirki i Wigury 61,
02-091 Warszawa;

represented by the Rector of the WUM.

- 2) The Administrator has appointed a Data Protection Officer who can be contacted: e-mail address: iod@wum.edu.pl, tel.: +48 22 57 20 320;
- 3) Your personal data will be processed on the basis of Article 6(1)(b) of the GDPR in order to obtain commercial information necessary for the estimation of the subject matter of the contract, in accordance with the provisions of the Act on Public Procurement or the conclusion of a contract as a result of this procurement procedure;
- 4) Your personal data will be processed on the basis of art. 6 sec. 1 lit. c GDPR for purposes related to the fulfillment of legal obligations, including those necessary to establish, assert or defend claims, as well as resulting from the archiving obligation based on applicable provisions;
- 5) Your personal data will be processed on the basis of art. 6 sec. 1 lit. f GDPR for purposes resulting from legitimate interests pursued by the Administrator or by a third party, in particular by conducting analytical and statistical activities promoting the Administrator's activities;
- 6) The recipients of your personal data will be persons or entities to whom the documentation of the proceedings will be made available on the basis of internal regulations, provisions of the Public Procurement Law, guidelines for operational programs, national and regional, as well as on the basis of the provisions of concluded grant agreements.
- 7) Your personal data will be stored for a period of 4 years from the date of completion of this procedure or a specific procurement procedure, and if the duration of the contract or the rules and guidelines for storage and archiving of project documentation exceeds 4 years, the storage period shall cover the

entire duration of the contract or the period indicated in the documents of national and regional operational programmes as well as in the concluded grant agreements;

- 8) The obligation for you to provide personal data concerning you directly is a formal requirement, related to the participation in the contract award procedure;
- 9) In relation to your personal data, decisions will not be taken in an automated manner, application to art. 22 General Data Protection Regulation
- 10) You have:
 - a) based on Article. 15 General Data Protection Regulation the right of access to your personal data related to you;
 - b) based on Article. 16 General Data Protection Regulation the right to correct your personal data ¹;
 - c) based on Article. 18 General Data Protection Regulation the right to request the administrator to restrict the processing of personal data, subject to the cases referred to in art. 18 para. 2 General Data Protection Regulation ²;
 - d) the right to file a complaint to the President of the Office for Personal Data Protection, if you decide that the processing of your personal data concerning you violates the provisions of the GDPR
- 11) You are not entitled to:
 - a) in connection with art. 17 sec. 3 lit. b, d or e GDPR right to delete personal data;
 - b) the right to transfer personal data referred to in art. 20 GDPR
 - c) based on Article. 21 GDPR the right to object to the processing of personal data, as the legal basis for the processing of your personal data is art. 6 par. 1 lit. b and c GDPR.

The Ordering Party at the same time informs that the Contractor, applying for the award of this contract is obliged to fulfil the information obligation provided for in art. 13 or 14 GDPR in relation to natural persons whose personal data the Contractor has directly or indirectly obtained and which data will be transferred to the Ordering Party, unless at least one of the exemptions referred to in art. 14 par. 5 of the GDPR or in accordance with art. 13 para. 4 GDPR, the natural person to whom the data relates, has the information referred to in the introduction.

XVI. FINAL PROVISIONS

1. The provisions of the Act of 23 April 1964 Civil Code (Journal of Laws of 2020, item 1740, as amended) and the Act of 17 November 1964 Civil Procedure Code (Journal of Laws of 2020, item 1575, as amended) - Civil Procedure Code (i.e. Journal of Laws of 2020, item 1575, as amended) shall apply to matters not regulated in this Invitation.
2. All costs related to the preparation of the offer shall be borne by the Contractor.
3. The offer submitted in the procedure shall cease to be binding in the event of selecting another offer or closing the procedure without selecting the Contractor.
4. The order will be implemented on the basis of a written contract concluded between the ordering party and the Contractor or based on a written order to perform the contract

¹**Explanation:** the exercise of the right of rectification shall not have the effect of modifying the outcome of the procurement procedure or of amending the provisions of the contract and shall not affect the integrity of the minutes and their annexes;

²**Explanation:** the right to limit processing does not apply to storage, to ensure the use of legal remedies or to protect the rights of another natural or legal person, or for important reasons of public interest of the European Union or a Member State;

Appendixes:

1. Tender form.
2. Standard Contract Template

Drawn up by:

Approved by: