

Contract No APP1/15/NCN31/2022

concluded on in Warsaw as a result of the procurement procedure conducted without the application of the Act of 11.09.2019. - Public Procurement Law (i.e. Journal of Laws of 2021, item 1129) pursuant to Article 11, paragraph 5, item 1 of that Act, in connection with the contractor's offer dated 24.09.2021. constituting Attachment No. 1 to this Agreement, submitted in response to the invitation to tender of

between:

Medical University of Warsaw with headquarters in Warsaw, at Żwirki i Wigury 61, 02-091 Warszawa, NIP [tax identification number]: 5250005828 , REGON 000288917, represented by: Dorota Szubstarska, Director of Scientific and Didactic Projects, under power of attorney No. AO-UP/0151/4072020 of 21 December 2020, countersigned by the WUM Quaestor or his deputy, hereinafter referred to as the " Contracting Authority ".

and

..... with registered offices at..... ,
NIP....., REGON

represented by:

.....

..... hereinafter referred to as "CONTRACTOR"

The Ordering Party and the Contractor are hereinafter jointly referred to as the "Parties", and separately the "Party". The following Agreement was concluded between them, hereinafter referred to as the "Agreement":

§ 1.

Subject of the Contract

1. The Ordering Party orders and the Contractor accepts the execution, 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 contract with the National Science Center No. UMO-2020/39/O/NZ5/03594, of the supply of the S-adenosylmethionine 200 mg supplement and the supply of a placebo for the above-mentioned supplement, in particular:

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

- a) 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.
- b) 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 2022, item 1273 as amended). Microbiological analysis of the supplied supplement required. Tablets may be coated to give an appearance identical to that of the placebo.
- c) 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:

- a) 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.

- b) Preparation of a placebo with an appearance, taste and smell identical to the supplement in accordance with the Good Manufacturing Practice (

GMP) in accordance with the Regulation of the Minister of Health on the requirements of Good Manufacturing Practice (Journal of Laws of 2022, item 1273, i.e. as amended). Tablets may be coated to give an appearance identical to that of the supplement.

- c) Creating a list of serial numbers enabling the identification of the placebo.
2. The subject of the contract does not include the collection by the Contractor of unused placebo and supplement packs from the place of delivery and their disposal.
 3. The subject of the contract should have a shelf life of at least 18 months on the date of delivery.
 4. The subject matter of the contract shall be delivered to the Clinic of Hepatology and Internal Diseases of the UCK WUM in accordance with the Contractor's offer no. of constituting Attachment No. 1 to the Contract.

§ 2.

Contractor's Obligations

1. The Contractor undertakes to perform the subject of the Contract described in §1 and hand it over to the Ordering Party in one delivery within 3 months from the date of signing the Contract.
2. The persons responsible for supervising the execution of this contract are:

on the part of the Ordering Party:

- doctor Emil Bik, e-mail: emil.bik@uckwum.pl, Department of Hepatology and Internal Medicine, WUM;
- prof. dr hab. Piotr Milkiewicz , e-mail: piotr.milkiewicz@wum.edu.pl, Department of Hepatology and Internal Medicine, WUM;

From the Contractor

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3. About each change in the above-mentioned responsible persons, the Ordering Party and the Contractor shall immediately notify each other in writing, damages resulting from failure to fulfill this obligation shall be borne by the obligated party. Changing the data of the persons indicated above does not require an annex to this contract.

§ 3.

Contractor's statements

1. The contractor hereby ensures that he has the knowledge, resources, experience and authorizations necessary to perform the subject of the contract.
2. The Contractor hereby declares that the supplied good referred to in §1 of the agreement:
 - a) is a supplement admitted to economic circulation in the territory of the Republic of Poland;
 - b) is free from physical and legal defects, in particular hidden defects;
 - c) is complete and has all the properties specified in detail in the invitation to tender: APP1/15/NCN31/2022 and this Agreement;
 - d) is not subject to any limited rights in rem, established for the benefit of third parties, and is not subject to any court, administrative or court-administrative proceedings, the consequence of which is (could be) the limitation or exclusion of the Contractor's right to dispose of it (provided that responsibility in this respect does not apply to the supplement, if the Contractor is not its manufacturer);
 - e) The Contractor guarantees and takes full responsibility towards the Ordering Party and third parties that the supplements delivered under this contract will have all the approvals and registrations required by Polish law for the entire period of its validity, as well as the validity

period of not less than 18 months, counting from the date of their delivery to the Ordering Party and that they will not pose a threat to human health and life. In addition, the Contractor undertakes, at his own cost and risk, to inform the Ordering Party on an ongoing basis about the withdrawal from the market of the above-mentioned products and other facts significant for their use in the field of medical services.

§ 4.

Duration of the contract

Deadline for the execution of this contract: up to 3 months from the date of conclusion of the contract.

§ 5.

Delivery of the supplement and collection procedure

1. Information on the date and method of delivery: strictly according to the indications of the responsible persons listed in §2: 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 §2. The delivery of goods will be confirmed by an Acceptance Protocol according to the template set out in Appendix 2 to this contract.
3. The ordering party reserves the right to return delivered and not ordered goods and goods that raise objections, in particular as to quality and completeness. The reimbursement will be made at the Contractor's expense within 7 days from the date of submission of the complaint.
4. The responsible person named in §2, without any financial claim on the part of the Contractor in connection therewith, may refuse to accept the delivery in whole or in part if:
 - a) all or part of the delivered goods are not packed in accordance with the requirements of this Contract;
 - b) all or part of the goods supplied have a shelf life of no less than 18 months from the date of delivery.

§ 6.

Complaints procedure

1. In the event of delivery of damaged, incomplete or otherwise non-compliant goods, the Contractor undertakes to immediately, but not later than within 30 days of submitting a complaint by a person authorized by the Ordering Party, replace the goods with a product that meets the requirements of the Agreement.
2. Complaints from the Ordering Party shall be lodged at the e-mail address
3. The Ordering Party reserves the right to return the defective goods to the Contractor - in a situation where the defectiveness of the goods was caused by the Contractor's fault - at his expense and risk.

§ 7.

Remuneration

1. For the performance of the work, the Parties agree on a maximum contractual remuneration of: PLN net + VAT, i.e. PLN gross (in words:) to which the Contractor is entitled in the event that the Ordering Party accepts the entire subject of the order in accordance with the description contained in §1.
2. 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 30 days of receipt of the advance invoice by the Contracting Authority;
 - b. payment of the remaining part of the remuneration including the advance payment made within 30 days on the basis of a VAT invoice issued by the Contractor and the Acceptance Protocol signed by both Parties, referred to in § 5 sec. 2 of the Contract to the bank account

indicated on the invoice.

3. The price covers all costs and expenses of the Contractor related to the implementation of the subject of the contract, in particular:
 - the cost of producing, delivering the goods,
 - the cost of insuring the goods for the time of delivery,
 - the cost of packaging the goods,
 - the cost of printing serial numbers.
4. The above-mentioned gross price may not be increased during the performance of the contract.

§ 8.

Terms of payment

1. The Ordering Party allows the submission of a VAT invoice in the form of:
 - a) paper print out;
 - b) structured electronic document submitted via the Electronic Invoicing Platform, hereinafter referred to as PEF, in accordance with the Act on Electronic Invoicing in Public Procurement, Concessions for Works or Services and Public-Private Partnership of 9 November 2018. (i.e. Journal of Laws 2020 item 1666 as amended).
2. The Ordering Party undertakes to make payment for the delivered object of the Contract, within 30 days from:
 - a) the date of submission to the WUM Chancellery, ul. Żwirki i Wigury 81, 02-091 Warsaw, room 6, of the original of a correctly issued VAT invoice, subject to the admissibility of submitting such an invoice in the form of a pdf file to the following address: efaktury@wum.edu.pl. In this case, the title of the message should include the invoice number, the procedure number and the name of the invoice issuer;
 - b) the date of sending the structured electronic invoice via PEF.
3. The basis for issuing a VAT invoice is the Acceptance Protocol, prepared in accordance with the template constituting Annex 2 to the contract, signed without reservations by the person indicated

in §2 section 2, as authorized by the Ordering Party to collect the subject of the Agreement. The signed Acceptance Protocol should be submitted by the Contractor to the WUM Office together with the invoice. The Ordering Party does not allow sending other structured electronic documents, with the exception of an invoice.

4. The Contractor is obliged to issue a VAT invoice referred to in paragraph 1, no later than by the 15th day of the month following the month in which the subject of the Agreement was received by the Acceptance Protocol. The invoice should be delivered to the Ordering Party immediately.
5. The payment will be made to the Contractor's bank account, no. Any change to the bank account number must be made in writing under pain of nullity. The day of debiting the bank account of the Ordering Party shall be considered as the day of payment.
6. The parties agree that the payment will be made only to the bank account number that is on the list referred to in Art. 96b of the Act of March 11, 2004 on tax on goods and services (i.e. Journal of Laws of 2022, item 1561, as amended), hereinafter referred to as the "List". The Contractor is obliged to notify the Ordering Party about the removal of the bank account from the List immediately, however not later than three working days before the invoice payment deadline. The notification should be sent to the following e-mail address: rachunki@wum.edu.pl. The Ordering Party reserves the right to withhold payment of the invoice until the account number is changed, which will be in the List, without the Contractor's right to demand interest for delay in commercial transactions, to which the Contractor agrees, subject to paragraph 7.
7. Provisions of sec. 6 apply only to Contractors who are active VAT taxpayers in Poland.
8. A structured electronic invoice (if this form of the document is selected) should consist of data required by the provisions of the Value Added Tax Act and min. data containing:
 - a) information about the recipient of the payment;
 - b) indication of the public procurement contract.
9. The Ordering Party informs that the PEPPOL identifier / PEF address of the Ordering Party, which will allow the submission of a structured electronic invoice, is: NIP 5250005828.

10. In the event of delay in payment, the Contractor has the right to charge statutory interest for late payment in commercial transactions referred to in Art. 4 pts 3 of the Act of March 8, 2013 on counteracting excessive delays in commercial transactions (i.e. Journal of Laws 2022, item 893, as amended).
11. The Ordering Party's obligation applies to the amount specified in the Contract. If the amount due on the Contractor's VAT invoice exceeds the agreed price, the Ordering Party will pay only to the agreed price, and the Contractor undertakes to immediately issue a correcting invoice

§ 9.

Guarantee and warranty

1. The Contractor shall provide the Ordering Party with a guarantee of fitness for use for the delivered object of the contract for a period of 18 months from the date of delivery.
2. The Ordering Party may exercise warranty rights independently of the warranty rights. The provisions of the Civil Code shall apply to warranty rights.

§ 10.

Maintaining Confidentiality

1. For the purposes of this Contract, Confidential Information shall be understood as: any information or material provided by the Contracting Authority to the Contractor in connection with the performance of the Contract, including in oral, written or otherwise recorded form (electronic, diskette, hard disk, etc.) with the exception of those which, at the time of disclosure or transfer to the Contractor, are expressly designated as non-confidential. In addition, Confidential Information shall also mean any information or material that the Contractor has produced or developed for the purpose of performing this contract. In the event that the transfer of information is made in an unspecified manner as to whether it is confidential or not, it shall be deemed to be Confidential Information.
2. The Contractor shall only be entitled to use Confidential Information to the extent related to the performance of the Contract.
3. Confidential Information will not be information that:
 - have been made public otherwise than as a result of a breach of the provisions of this Contract, in particular by their publication or transfer to third parties by the Ordering Party, or
 - was known to the Contractor prior to disclosure under the provisions of this Contract, with the Contractor bearing the burden of proof that any of the aforementioned circumstances existed.
4. The Contractor shall keep the Confidential Information received from the Contracting Authority confidential and shall not disclose it to any entity and shall not use such information for any purpose other than as set out in this Contract. With the proviso that it is possible for the Contractor to disclose Confidential Information to:
 - a) to the Contractor's employees and only if this is necessary for the proper achievement of the purpose of this Agreement,
 - b) to the Contractor's associates / contractors /, and only if it is necessary for the proper performance of their services for the Ordering Party, - provided that such entities are informed about the obligations arising from this Contract and undertake to keep the Information confidential at least as set out in this Contract.
5. The Contractor may disclose Confidential Information without the consent of the Contracting Authority only to the extent that it is required to do so by a court or other authorised body, provided that it is shown that such disclosure is compulsory and in accordance with the law. The Contractor shall promptly notify the Contracting Authority, if possible before complying with such a request.
6. The Contractor bears full contractual and tort liability towards the Ordering Party, also for damages caused by third parties to whom he entrusted Confidential Information, regardless of the lack of fault in their selection and entrusting activities to entities that, in the scope of their professional activity, perform such activities. The contractor is responsible for the persons and entities referred to in the preceding sentence, as for their own actions and omissions.
7. Unless the Ordering Party decides otherwise in writing, all Confidential Information, including copies thereof, will remain the property of the Ordering Party and, upon written request of the Ordering Party, will be destroyed on the date of expiry or termination of this Agreement at the latest. At each request, the Contractor is obliged to submit a written protocol confirming the destruction of Confidential Information within 7 days.

8. The Parties agree that the Contracting Authority may at any time demand the return of any or all of the Confidential Information disclosed, together with the relevant media, and prohibit its further use.

9. In the event of a breach by the Contractor of any of its obligations under

under this Agreement, the Contracting Authority shall have the right to demand immediate cessation and remedy of the breach. The summons to cease the violations and remove its consequences should be sent to the Contractor in writing and will include the deadline for the execution of the summons.

10. In each case of breach of the provisions of this Contract by the Contractor, the Contracting Authority shall be entitled to assert against the Contractor all claims prescribed by law for the protection of its rights, in particular, in the event of disclosure of Confidential Information to a third party that would expose the Contracting Authority to material or non-pecuniary damage, the Contractor shall undertake, on a general basis, to cover the damage caused to the Contracting Authority as a result of such breach or disclosure.

11. Notwithstanding the rights set out in paragraphs 9 and 10, the Contracting Authority shall be entitled to charge and claim from the Contractor a contractual penalty in the amount of PLN 5,000.00 for each case of breach of obligations under this paragraph.

12. The Ordering Party shall be entitled to claim supplementary damages on the general terms and conditions specified in the Civil Code if the value of the contractual penalty referred to in paragraph 11 is lower than the value of the damage incurred, or if the damage does not arise

from the above scope.

13. The obligation of confidentiality comes into force on the date of conclusion of the Agreement and will be in force for a period of 10 years from the date of its conclusion. Termination, expiry, termination or withdrawal from the Agreement does not waive the Contractor's obligation,

referred to in this paragraph, including the obligation to pay a contractual penalty.

§ 11.

Contractual Penalties

1. In the event of non-performance or improper performance of the contract, the Ordering Party has the right to charge the following contractual penalties:

- a) for untimely performance of the subject of the contract in the amount of 0.1% of the total gross value of the subject of the contract specified in § 7 section 1 for each commenced day of delay;
- b) for untimely implementation of the complaint procedure referred to in § 6 sec. 1, in the amount of 0.2% of the gross value of the subject of the contract in question, for each commenced day of delay;
- c) in the event of withdrawal from the contract by the Ordering Party for reasons attributable to the Contractor, in the amount of 10% of the total gross value of the subject of the contract specified in § 7 sec. 1;
- d) in the event of withdrawal from the contract by the Contractor for reasons not attributable to the Ordering Party in the amount of 10% of the total gross value of the subject of the contract specified in § 7 sec. 1.

2. The Contractor agrees to deduct the amount of the contractual penalty directly when paying the VAT invoice relating to the performance of the subject of the contract.

3. The Ordering Party shall retain the right to claim additional compensation if the value of the contractual penalties is lower than the value of the damage incurred. Claims may only be pursued up to the value of the damage incurred.

§ 12.

Amendment of the agreement

1. 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;
2. 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.
3. 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.

§ 13.

Withdrawal from the contract

1. In addition to the cases listed in the Civil Code, the Ordering Party has the right to withdraw from the contract in whole or in part in the event of:
 - 1) in the public interest, which could not have been foreseen when the contract was concluded;
 - 2) loss by the Ordering Party of the source of financing of the contract in whole or in part, as well as in the case of shifting the sources of financing of the contract;
 - 3) a delay in the performance of the subject matter of the contract exceeding 14 days or a delay in the processing of a complaint exceeding 14 days;
 - 4) gross breach of the provisions of this contract by the Contractor.
2. Withdrawal from the contract shall be in writing under pain of invalidity of such declaration. The right of withdrawal referred to in this Agreement may be exercised by the Contracting Authority within 30 days of becoming aware of the events giving rise to the withdrawal.
3. In the event of withdrawal from this contract for the reasons set out in paragraph 1(1) to (4), the Contractor shall only be entitled to a claim for payment for the goods already produced up to the moment the Ordering Party exercises its right of withdrawal. The Contractor shall be obliged to submit to the Ordering Party documents proving the production of the relevant series of goods before the Ordering Party exercises its right of withdrawal.

§ 14.

Final Provisions

1. The change of this contract requires a written form under pain of nullity.
2. In matters not covered by this Agreement, the provisions of Polish law shall apply, including the provisions of the Civil Code.
3. The parties agree to settle amicably disputes arising from the implementation of this contract within 14 days, and in the event of a lack of settlement, to be settled by court proceedings before a common court of competent jurisdiction for the registered office of the Ordering Party.
4. The contract was drawn up in three identical copies: one for the Contractor

and two for the Ordering Party or in electronic form in the case of concluding the contract with the use of a qualified electronic signature.

The following Annexes form an integral part of the contract:

- Annex No. 1 - Contractor's offer dated;
- Annex No. 2 - Template of the Acceptance Protocol.
- Annex No. 3 - Copy of power of attorney No. AO-UP/0151/4072020 dated 21 December 2020,