

Warsaw, 04/07/2024

**INVITATION TO SUBMIT PRICE OFFERS WITHIN THE FRAMEWORK OF MARKET RECOGNITION  
APP/487/ABM05/2024**

carried out as part of the project entitled "EMpagliflozin and daPAgliflozin in patients hospitalised for acute heart failure (EMPATHY study) - Phase III study" with the acronym "EMPATHY" which is a non-commercial clinical trial (hereinafter referred to as the "Study"), under the agreement concluded with the Medical Research Agency No. 2019/ABM/01/00037-00."

**I. ORDERING PARTY/SPONSOR**

<b>Medical University of Warsaw</b> ul. Żwirki i Wigury 61 02-091 Warszawa REGON: 000288917 NIP: 525-00-05-828	<b>Contact persons with the Contractor</b> <b>Ceren Eyileten Postula +48 501 495 526</b> <b>ceren.eyileten-postula@wum.edu.pl</b> Department of Experimental and Clinical Pharmacology MUW ul. Banacha 1b, 02-091 Warszawa <b>Aleksandra Bator</b> aleksandra.bator@wum.edu.pl Research Department MUW ul. Żwirki i Wigury 81, 02-091 Warszawa
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**II. CONTRACT AWARDING PROCEDURE**

The procedure for the award of the present contract is conducted pursuant to Article 11(1)(3) of the Public Procurement Law (i.e. Journal of Laws 2022.0.1710, i.e. the Act of 11 September 2019), in compliance with the rules resulting from § 14. of the Subsidy Agreement

**III. DESCRIPTION OF THE OBJECT OF THE CONTRACT**

Researcher and sponsor liability insurance service in connection with the conduct of the clinical trial: "EMpagliflozin and daPAgliflozin in patients hospitalised for acute decompensated Heart failure (EMPATHY trial)":

I. Details of the clinical trial:

Policyholder/insured:

Sponsor: Medical University of Warsaw, 63 Żwirki i Wigury Street, 02-091 Warsaw: TAX ID: 525 000 58 28, REGON: 000288917.

Researchers:

Leader: prof, Jolanta Siller-Matula, prof, Marek Postula.

Other researchers:

Dilek Ural, Mert Pehlivan Altın, Gökhan Gönenli, Ahmet Çelik, Yüksel Çavuşoğlu, Tayfun Şahin, Ali Kemal Kalkan, Lütfü Bekar, Nihan Kahya Eren, Serkan Ünlü, Volkan Kozluca, Uğur Canpolat, Ahmet Genç

Study title: EMpagliflozin and daPAgliflozin in patients hospitalised for acute decompensated Heart failure (EMPATHY trial).

Number of study participants: **500**

Phase of study: **III**

Number of study sites: **11**

Country of conduct of the non-commercial clinical trial - **TURKEY**

Period of insurance: from **01.08.2024 to 31.12.2025**.

- II. Scope and subject of insurance : Compulsory civil liability insurance of the researcher and the sponsor, under the terms of the Decree of the Minister of Finance dated 30.04.2004, as amended by the Decree of the Minister of Finance dated 18.05.2005:

Civil liability of the investigator and sponsor for causing bodily injury, health disorder or death of a clinical trial participant as a result of an act or omission of the insured or persons for whom he/she is responsible, during the period of insurance coverage, caused in connection with the conduct of the clinical trial.

- III. Sum insured: **EUR 5,000,000** for one and all events during the insurance period.

#### IV. GROUNDS FOR EXCLUSION FROM THE PROCEDURE

(1) Contractors in relation to whom there are capital or personal links, which means mutual links between the Ordering Party or persons authorised to enter into commitments on behalf of the Ordering Party or persons carrying out activities related to the execution of the procedure for selecting the Contractor and the Contractor, consisting in particular of the following:

- a) participation in the company as a partner in a civil partnership or partnership,
- b) holding at least 10% of shares or stocks,
- c) performing the function of a member of a supervisory or managerial body, proxy, attorney,
- d) be in a marital relationship, or in a relationship of kinship or affinity in a straight line, in a relationship of kinship or affinity of the second degree in the collateral line, or in a relationship of adoption, custody or guardianship.

(2) Contractors who are subject to exclusion pursuant to Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's destabilising actions in Ukraine (Official Journal of the EU No. L 229 of 31.7.2014, p. 1), hereinafter: Regulation 833/2014, as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (Official Journal of the EU No L 111, 8.4.2022, p. 1), hereinafter: Regulation 2022/576, i.e. the Ordering Party excludes from participation in the proceedings:

- (a) Russian citizens or natural or legal persons, entities or bodies based in Russia,
- b) legal persons, entities or bodies whose ownership rights directly or indirectly in more than 50 % belong to the entity referred to in point (a) of this paragraph;
- (c) natural or legal persons, entities or bodies acting on behalf of or at the direction of an entity referred to in (a) or (b) of this point,
- (d) including subcontractors or suppliers where they account for more than 10% of the value of the contract.

(3) Contractors, who are subject to exclusion pursuant to Article 7(1) of the Act of 13 April 2022 on special solutions to counteract support for aggression against Ukraine and to protect national security

(Journal of Laws of 2022, item 853) from the procurement procedure are excluded from participation, i.e. the Ordering Party excludes:

- (a) an economic operator listed in the lists set out in Regulation 765/2006 and Regulation 269/2014 or included in the list on the basis of a decision on inclusion in the list ruling on the application of the measure referred to in Article 1(3) of the Act,
  - (b) a Contractor whose beneficial owner, within the meaning of the Act of 1 March 2018 on the prevention of money laundering and terrorist financing (Journal of Laws of 2022, items 593 and 655), is a person listed in the lists set out in Regulation 765/2006 and Regulation 269/2014 or listed or being such a beneficial owner as from 24 February 2022, provided that it has been listed on the basis of a decision on listing conclusive of the measure referred to in Article 1, point 3 of the Act,
  - (c) a Contractor whose parent undertaking within the meaning of Article 3(1)(37) of the Accounting Act of 29 September 1994 (Journal of Laws of 2021, item 217, 2105 and 2106) is an entity included in the lists set out in Regulation 765/2006 and Regulation 269/2014 or included in the list or being such a parent undertaking as of 24 February 2022, provided that it has been included in the list on the basis of a decision on inclusion in the list conclusive of the measure referred to in Article 1(3) of the Act.
- (4) In order to prove that there are no grounds for exclusion from the procedure for awarding the subject contract referred to in item 1 above, the Contractor should submit, together with the tender, a self-declaration contained in the part "Declaration on no relations with the Ordering Party" of the Appendix No. 2 to the Request for Quotation.
- (5) The tender of a Contractor excluded shall be deemed rejected.

## **V. HOW TO PREPARE A TENDER**

- (1) The tender submitted by the Contractor should be drawn up on the form constituting the Appendix to the Request for Quotation - Model tender form. Appendix No. 1
- (2) Tenders should be drawn up in Polish or English. Documents prepared in another language should be submitted with a translation into Polish or English.
- (3) The tender and appendices to the tender must be signed by an authorised representative(s) of the Contractor in accordance with the form of representation of the Contractor specified in the Contractor's registration document or by a proxy in a way which makes it possible to identify the person signing the documents (legible signature indicating the position or signature with a name stamp).
- (4) The Ordering Party recommends that each page of the tender (including the appendices to the tender) should be numbered consecutively.
- (5) The Contractor shall not reserve information concerning the name (company) and address, price, contract completion date, terms of payment contained in the tender.
- (6) The Contractor may submit only one tender for a given part of the subject matter of the contract.
- (7) The Contractor shall bear all costs related to the preparation and submission of a tender.
- (8) The Ordering Party reserves the right to amend or supplement the contents of the invitation to tender at any time before the deadline for submission of tenders. In the event of such a change or addition, information about it will be immediately included in a notice published on the Ordering Party's website.
- (9) In the event that the amendment referred to in point 8 above results in a need to modify the tenders, the Ordering Party shall, at the same time, extend the deadline for submission of tenders as described in point 8 above.

## VI. TENDER VALIDITY

- (1) A contractor shall remain bound by a tender for a period of 60 days.
- (2) The tender validity period shall commence on the expiry of the deadline for submission of tenders.
- (3) The Contractor, on independently or at the request of the Ordering Party, may extend the tender validity period.

## VII. PLACE AND DEADLINE FOR SUBMISSION OF TENDERS

- (1) Tenders must be submitted no later than 12.07.2024 until 16:00.**
- (2) Tenders responding to the Request for Quotation shall be submitted in the form indicated below:
  - (a) by email, to the following email address: [aleksandra.bator@wum.edu.pl](mailto:aleksandra.bator@wum.edu.pl)
- (3) If an offer is submitted in the form indicated above, the title of the e-mail with the offer should state "Request for Quotation No APP/487/ABM05/2024" and the offer, together with the required attachments, must be sent as a scanned signed offer or signed with an electronic qualified signature.
- (4) The date and time of submission of the tender shall be understood as the date and time:
  - (a) receipt of the offer by the Ordering Party, i.e. its receipt at the e-mail address indicated in para. 2a above,
- (5) The Ordering Party reserves the right to extend the tender submission deadline. Each time it will post a relevant information at: <https://www.pnitt.wum.edu.pl> in the text of the announcement.

## VIII. CRITERIA FOR EVALUATING TENDERS AND HOW TO CARRY OUT THE EVALUATION

- (1) The tenders from Contractors, prepared in accordance with the requirements set out in Section V of this Request for Quotations and not subject to exclusion in accordance with Section IV of this Request for Quotations, will be evaluated according to the following criteria:

KTENDER EVALUATION CRITERIA	POINT WEIGHT	DESCRIPTION OF HOW POINTS WILL BE AWARDED FOR EACH TENDER CRITERION
<b>Total gross price</b>	100	<p>In the criterion "Total gross price", the Ordering Party will make the evaluation on the basis of the information provided by the Contractor in the Tender/Offer Form, constituting Appendix No. 1 to this Request for Quotation.</p> <p>The Contractor shall provide the net price, the applicable VAT rate and the gross value, rounded to two decimal places, observing the mathematical rule of rounding numbers. It is the Contractor's responsibility to correctly determine the VAT. Foreign contractors who, based on separate regulations, are not obliged to pay tax in Poland shall quote only the net price. For the purpose of comparing tenders, the Ordering Party will add to the presented net tender price of foreign Contractors the amount of the value added tax due (chargeable to the Ordering Party in respect of the performance of the contract) and any customs duty which it would be obliged to settle in accordance with applicable regulations.</p> <p>The gross total price shall be the final price including all costs and price components related to the performance of the subject of the order. 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.</p>

		<p>The price for the offered subject matter of the contract can be only one, no price variants are allowed.</p> <p>To compare the offers, the gross offer price shall be taken into consideration in PLN.</p> <p>If the Economic Operator specifies the price in a currency other than PLN, the Ordering Party shall use as currency conversion rate the average exchange rate of the National Bank of Poland (NBP) which is available at <a href="http://www.nbp.pl">www.nbp.pl</a> published on the day of publishing this Request for Quotation in the Competitive Database.</p> <p>The point value in this criterion will be calculated as follows:</p> $K_{\text{price}} = \frac{\textit{cena brutto najtańszej spośród złożonych ofert}}{\textit{cena brutto badanej oferty}} \times 100$ <p>An offer can receive a maximum of 100 points for the criterion "Total gross price".</p>
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(2) Scores will be rounded to two decimal places using the mathematical rule of rounding numbers.

(3) The most advantageous tender shall be the one submitted by a Contractor not subject to exclusion from the procedure, which meets the requirements specified for the subject matter of the contract and which scores the highest number of points in the course of evaluation.

(4) In the case where the Ordering party is unable to select the most advantageous tender due to the fact that two or more Contractors submit the same price for the subject matter of the contract, the Ordering Party shall call upon the Contractors who submitted such tenders to submit additional tenders. Contractors submitting additional offers may not offer prices higher than those offered in their tenders.

(5) In the case of Contractors who submitted tenders on the above specified date but they do not contain the required documents and statements or the submitted documents and statements are incomplete, contain errors or raise doubts indicated by the Ordering Party, the Ordering Party shall call for the missing documents or statements to be submitted, supplemented or corrected or for explanations within the deadline indicated by the Ordering party, unless the Contractor's tender has to be rejected or the procedure has to be invalidated in spite of submission, supplementation, correction or issuance of explanations. Failure by the Contractor to meet the deadline indicated by the Ordering party shall result in rejection of the tender. Only formal deficiencies or errors shall be subject to supplementation, correction or clarification. It is not possible to change the conditions of a tender submitted.

(6) In the case of an Contractor whose tender may contain an abnormally low price in relation to the subject matter of the contract, the Ordering Party reserves the right to call upon the Contractor, pursuant to the procedure described in item 5 above, to submit relevant explanations. 5 above, to submit relevant explanations and present the manner of calculating the gross price of the contract. A price may be considered abnormally low if it is lower by at least 30% than the estimated contract value or the arithmetic mean of prices of all submitted tenders which are not subject to rejection. The Ordering Party shall reject the tender of the Contractor who did not submit explanations, did not submit them within the deadline or if the evaluation of the explanations along with the evidence provided confirms that the tender contains an abnormally low price in relation to the subject matter of the contract. The obligation to prove that the tender does not contain an abnormally low price shall rest with the Contractor.

(7) The Ordering Party will post information on the result of the procedure at <https://www.pnitt.wum.edu.pl> in the Request for Quotation sheet.

(8) The Ordering Party reserves the right to invalidate or cancel the procedure, in whole or in part, at any stage, if:

- a) no tender was submitted or no non-rejectable tender was submitted;
- b) the price of the most advantageous tender or the tender with the lowest price exceeds the amount which the Ordering Party intends to allocate to finance the contract, unless the Ordering Party is able to increase that amount to the price of the most advantageous tender;
- c) the procedure suffers from an irremovable defect which makes it impossible to award the contract while observing the principle of fair competition and equal treatment of economic operators or the applicable provisions of law;
- d) a material change of circumstances has occurred, which makes it impossible to conduct the procedure or perform the contract in the interest of the Ordering Party, which could not have been foreseen at the time of publication of the Request for Quotation.

(8) Contractors shall not be entitled to any claims against the Ordering Party if they exercise any of the rights indicated in the preceding sentence.

## **IX. TERMS AND CONDITIONS OF AMENDING A CONTRACT CONCLUDED AS A RESULT OF A TENDER PROCEDURE**

1. The Ordering Party reserves the right to change the contract concluded with the Contractor selected in the course of the proceedings in the event of one of the circumstances listed below, taking into account the given conditions for their introduction:

1.1 The term or scope of the contract may change in the following situations:

- a) In the event of force majeure, i.e. an extraordinary and external event over the occurrence and duration of which the Ordering Party or the Contractor has no influence and which they were unable to prevent despite exercising due diligence. In such a case, the deadline for implementing the Agreement will be extended by the time of occurrence of the case of force majeure and removal of its effects;
- b) In the event of circumstances beyond the control of the Contractor or the Ordering Party, provided that this change results from circumstances that the Contractor or the Ordering Party could not foresee at the stage of publishing the Request for Quotation or submitting the offer and is not their fault. The deadline for the implementation of the Agreement will be extended by the time necessary to eliminate circumstances for which the Ordering Party or the Contractor are not responsible;
- c) If it is necessary to introduce changes to the Ordering Party's project requiring the approval of the Financing Institution. In such a case, the order completion date may be extended by the time corresponding to the period from the submission of an application for a change to the project by the Ordering Party until the changes are accepted by the Financing Institution.
- d) If the need for a change results from the course of research work under the Ordering Party's project. In connection with the implementation of the order as part of a broader research project of the Ordering Party, the Ordering Party reserves the right to extend the period of implementation of the subject of the order if the need for a change results from the course of research work within the project, i.e. if it is necessary to extend the research stages of the project, in the implementation of which the Contractor is involved, or failure to achieve the milestones of the research stage of the project.

1.2. The Contractor's remuneration specified in the contract may be changed in the following cases:

- a) Change in the applicable VAT rate. In such a situation, the remuneration will be changed appropriately so as to correspond to the updated tax rate for the part of the remuneration covered by the contract which has not yet been settled as of the date of the tax rate change.
- b) In the event of a change in legal regulations in force on the day of submitting the offer by the Contractor or signing a contract that will introduce new requirements as to the method of implementing any topic covered by the contract.

1.3 Other changes:

- a) In the event of a change in legal regulations in force on the date of submission of the offer by Contractor or signing a contract that will introduce new requirements as to the method of implementing any topic covered by the contract;
- b) In the event of receiving a decision from the Financing Institution or the Program Managing Authority containing changes to the scope of tasks, implementation deadlines or establishing additional provisions to which the Ordering Party will be obliged.
- c) The sponsor may change the time frame for research implementation adopted in the request for quotation if recruitment to the study does not achieve the statistically assumed target within the assumed deadline.
- d) The value of financial limitations on the part of the Ordering Party making it necessary to limit the scope of work included in the offer.

1.4. Change conditions:

- a) Initiating changes - at the request of the Contractor or the Ordering Party;
- b) Any changes and additions to the contract concluded with the selected Contractor will be made in the form of written annexes to the contract signed by both parties, under pain of invalidity.

## **X. IMPORTANT PROVISIONS OF THE AGREEMENT**

1. Information on the date and method of task implementation: based on the contract concluded with the Ordering Party.
2. Information on the method of payment: based on the contract concluded with the Ordering Party and the submitted invoice approved by the Project Manager.

## **XI. CANCELLATION OR CLOSURE OF PROCEEDINGS**

1. The Ordering Party will invalidate the contract award procedure if:
  - a) no non-rejectionable offer has been submitted;
  - b) the price of the most advantageous offer exceeds the amount that the Ordering Party intends to allocate to finance the order, unless the Ordering Party may increase this amount to the price of the most advantageous offer;
  - c) there has been a significant change in circumstances which means that the performance of the contract is no longer in the public interest or the Ordering Party's interest, which could not have been predicted in advance;
  - d) the proceedings contain an irremediable defect that makes it impossible to conclude a valid contract.
2. The Ordering Party reserves the right to close the procedure at any stage, without selecting the Contractor.

3. The Ordering Party will simultaneously notify all Bidders about the cancellation or closure of the procedure.

**XII. INFORMATION CLAUSE REGARDING ART. 13 AND ART. 14 REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (GDPR)**

1. The Ordering Party informs you that:

- a) The administrator of your personal data is:
- b) The Administrator has appointed a Personal Data Protection Inspector, who can be contacted at: e-mail address: [iod@wum.edu.pl](mailto:iod@wum.edu.pl), tel.: +48 22 57 20 320.
- c) Your personal data will be processed pursuant to Art. 6 section 1 letter b GDPR in order to obtain commercial information necessary to estimate the subject of the order, in accordance with the provisions of the Public Procurement Act or to conclude a contract as a result of this procurement procedure.
- d) Your personal data will be processed pursuant to Art. 6 section 1 letter c GDPR for the purpose of fulfilling legal obligations, including those necessary to establish, pursue or defend claims, as well as those arising from the archiving obligation based on applicable regulations.
- e) Your personal data will be processed pursuant to Art. 6 section 1 letter f GDPR for purposes arising from legitimate interests pursued by the Administrator or a third party, in particular by conducting analytical and statistical activities promoting the Administrator's activities.
- f) The recipients of your personal data will be persons or entities to which the documentation of the proceedings will be made available based on internal regulations, provisions of the Public Procurement Act, guidelines of operational, national and regional programs, as well as on the basis of the provisions of concluded co-financing agreements.
- g) 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 storing and archiving design documentation exceed 4 years, the storage period covers the entire duration of the contract or the period indicated in the documents of national and regional operational programs as well as in the concluded co-financing agreements.
- h) The obligation to provide personal data relating directly to you is a formal requirement related to participation in the contract award procedure.
- i) With respect to your personal data, decisions will not be made in an automated manner, pursuant to Art. 22 GDPR.
- j) Do you have:
  - based on Article. 15 GDPR, the right to access your personal data;
  - based on Article. 16 GDPR, the right to rectify your personal data1;
  - based on Article. 18 GDPR, the right to request the administrator to limit the processing of personal data, subject to the cases referred to in Art. 18 section 2 GDPR2 ;
  - the right to lodge a complaint with the President of the Personal Data Protection Office if you believe that the processing of your personal data violates the provisions of the GDPR.
- k) You are not entitled to: in connection with Art. 17 section 3 letter b, d or e of the GDPR, the right to delete personal data; the right to transfer personal data referred to in Art. 20 GDPR;



based on Article. 21 GDPR, the right to object to the processing of personal data, because the legal basis for the processing of your personal data is Art. 6 section 1 letter b and c GDPR.

2. The Ordering Party also informs that the Contractor, when applying for this contract, is obliged to fulfil the information obligation provided for in Art. 13 or 14 of the GDPR towards natural persons whose personal data the Contractor has directly or indirectly obtained and whose data will be provided to the Ordering Party, unless at least one of the exclusions referred to in Art. 14 section 5 GDPR or in accordance with Art. 13 section 4 GDPR, the data subject has the information referred to at the beginning

### **XIII. ATTACHMENTS TO THE REQUEST FOR QUOTATION**

1. Offer form with declarations
2. Synopsis and schedule of the study implementation

Prepared by:

Approved by: