REQUEST FOR QUOTATION No. 2022-26421-107391

Zakłady Farmaceutyczne Polpharma Spółka Akcyjna is carrying out the project titled **"Development of innovative fixed-dose antihypertensives"** as part of the Smart Growth Operational Programme 2014-2020, Sub-measure 1.1.1 Industrial Research and Development work implemented by the enterprise, and invites businesses to submit bids for the **conduct of toxicological studies.**

I. NAME AND ADDRESS OF THE ORDERING PARTY

Zakłady Farmaceutyczne Polpharma Spółka Akcyjna
ul. Pelplińska 19
83-200 Starogard Gdański
website: https://www.polpharma.pl/

II. CONTRACT AWARD PROCEDURE AND TYPE OF CONTRACT

The procedure will be carried out as a Request for Quotation in line with the competitiveness principle as defined in the "Guidelines on the eligibility of expenditures under the European Regional Development Fund, European Social Fund and the Cohesion Fund for the years 2014-2020", version of 21 December 2020. The Public Procurement Law of 11 September 2019 does not apply to this Request for Quotation (Journal of Laws of 2019, item 2019, as amended).

III. SUBJECT OF THE CONTRACT

3.1 Subject of the contract

The subject of the contract is to conduct two toxicological studies on a combination of two active substances in rats. The purpose of the study is to compare the toxicological parameters (including toxicokinetics) of a combination of nebivolol and telmisartan, vs. nebivolol and telmisartan administered alone.

The contract consists of the following tasks:

- 21-day, repeat-dose, dose-range finding toxicological study
- Development and validation of an analytical method for determination of the concentration of the investigated substances in samples administered to the animals
- Development and validation of a bioanalytical method for determination of the concentration of the investigated substances in animal blood samples
- 90-day, repeat-dose toxicological study (with toxicokinetics)

3.2 Description of the study

3.2.1 21-day, repeat-dose, dose-range finding toxicological study

- Species: rat
- Number of examined animals: 50 (25 males and 25 females)

- Number of study groups: 5 (4 groups receiving the investigated combination + 1 placebo control group)
- Dosage: oral administration once daily for 21 days
- Study endpoints (and frequency of assessment):
    - Mortality, morbidity and clinical signs (min. twice daily)
    - Food consumption (weekly)
    - Body mass (weekly)
    - Hematology, clinical chemistry (before the first administration of investigated substances and on last day of dosing)
    - Necropsy and macroscopic post-mortem examinations

3.2.2 Development and validation of an analytical method for determination of the concentration of the investigated substances in samples administered to the animals

- Method: LC-MS/MS, internal standard
- Analytes: nebivolol (racemate), telmisartan
- Elements of assessment include at least: linearity, accuracy and precision, selectivity, robustness, stability

3.2.3 Development and validation of a bioanalytical method for determination of the concentration of the investigated substances in animal blood samples

- Method: LC-MS/MS, internal standard
- Analytes: nebivolol (racemate), telmisartan in rat blood plasma
- Elements of assessment include at least: linearity, accuracy and precision, selectivity and specificity (including in the presence of concomitantly administered active substance), robustness, matrix effect, carry over, dilution integrity, matrix factor, stability, Incurred Sample Reanalysis

3.2.4 90-day, repeat-dose toxicological study (with toxicokinetics)

- Species: rat
- Number of examined animals: 250 (125 males and 125 females)
- Number of study group:
    - 1st study arm (toxicological assessment): 6 groups of 20 animals (3 groups receiving the investigated combination + 2 groups receiving one of the investigated substances + 1 placebo control group)
    - 2nd study arm (toxicokinetic assessment): 6 groups of animals (3 groups of 24 animals receiving the investigated combination + 2 groups of 24 animals receiving one of the investigated substances + 1 group of 10 animals as placebo control group)
- Dosage: oral administration once daily for 90 days
- Study endpoints (and frequency of assessment):
    - Mortality, morbidity and clinical signs (min. once daily) – concerns all the animals
    - Detailed assessment of clinical signs (weekly) – concerns all the animals
    - Food consumption (weekly) – concerns all the animals
    - Body mass (weekly) – concerns all the animals
    - Ophthalmoscopy (before the first administration of investigated substances and during last week of dosing) – concerns the animals from the toxicological assessment arm
    - Hematology, clinical chemistry (before the first administration of investigated substances and on last day of dosing) – concerns the animals from the toxicological assessment arm

- Urinalysis (before the first administration of investigated substances and on last day of dosing) – concerns the animals from the toxicological assessment arm
- Toxicokinetics of the investigated substances in blood plasma (after first and last dose; 10 sampling points for up to 24 hours post-dosing) – concerns the animals from the toxicokinetic assessment arm (an already developed and validated analytical method is required for both analytes at the start of dosing of the investigational substances in the 90-day toxicological study)
- Necropsy, post-mortem examination: macroscopic and histopathological – concerns the animals from the toxicological assessment arm

3.3 Activities covered by the contract

3.3.1 Planning and conducting two repeat-dose toxicological studies (21-day dose-range finding study and 90-day study with toxicokinetic assessment) including:

- Providing the appropriate number of animals and their appropriate allocation to the study groups,
- Preparation of complete documentation of the study – i.a. study plan with amendments (if applicable), submission of non-clinical study application to regulatory body and ethics committee (including fees), as well as data management and study management,
- Management of the investigated active substances (including destruction and reconciliation of substances),
- Preparation of formulations (samples) containing single investigated active substances and their combinations at different concentrations (including labelling and preparation for administration),
- Development and validation of an analytical method for determination of the concentration of active substances in samples administered to the animals,
- Administration of investigated substances to animals,
- Evaluation of health status of animals during screening, during the course of the study, and post-mortem examination, as well as statistical and toxicological analyses (in accordance with local requirements, relevant European guidelines and regulations, and contractor's procedures),
- Performing active substances concentration analysis in blood samples using a validated method (with ISR analysis) followed by toxicokinetic and statistical calculations,
- Preparation of toxicological reports, including analytical report, bioanalytical report and toxicokinetic report in accordance with the requirements of the European Medicines Agency (EMA), as well as archiving study documentation for 10 years (or longer, if required by local authorities),

3.3.2 The Contractor is responsible for complete execution of the study (including preparation of complete documentation specified in the description of the order), including the main experimental part, the analytical, bioanalytical, toxicokinetic, and toxicological-statistical part of the study along with the preparation of reports, as well as data management and study management,

3.3.3 The study must be designed, performed and documented in accordance with the principles of Good Laboratory Practice (GLP, not applicable for 21-day repeat-dose dose-range finding toxicological study), Directive 2010/63/EU, 2001/83/EC, and applicable European guidelines, including:

- ICH Guidelines M3 (R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals (EMA/CPMP/ICH/286/1995),
- Guideline on the Non-clinical development of fixed combinations of medicinal products (EMEA/CHMP/SWP/258498/2005),
- Guideline on repeated dose toxicity (EMA/CPMP/SWP/1042/99),
- ICH Topic S 3 A Toxicokinetics: A Guidance for Assessing Systemic Exposure in Toxicology Studies. Step 5. Note for guidance on toxicokinetics: a guidance for assessing systemic exposure in toxicology studies (CPMP/ICH/384/95),

3.3.4 The analytical method must be developed and validated according to applicable guidelines, in particular the guideline on bioanalytical method validation (CHMP/EWP/192217/2009 Rev. 1 Corr.2**) in case of the bioanalytical method,

3.3.5 Documentation (including the Study Plans and Final Study Reports) must be prepared in English and the local language if required by local law. Final Study Reports should contain all relevant data in the form of text, charts, summary tables and related reports. Final reports should be submitted in the form of pdf files, with the possibility of searching the text, with hyperlinks and bookmarks.

3.3.6 The Contractor will represent the Ordering Party before the relevant authorities and the ethics committee in the process of obtaining authorisation to conduct the study, as well as respond to inquiries from regulatory agencies in the procedure of obtaining the marketing authorisation, and from potential documentation auditors.

3.3.7 Performing internal audits of documentation and processes by the contractor during the performance of tests,

3.3.8 The contract does not include study monitoring.

3.4 The minimum resource requirements are set out in section V. CONDITIONS FOR PARTICIPATING IN THE TENDER AND GROUNDS FOR EXCLUSION. Bids that do not meet the minimum requirements will not be considered.

3.5 Category of the subject of the contract in accordance with the Common Procurement Vocabulary (CPV):

73000000-2 - Research and development services and related consultancy services

3.6 The Ordering Party does not allow partial or variant bids to be submitted.

IV. COMPLETION DATE

4.1 Study timelines:

Planned date of signing the contract: 30 days from the choice of the Contractor

Planned date of delivery of investigated active substances: 30 days from signing the contract.

Planned start date of 21-day, repeat-dose, dose-range finding toxicological study: 10.2022

Planned start date of 90-day, repeat-dose toxicological study (with toxicokinetics): 01.2023

Final 90-day, repeat-dose toxicological study (with toxicokinetics) report: 06.2023

4.2 The completion of the contract is to take place within 360 days from signing the contract, not later than 06.2023.

4.3 Study results and the necessary documents (in electronic and paper form) obtained in connection with the service must be delivered at the Contractor's expense to the registered office of the Ordering Party.

4.4 The completion date constitutes an evaluation criterion for the bid and will be counted as the time from the moment of signing the contract to the moment of handing over all the final study reports to the Ordering Party.

V. CONDITIONS FOR PARTICIPATING IN THE TENDER AND GROUNDS FOR EXCLUSION

CONDITIONS FOR PARTICIPATION IN THE TENDER

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

5.1.1 Economic or financial situation

The Contractor is in an economic and financial situation ensuring the timely and compliant performance of the contract in question, is not in bankruptcy and is not under liquidation or reorganization proceedings.

Evaluating the condition:

The Ordering Party will consider that the Contractor meets this condition if the Contractor submits a declaration of compliance with the conditions for participation in the tender (Appendix 2 to the Request for Quotation).

5.1.2 Technical or professional capacity

The Ordering Party will consider that the Contractor meets this condition if the Contractor demonstrates that it has the appropriate potential to perform the contract:

The Contractor has the capacity to carry out the experimental part, including analytical, bioanalytical, toxicokinetic and toxicological-statistical part in accordance with the principles of Good Laboratory Practice (GLP, not applicable for 21-day repeat-dose dose-range finding study), Directive 2010/63/EU, 2001/83/EC, and the applicable European guidelines, Including:
• ICH Guidelines M3 (R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals (EMA/CPMP/ICH/286/1995),
• Guideline on the Non-clinical development of fixed combinations of medicinal products (EMEA/CHMP/SWP/258498/2005),
• Guideline on repeated dose toxicity (EMA/CPMP/SWP/1042/99),
• ICH Topic S 3 A Toxicokinetics: A Guidance for Assessing Systemic Exposure in Toxicology Studies. Step 5. Note for guidance on toxicokinetics: a guidance for assessing systemic exposure in toxicology studies (CPMP/ICH/384/95),

Evaluating the condition:
The condition will be verified on the basis of a declaration of meeting the conditions for participation in the tender (Appendix 2 to the Request for Quotation). The Ordering Party reserves the right to verify the compliance of the Contractor's declaration with the state of facts and to conduct an audit at the Contractor's.

5.1.3 Personnel capacity

The Ordering Party shall consider that the Contractor meets this condition if the Contractor demonstrates that it has appropriate personnel, including qualified scientific staff (with secondary or higher veterinary, medical or natural sciences education), as well as key personnel necessary to perform the contract, including at least one person in the position of: Principal Investigator, Head of the Bioanalytical Laboratory, Statistician or an equivalent position.
Each of the above-mentioned persons, according to their function, must:

a) have experience in conducting non-clinical trials (for the Principal Investigator: min. 5 years of experience, for Statistician: min. 5 years of experience, for the Head of the Bioanalytical Laboratory: min. 10 years of experience).
b) have specialized education (for the Principal Investigator: veterinary medicine, medicine, pharmacy, biology, chemistry or related; for the Head of the Bioanalytical Laboratory and Statistician: medicine, biotechnology, pharmacy, biology, chemistry, mathematics, physics or related),
c) have the ability to analyze the results obtained in the non-clinical trial and correctly report study data in accordance with the relevant procedures and standards.

Criteria for the qualification of key personnel should be included in the Contractor's relevant procedures.

Evaluating the condition:
The contractor must meet all the conditions jointly. Items a-c will be verified on the basis of a declaration of meeting the conditions for participation in the tender (Appendix 2 to the Request for Quotation).

5.1.4 Experience

The Ordering Party will consider that the Contractor meets this condition if the Contractor demonstrates that it has the appropriate potential to perform the contract:

1. The Contractor has a developed and validated analytical method for at least one of the two analytes (nebivolol and telmisartan) with the appropriate quantification limit in accordance with the requirements of guideline CHMP/EWP/192217/2009 Rev. 1 Corr.2**.

   The Ordering Party considers the condition to be fulfilled on the basis of the Contractor's declaration (Appendix 2) and ***a list of validated analytical methods together with LLOQ values****.*

2. The Contractor has experience in conducting toxicological studies, including studies on combination of active substances.

   The Ordering Party considers the condition to be fulfilled on the basis of a declaration (Appendix 2) that the Contractor has performed at least 10 toxicological studies on rats (including the toxicokinetic part), including at least 2 studies for combinations of active substances in the last 10 years (if the Contractor's period of operation is shorter, during its operation)

3. The Contractor for the main experimental part, analytical, bioanalytical, toxicokinetic and toxicological-statistical parts will present a list of inspections for the last 10 years (if the Contractor's period of operation is shorter - during its operation) with a summary of the inspection results. At least 1 inspection must be carried out by an appropriate authority of one of the European Union countries in the field of GLP (Good Laboratory Practice), and the results of all inspections within the specified period must not include critical non-conformities. Inspections of studies carried out by the Contractor before 2012 will not be taken into account.

   *The Ordering Party considers the condition to be met on the basis of the Contractor's declaration (Appendix 2) and t****he presentation of the above-mentioned inspection list****.*

<u>Evaluating the condition:</u>

The contractor must meet all the requirements jointly. The Ordering Party considers the condition to be met on the basis of the Contractor's declaration (Appendix 2 to the Request for Quotation), the list of validated analytical methods referred to in item 1 and the list of inspections referred to in item 3.

<u>GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE TENDER</u>

5.2 Only bids that fully meet the requirements set out in the section "CONDITIONS FOR PARTICIPATION IN THE TENDER" and “BID PREPARATION" will be considered for evaluation.

5.3 The Ordering Party allows one request to the Contractor to supplement deficiencies in the submitted bid. The deadline for submitting supplements will be given in the letter to the Contractor (up to 3 working days from receiving the request for clarifications).

5.4 Grounds for exclusion

Entities with capital or personal ties to the Contracting Party are excluded from the tender.
Capital or personal ties are understood as mutual connections between the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party or persons performing activities on behalf of the Ordering Party related to the preparation and conduct of the contractor selection procedure, and the Contractor, consisting in particular in:

a) participating in the company as a partner in a civil-law partnership or general partnership,
b) owning at least 10% of shares or stocks,
c) acting as a member of the supervisory or management board, proxy, plenipotentiary,
d) remaining in a marriage relationship, in a family relationship or affinity in a straight line, relationship or affinity in the collateral line to the second degree, or in a relationship of adoption, guardianship or custody.

Evaluation of no grounds for exclusion:
The verification will be based on the Contractor's declaration that there are no personal or capital ties with the Ordering Party in accordance with Appendix 3 to the Request for Quotation.

5.5 Bids from Contractors who demonstrate that the required conditions are met and that there are no grounds for exclusion will be admitted for examination and evaluation. Assessment of fulfillment of the above conditions will be made according to the formula: “does meet - does not meet". A contractor who fails to meet any of the conditions will be rejected in the procedure. Bids which are incomplete or inconsistent with the subject of the request will also be rejected.

VI. PRICE CALCULATION

6.1. Bid price calculation: the price should be calculated as a net amount.
6.2. The price should be given in Polish zloty.
6.3. The bids with the price given in a currency other than the Polish zloty will be converted into Polish zloty at the average exchange rate of the National Bank of Poland on the bid submission deadline.
6.4. The price should include all the costs related to preparation and performance of the subject of the contract.
6.5. The price given in the bid cannot change during contract performance.

VII. CRITERIA USED BY THE ORDERING PARTY FOR BID SELECTION

7.1 When evaluating the bids, the Ordering Party will use the following criteria:

- **Price** (calculated on the basis of net prices expressed in PLN, taking into account the additional costs of conducting the study in the current epidemic conditions: if the offer price is expressed in a currency other than PLN, the price will be converted using the average selling

rate announced by the National Bank of Poland, applicable on the last day of submitting bids) - 40 points,

- **Completion date** (expressed as the number of calendar days, counted as the time from signing the contract to handing over all the final study reports to the Ordering Party) - 40 points,
- **Having fully validated analytical methods for both analytes** in blood plasma with the appropriate limit of quantification (LLOQ), according to EMA Guideline (EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2**), documented with a method validation report (in English) - 10 points
- **Offering blood pressure measurements** in animals assigned to toxicological assessment in a 90-day repeat-dose toxicological study (as part of the offered price; only non-invasive methods of BP measurement are allowed) - 10 points

7.2 The bid will be scored according to the formula:

$$\boldsymbol{O_P = P_C + P_T + P_M + P_B}$$

where:

O_P - bid score
P_C - score for the "Price" criterion
P_T - score for the “Completion date" criterion
P_M - score for the criterion "Having fully validated analytical methods for all 3 analytes"
P_B - score for the criterion “Offering blood pressure measurements”

7.3 The score (P_C) for the "Price" criterion will be calculated for the net price according to the formula:

$$P_C = \frac{C_N}{C_B} * 40 \text{ pts}$$

where:

P_C - score for the "Price" criterion
C_N - out of non-rejected bids, the lowest total net price of the bid
C_B - total net price of the bid

7.4 The score (P_T) for the "Completion date" criterion will be calculated in days according to the formula:

$$P_T = \frac{T_N}{T_B} * 40 \text{ pts}$$

where:

P_T - score for the “Completion date" criterion
T_N - out of non-rejected bids, the shortest completion date of the bid
T_B - completion date for the bid

The completion date will be counted in days. If the completion date in the bid is not expressed in days, the Ordering Party will calculate it in accordance with the assumption that one week = 7 days, two weeks = 14 days, three weeks = 21 days, one month = 30 days, and accordingly for other deadlines expressed in weeks and/or months.

7.5 The score (P_M) for the criterion "Having fully validated analytical methods for both analytes" will be awarded as follows:

- The contractor has fully validated analytical methods for all 3 analytes - 10 points.
- The contractor does not have fully validated analytical methods for all 3 analytes - 0 points.

7.6 The Score (P_B) for the criterion “Offering blood pressure measurements” will be awarded as follows:

-The contractor includes non-invasive blood pressure measurements in the bid – 10 points.

-The contactor does not include non-invasive blood pressure measurements in the bid – 0 points.

7.7 The bid with the highest total score will be considered the best from among the non-rejected bids. The Contractor may earn a maximum of 100 points. Calculations will be made to two decimal places.

7.8 In the event that two or more bids obtain the same number of points, the Ordering Party will apply the following environmental criterion as the decisive criterion. Criterion name: "The bidder has an implemented environmental management/protection system"

Criterion weight: 100%

Scoring method: The Ordering Party will sign a contract with the Bidder that presents a document confirming that they have an implemented environmental management/protection system.

7.9 In order to evaluate the decisive criterion, the Ordering Party has the right to call Bidders whose offers received the highest scores to supplement their bids by providing the information requested by the Ordering Party regarding the environmental impact of the subject of the bid. The deadline for supplementing the bid will be specified by the Ordering Party, however, it may not be shorter than 3 working days from the receipt of the request.

VIII. PLACE AND DEADLINE FOR THE SUBMISSION AND OPENING OF BIDS

8.1. Bids must be submitted within the non-extendable deadline of 07.06.2022
– in electronic format in a non-editable file, such as pdf (scan) to the address: clinical2@polpharma.com
or

- in electronic format via the Competitiveness Database, following the "Bidder's BK2021 Instruction" [https://archiwum-bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/info/web_instruction].

8.2. A bid is considered to be properly submitted if a complete bid has been delivered to the above e-mail address or via the Competitiveness Database within the deadline specified in this section.

8.3. Bids submitted past the submission deadline will not be considered.

8.4. The Ordering Party does not plan to open the bids in public.

IX. BID PREPARATION

9.1. The bidders are obliged to carefully read the information in the Request for Quotation and any explanations and answers published by the Ordering Party during the tender procedure, and to prepare the bid as per the Ordering Party's requirements.

9.2. The Contractor may submit one bid, which must be submitted on the bid form (Appendix 1).

9.3. The bid must be made in writing to be valid.

9.4. The bid must be prepared in the Polish or English language.

9.5. The bid, together with the appendices, must be signed.

9.6. The bid must include at least the following:

a) declaration on meeting the conditions for participating in the tender (Appendix 2) – signed by persons authorized to represent the Contractor under representation as per the relevant register or under a power of attorney,
b) declaration on not having capital or personal links with the Ordering Party (Appendix 3) – signed by persons authorized to represent the Contractor under representation as per the relevant register or under a power of attorney,
c) declaration that the Contractor has read and unconditionally accepts all the conditions listed in the published Request for Quotation (Appendix 4) – signed by persons authorized to represent the Contractor under representation as per the relevant register or under power of attorney,
d) power of attorney to act on behalf of the Contractor (if applicable),
e) a list of inspections for the last 10 years (if the Contractor's period of operation is shorter - for the period of its operation) with a summary of the inspection result,
f) a list of validated analytical methods along with the determination of LLOQ values,
g) Contractor's name and address,
h) number of the Request for Quotation,
i) name of the service,
j) bid preparation date and bid validity date,
k) net price,
l) contract completion date,
m) information on having fully validated analytical methods for both analytes
n) information on inclusion of non-invasive blood pressure measurements in the bid.

9.7. The bid message header should include the number "2022-26421-107391".

9.8. Before the bid submission deadline the Contractor may change or withdraw the bid. Changes to or notification of withdrawal of the bid should be delivered to the Ordering Party before the bid submission deadline by electronically submitting a written declaration to the e-mail address provided in this Request for Quotation; otherwise the changes or withdrawal will be invalid. A change to the bid must be submitted on the same terms as the bid.

9.9. The bidders are obliged to carefully read the information in the Request for Quotation and any explanations and answers published by the Ordering Party during the tender procedure, and to prepare the Bid as per the Ordering Party's requirements.

X. COMMUNICATIONS BETWEEN THE ORDERING PARTY AND THE CONTRACTORS, PERSONS AUTHORIZED FOR CONTACT

10.1. During the tender procedure the Ordering Party and the Contractor submit all declarations, requests, notices and information in Polish or in English.

10.2. The receipt of any notices, declarations, requests and information submitted electronically must be immediately confirmed at the request of each of the Parties.

10.3. If the Contractor has not confirmed the receipt of the correspondence, the Ordering Party will assume that the correspondence sent by the Ordering Party to the e-mail address provided by the Contractor has been delivered in a way that enables the Contractor to read it.

10.4. The bid and its change/withdrawal should be sent to the e-mail address: clinical2@polpharma.com or via the Competitiveness Database.

10.5. In any correspondence related to this tender the Contractors should use the tender number: Request for Quotation No. 2022-26421-107391.

10.6. The person competent to provide information on the Request for Quotation is:

Mariusz Mogielnicki (clinical2@polpharma.com)

10.7. The Ordering Party will not provide information, clarifications or replies to any queries submitted to the Ordering Party orally or by phone.

10.8. Any questions about this Request for Quotation should be sent by e-mail to the address provided in section 10.6, not later than 5 business days before the closing of the tender procedure, or via the Competitiveness Database via the "Questions" tab [https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/] no later than 5 days before the offer submission deadline.

10.9. Replies to the answers and adding more detailed information to the Request for Quotation following from questions from prospective Contractors will be published on the website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl and sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

11.1. During the examination and evaluation of the submitted bids the Ordering Party may request the Contractors to provide additional information (if it does not infringe competition) and

clarifications related to the submitted bid. The Ordering Party may also ask the Contractors to correct evident mistakes and calculation errors. The deadline for the submission of additional information will be provided in the request (up to 3 business days).

11.2. The Ordering Party reserves the right to conduct an audit in order to verify the documents, declarations, lists, data and information provided by the Contractors.

11.3. Information on the tender results will be published on the website: https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl.

11.4. The winning Contractor will be informed by phone or by e-mail on the date when and place where the Contract will be signed. The Contract is deemed to have been concluded after both parties have signed it.

11.5. After the publication of the tender results, the Ordering Party reserves the right to start negotiations with the Contractor with whom the Contract is to be signed. Negotiations may cover the price and the duration.

11.6. If the Contractor with the best bid fails to conclude the Contract, the Ordering Party reserves the right to sign the Contract with the Contractor who had the next highest score, without organizing a second tender procedure.

XII. AMENDMENTS TO THE CONTRACT

12.1. The Ordering Party reserves the right to make material amendments to the concluded Contract in relation to the bid on the basis of which the Contractor was selected to the following extent and in the following situations:

12.1.1. changes to the European Union or national law that affect the performance of the Contract (in particular changes of the VAT rate);

12.1.2. improving technical standards of the subject of the contract resulting from new solutions brought about by technological progress, without any impact on the gross flat rate;

12.1.3. extending the deadline for the performance of the Contract due to additional work which must be completed for the proper performance of the Contract and which the Ordering Party, acting with due diligence, could not have foreseen earlier, subject to subsection 12.1.6 below;

12.1.4. extending the deadline for the performance of the Contract due to force majeure, with all the consequences of such extension;

12.1.5. changing the parameters of the subject of the Contract which does not lead to a change in the nature of the Contract – technological changes, in particular: the need to perform the Contract using technical/technological or material-related solutions other than as specified in the Request for Quotation if the application of the planned solutions could lead to a failure to perform or to improper performance of the Contract, subject to subsection 12.1.7. below;

12.1.6. changes related to additional supplies or services from the Contractor which are not covered by the Contract, as long as they are necessary and all of the following conditions are met: – the Contractor cannot be changed due to economic or technical reasons, in particular relating to the interchangeability or interoperability of the equipment, services or installation ordered in connection with the original subject of the Contract,

– the change of the Contractor would cause significant inconvenience or a considerable increase of costs for the Ordering Party,

– the value of each subsequent change does not exceed 50% of the value of the original subject of the Contract (net amount);

12.1.7. the change does not lead to a change in the nature of the Contract and all of the following conditions are met:
– the Contract must be changed due to the circumstances which the Ordering Party, acting with due diligence, could not have foreseen,
– the value of the change does not exceed 50% of the value of the original subject matter of the Contract (net amount);

12.1.8. The Contractor may be replaced with a new contractor:
– as a result of merger, division, transformation, bankruptcy, restructuring or purchase of the Contractor or its enterprise as long as the new contractor meets the conditions for participating in the tender procedure, there are no grounds for exclusion and the change does not entail other material changes to the Contract,
– as a result of the Ordering Party taking over the Contractor's obligations towards the subcontractors;

12.1.9. the amendment to the Contract does not lead to a change in the nature of the Contract and the total value of the amendments is less than EUR 215,000 and at the same time is lower than 10% of the value of the original subject of the Contract (net amount).

12.2. The Ordering Party also allows for making non-material amendments to the concluded Contract in relation to the bid on the basis of which the Contractor was selected.

12.3. Amendments to the Contract will be made in the form of an annex signed by both parties and they are subject to the Ordering Party's approval.

XIII. OTHER INFORMATION

13.1. The Ordering Party reserves the right to change or supplement the Request for Quotation before the bid submission deadline. Information on changing or supplementing the Request for Quotation will be published in the same place where the original Request was published.

13.2. If the changes or supplements to the Request for Quotation entail the need to change the bids, the Ordering Party will extend the bid submission deadline to allow for making changes to the bids.

13.3. The Ordering Party will not reimburse the cost of participation in the tender procedure.

13.4. The Contractor will bear all the costs related to bid preparation and submission.

13.5. The Contractor submitting the bid will be bound by it for a period of 60 days from the bidding deadline.

13.6. The bid will remain unchanged throughout contract performance.

13.7. Following the procedure the Ordering Party may conclude the Contract for the performance of the subject of the contract with the Contractor whose bid is considered to be the best. The selection of the best bid does not mean that the Ordering Party is obliged to conclude the Contract with the Contractor.

13.8. The Ordering Party reserves the right to place with the Contractor additional orders, not covered by the subject of the original contract, up to 50% of the value of the subject of the original contract, necessary for the proper performance of the task and resulting among others from the following circumstances:
– due to technical or economic reasons the separation of the additional order from the subject of the original contract would incur excessively large costs,
– the performance of the subject of the original contract depends on the performance of the additional order.

13.9. The Ordering Party reserves the right to place with the Contractor a supplementary order (consistent with the description of the subject of the original contract) up to 50% of the value of the subject of the original order specified in the contract concluded with the Contractor.

13.10. The Ordering Party reserves the following rights:
- the right not to choose any of the submitted bids;
- the right to cancel the Tender Procedure at any time, without giving the reason or without prior notification of the Contractors;
- the right to change or supplement the documents making up the Request for Quotation before the bid submission deadline, in which case such documents will become an integral part of the Request;
- the right to change or supplement the content of the Request for Quotation before the bid submission deadline;
- the right to extend the bid submission deadline;

and the Contractors have no claims against the Ordering Party with respect to the above rights.

13.11. The Contractor will pay to the Ordering Party contractual penalty for any delay in the performance of the service more than 60 days after the originally determined deadline for the performance (subject of the contract). The Ordering Party may impose a penalty of 5% of the value of the order if the delay was not caused by the Ordering Party.

13.12. The Ordering Party may decide not to impose the contractual penalty if the performance of the order was affected by force majeure.

13.13. The Contractor consents to the deduction of the contractual penalty directly at the time of settlement of the VAT invoice for the completed delivery.

XIV. LIST OF APPENDICES

The following documents are appendices to the Request for Quotation:

Appendix number	Appendix name
Appendix 1	Bid form
Appendix 2	Declaration on meeting conditions for participating in the tender
Appendix 3	Declaration on not having capital or personal ties with the Ordering Party
Appendix 4	Declaration on accepting tender conditions