REQUEST FOR PROPOSALS

RFP 022663 CENTRAL LABORATORY TESTING SERVICE WITH TEST RESULT MANAGEMENT AND LOGISTICS OF LABORATORY DIAGNOSTIC MATERIALS AND SAMPLES FOR A PHASE II CLINICAL STUDY

In connection with obtaining the grant for the project: "Development of innovative drug for the treatment of vaginal infections" No. POIR.01.01.01-00-0294/17 under Measure 1.2 Sectoral R&D programmes of the Operational Programme Smart Growth 2014-2020, acting on the basis of Article 13 of the financial project support contract, Adamed Pharma S.A. invites to submit tenders for the below defined service.

I. Subject of the contract:

Central laboratory service and logistics of materials and samples for microbiological diagnostics in a phase II clinical study at selected study sites and in selected countries identified by Adamed Pharma, as well as management of the obtained test results and cooperation with the CRO designated by Adamed Pharma for a newly developed topical agent based on a known active substance, used in the treatment of bacterial vaginoses.

Clinical study Sponsor (Ordering Party): **Adamed Pharma S.A.**

The Ordering Party declares that full details of the subject of the contract will be disclosed once the confidentiality agreement/statement (for contracting parties who have not previously signed the agreement), attached as an appendix to this RFP (**Appendix No. 1**), is signed.

II. Scope of services:

1. Identification of bacteria specified in **Appendix No. 2** (confidential) in specimens obtained from ca. 185 subjects (please specify the unit cost per identification procedure).
2. Semi-quantitative cultures for bacteria identified in **Appendix No. 2** in specimens obtained from ca. 185 subjects (please specify the unit cost per culture assuming that: 185 patients will be attending in V1 (V=visit), 130 patients will be attend in V3 and V4, additionally 15% of unscheduled visits).
3. Antibiotic susceptibility testing with MIC determination (gradient concentration strip/E-test or manual methods) (ca. 10 antibiotics most commonly used in the treatment of bacterial vaginoses). The list of antibiotics will be determined with the contractor once the tender is resolved.
4. Determination of Minimum Inhibitory Concentration (MIC) for novel molecule using EUCAST/CLISI-recommended methods: agar/broth microdilution method, an ISO 20776-1 compliant method for broth microdilution.
5. Prepare and evaluate Gram stained specimens (for the Nugent test) – ca. 600-700 specimens (185 for V1, 185 for V2, 130 for V3 and V4 and unscheduled visits (UNS)) .

6. Prepare microbiological testing kits, which should include all the materials necessary to collect and transport the specimens for the Nugent test, vaginal swabs for culture and wet mount microscopy slides.
7. Prepare, together with the CRO identified by the Ordering Party, a protocol to be followed for the sampling, storing and shipment of the biological samples to the central laboratory.
8. Bank and store strains for a period of ca. 6 years; amount: 4000-5000; storage temperature: -80°C.
9. Comprehensive logistics for study sites: Nugent test and vaginal swab for culture kits, wet mount microscopy slides, transport media for the shipment of the specimens from the sites to the central laboratory, including:

a) purchase,

b) compilation,

c) delivery prior to the start of the study (to designated locations at the study sites included in this study) of all the necessary kits identified above,

d) delivery of the materials identified above during the course of the study as needed by the sites,

e) collection of the obtained biological samples from the sites and their transportation to the central laboratory under controlled conditions as recommended by the bidder,

III. General requirements:

1. The laboratory should hold a PN – EN ISO 15189 certificate or an equivalent certificate authorising medical laboratory diagnostic testing and quality management.
2. The laboratory should have (at least 3 years of) experience in clinical studies – a relevant declaration will be required from the Bidder, including the number of trials conducted.
3. The kits should include dispatch forms for particular shipments. Individual kits should be provided with primary and secondary packaging. The biological material should be transported to the central laboratory under controlled conditions (temperature), using a validated temperature logger.
4. In cooperation with the CRO, the laboratory will develop laboratory manuals detailing the sampling methods of the biological material for testing the parameters of the panels listed in items 1-4 (section "Scope of services"), as well as the procedure for the pre-analytical preparation of the biological samples, their preparation for dispatch and the dispatching of the biological samples for the panels listed in items 1-5 (section "Scope of services").

5. Additional services, including:

a) Central laboratory project management, including accounting for and verifying the conformity of the number of samples delivered from the study sites as part of the clinical study and the completeness of all labelling.

Supplementary information:

1. Agreements for the delivery of the above mentioned services and solutions will only be signed if the requirements included in this tender procedure are met.
2. Moreover, the submitted bid should take account of the following details:
   • Countries where the Sponsor is planning to conduct the study: **Poland, Hungary.**
   • Planned number of sites where the core phase II clinical study is to be conducted (in total): **ca. 15 clinical sites in Europe, including: Poland (10), Hungary (5).** The final number of sites

participating in the clinical study will be agreed once the sites are selected and it will be confirmed when the agreement is signed.

• Study timeframe:

– Study initiation at the first site: **June 2022**

– Recruitment period: **7 months**

– FPI: **August 2022**

– LPI: **February 2023**

The service provision schedule is subject to change due to recruitment rate.

IV. Terms for participating in the tender:

1. Orders cannot be awarded to Entities affiliated personally of financially with the Contracting Authority. Through financial or personal connection we understand the interactions between the Contracting Authority or persons authorized to enter into commitments on behalf of the Contracting Authority or persons performing on behalf of the Purchaser activities associated with the preparation and the procedure for selecting Tenderers and Tenderer, in particular by:

   a) participation in the company as a partner or partnership,
   b) owning at least 10% of the shares,
   c) the functions of a member of the supervisory or management, proxy,
   d) remaining married in consanguinity or affinity in a straight line, second-degree consanguinity or affinity of the second degree in the collateral line or by adoption or guardianship.

In order to meet this condition, the Tenderer is obliged to send with the offer signed declaration (**Appendix no. 4**).

2. <u>The request is directed to entities which:</u>

a) declare that they are capable of providing the required services in accordance with all the requirements set out in the RFP;, the Bidder should, upon the Ordering Party's request, present its organizational chart and a list of the implemented SOPs, as well as an up-to-date list of reference values for particular laboratory tests according to the specification included in the bid submission terms and conditions, along with a description of the relevant testing methodology;

b) declare that the Bidder's team includes members, i.e. lab managers, specialists and subordinate technicians with demonstrable relevant education in medical analytics and a license to practice the profession of a biomedical analyst (in Poland) or equivalent education in laboratory medicine and an equivalent title of biomedical analyst in countries other than Poland. The resumes (CVs) of the team members should be attached to the bid upon the Ordering Party's request and the Sponsor reserves the right to contact such team members to confirm the expected experience and ask additional questions. CVs will be presented on the request of the authority

c) submit, upon the Ordering Party's request, valid certificates of laboratory quality control (e.g. Central Quality Evaluation Centre for Medical Laboratory Science in Łódź) and by other institutions in the case of foreign laboratories;

d) present a statement to confirm that they possess the required microbiological testing experience in clinical studies and to confirm the number of studies conducted so far (at least 3);

e) declare that they are prepared to disclose and share for the purpose of scientific reporting, the full documentation of the testing methodology for the microbiological panel parameters, used for the execution of the subject of the contract described in detail in this Request for Proposals;
f) declare that they are prepared to collect the obtained samples and pooled biological material from the study site and deliver them to the central laboratory within no more than 72 hours under controlled conditions and with transport temperature monitoring;
g) present, upon the Ordering Party's consent, a valid PN – EN ISO 15189 certificate or an equivalent certificate authorising them to perform medical laboratory diagnostic testing and quality management;
h) The laboratory should have a database of diagnostic parameter test results, including:

- the set-up of the study, i.e. the sites and investigators in the Bidder's database.
- allowing access to the database on the basis of the authorization criteria set out in the study for investigators, co-investigators, CRO experts and the Sponsor;
- ensuring an interface for the viewing, analysis (with an option to create reports and printouts) and migration/transfer of the data and for the integration of the data with the eCRF database;

The Tenderer is obliged to send with the offer signed declaration confirming that all conditions listed above are met (**Appendix no. 5**).

3. Each of the submitted CVs should include the following clause: *"I hereby authorize Adamed Pharma S.A. to process my personal data for the purpose of evaluating the bid submitted in reply to RFP 022663 – CENTRAL LABORATORY SERVICE WITH THE MANAGEMENT OF TEST RESULTS AND LOGISTICS OF MATERIALS AND SAMPLES FOR MICROBIOLOGICAL DIAGNOSTICS IN A PHASE II CLINICAL STUDY pursuant to Article 6(1)(a) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)".*

V. Submission deadline and bid preparation method:

1. Any correspondence should include the RFP number in the message title: **RFP- 022663 – CENTRAL LABORATORY SERVICE - *Company name***
2. Bids must be submitted by **10 th October 2022 at 23:59 CET.** Any changes to the deadline shall be communicated to all Suppliers.
3. Questions may be submitted on the website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl or by e-mail: aleksandra.stojak(at)adamed.com. *Sponsor reserves the right not to answer if the question(s) are addressed two days before the end of the procedure*. In order to ensure equal access to information for all Bidders participating in the proceedings, questions and answers (with the author of the questions hidden) will be sent to all Bidders
4. The cost estimate should be developed in a calculation worksheet and attached to the Bid as **Appendix No. 3.** Bids without the completed Appendix No. 3 to the Bid will not be considered. In addition, the Vendor may present the Cost Estimate in its own template.

5. **The offer should contain at least the following information:** name and address of the Supplier, number of the request for proposal, net price (PLN/EUR), payment term.
   Attachments **1 through 7** should be attached to the Tender.
6. The bid, together with the required appendices, should be submitted on the website https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl or by e-mail: aleksandra.stojak(at)adamed.com
7. The Ordering Party will not accept partial bids, as it needs to ensure that the service will be performed by a single entity operating as a Central Laboratory.
8. The Ordering Party allows for subcontractors and third parties to be contracted by the Bidder.
9. The bid shall be prepared in the Polish or English language.
10. Prices listed in the bid should be expressed as net prices in Polish zlotys (PLN) or euros (EUR).
11. If the prices in the offer are expressed in EUR, they will be converted using the exchange rate of 4,4536 PLN/EUR, in accordance with the Notice of the President of the Public Procurement Office of 3 December 2021 on the current EU thresholds, their PLN equivalent, PLN equivalent of amounts expressed in EUR and the average PLN / EUR exchange rate constituting the basis for converting the value of public contracts or design contests.
12. The offers submitted after the deadline shall not be taken into consideration.
13. Prior to the offer submission deadline, the Bidder has the right to:
    a) withdraw the offer by submitting a notification in writing in the manner described for the offer submission,
    b) change the offer – a notification of the changes made must be submitted in the same manner as the offer and be labelled 'CHANGE TO THE OFFER'.

VI. Selection criteria and method of assessing submitted offers

1) The Contracting Authority is entitled to reject the tender submitted by the Tenderer who does not meet the conditions for participation in the proceedings, or if the offer is incomplete or incompatible with this request. *In particular, the Contracting Authority emphasizes that the Bidder's failure to submit the required documents in points 2 a) through h) will result in rejection of the bid.*

2) Formal compliance, the degree of compliance with the RFP requirements.

3) Possibility of realization of service within the above presented timeframes.

4) Selection criteria:

   a) **net price (weight criterion – 95%); -** according to **Appendix no. 3**

   b) **environmental criterion – 5% of the overall assessment –** assessment based on the Statement confirming compliance with the environmental criterion (**Appendix no. 6)** provided by the Tenderer.

The Contracting Authority shall evaluate offers based on the result of the accumulated number of points calculated on the basis of above criteria and scores:

Criteria	Weight [%]	Method of evaluation in accordance with the formula
Price	95%	net price of the offer with the lowest price/net price tested offer x 100 x 95 % = number of points
Environmental criterion	5%	removal of emission of pollutants into the environment by at least one of two means listed in the statement = 5 points

5) As the most advantageous offer will be considered that which obtains the highest number of points. In case of the same number of points, the decisive criterion is the price.

6) The results of the mathematical calculations carried out in the evaluation of tenders are rounded to the second decimal place.

VII. Tenderer selection and the manner of notification

1) The Contracting Authority shall select the best offer based on the offer evaluation criteria specified in this call for offers

2) In the event that the selected Contractor refuses to sign the contract, in accordance with the Request for Proposal, within the period specified by the Contracting Authority, the Contracting Authority may conclude a contract with the Contractor who meets the requirements of the Request for Proposal and whose bid received the highest number of points consecutively.

3) If the submitted bids obtain the same number of points as a result of the evaluation, the Contracting Authority shall select the bid following the principle that the bid which obtained the highest number of points due to the price offered shall be selected

4) The Contracting Authority shall post information concerning the outcome of the procedure on the, www.bazakonkurencyjnosci.gov.pl/publication/list/ website, and send it to each Tenderer.

VIII. General provisions

1) The Contracting Authority reserves the right to invalidated or terminate the procedure at each stage without giving any reason.

2) In the case of cancellation of the contract the Tenderer are not entitled to claim for reimbursement of the costs of participation in the proceedings.

3) Submission of the application for registration in the process or tender is implies acceptance without reservation all the conditions of the proceedings.

4) Withdrawal by the Contracting Authority from the conclusion of the contract after the notification the Tenderer about the selecting the offer, cannot be the basis for claims of incurred costs of participation in the proceedings.

5) In the process of evaluating Offers the Contracting Authority may seek information from the contractors concerning the content of their documents.

6) If the application does not contain all the required elements, the Contracting Authority may in justified cases call the Tenderer to complete it.

7) The Contracting Authority reserves the right to record sound during technical meetings with Tenderer. Submission of the offer will be treated as giving consent to the recording of the meeting.

8) The Contracting Authority **reserves the right to negotiate the proposal** with all Tenderers.

9) The Contracting Authority allows negotiations of the contract terms and conditions with the Tenderer.

10) It is permitted to grant to the selected Tenderer supplementary orders, which are in line with the subject of this basic contract, amounting to 50% of this order.

11) Terms of contract change:

The contracting authority envisages the possibility of introducing significant changes to the contract concluded as a result of the conducted contract award procedure in relation to the content of the offer, on the basis of which the contractor was selected, in the event of the necessity to change the indicated scope of works specified in the offer:

11.1. necessary or justified changes in the project documentation resulting from unforeseeable reasons

11.2. the necessity or technical and economic viability of using equivalent materials and equipment

11.3. necessity to perform equivalent solutions resulting from technological or utility considerations

11.4. financial constraints on the part of the contracting authority causing the need to reduce the scope of work included in the offer

11.5. necessary or reasonable changes to the date and terms of delivery of the subject matter of the contract arising for reasons impossible to foresee

11.6. the implementation schedule may be subject to change due to the pace of recruitment of patients for the study

11.7. Any changes and additions to the contract concluded with the selected Tenderer will be made in the form of written annexes to the contract signed by both parties, under rigor of invalidity.

IX. Additional information

1) Checklist is provided in **Appendix No. 7**

2) The person authorized to contact the Bidders (Monday-Friday between 08:00-16:00) is: Aleksandra Stojak [aleksandra.stojak(at)adamed.com]