Rzeczpospolita Polska

Warsaw, 03/02/2023

REQUEST FOR PROPOSAL No. 03/2023-ABM

In connection with the preparation of an application for co-financing of the project "Phase II development of breakthrough targeted therapy including evaluation of efficacy and safety of OATD-01 in patients with pulmonary sarcoidosis" (working title), Molecure S.A. invites you to submit an offer for the execution of the subject of the order defined below.

I. ORDERING PARTY ("SPONSOR")

Molecure S. A. ul. Żwirki i Wigury 101 02-089 Warsaw VAT ID: 728 27 89 248	**Contact persons**	
	Kinga Kazimierczak	**e-mail: k.kazimierczak@molecure.com**
	Katarzyna Aranowska	**e-mail: k.aranowska@molecure.com** **phone no. +48 605 279 010**

II. SCOPE OF THE REQUEST

Preparation and comprehensive execution of the phase II, Proof-of-Concept, clinical trial in order to assess efficacy, pharmacokinetics, pharmacodynamics and safety of chitinase inhibitor OATD-01 in patients with active pulmonary sarcoidosis ("Project").

The Sponsor stipulates that full information regarding the Project will be disclosed to bidders after execution of Confidentiality Disclosure Agreement (CDA), which is attached to this Request for Proposal (Appendix No. 1). Counterparties with whom the CDA has already been concluded must provide a signed document before full information on this request is disclosed to them. The scanned copy of the signed CDA needs to be sent via email to k.aranowska@molecure.com

The handwritten original of the confidentiality agreement should be sent to the following address: Molecure S.A., ul. Żwirki I Wigury 101, 02-089 Warsaw.

The order is carried out in connection with the preparation of an application for co-financing as part of the competition: Development of targeted or personalised medicine based on nucleic acid and small molecule compounds-based medicinal products _ABM/2022/6, financed by the Medical Research Agency and is in line with Call for proposals Regulation of the competition.

III. THE MODE OF THE ORDERING

III.1 The request is not subjected to the provisions of the Act of 11 September 2019 - Public Procurement Law (Journal of laws of 2019, item 2019 as mentioned).

III.2 This order is carried out in accordance with the principle of fair competitiveness, openness, transparency and equal access.

III.3 The Sponsor reserves the right to cancel this procedure without providing reasons and also to complete the procedure without choosing the winning Bidder.

III.4 In the course of examination and evaluation of the offers the Sponsor may require Bidders to present explanations concerning the content of submitted bids.

III.5 In justified cases, at any time, before the deadline for the submission of the offers, Sponsor reserves the right to change the content of this request. If the changes can affect the content of tenders, the Sponsor shall extend the tender submission deadline. The Sponsor shall inform potential Contractors about the changes made by publishing relevant information on its website and by e-mail to all Bidders to which the request was sent or to all Bidders who submitted bids.

III.6 This procedure (also referred to in the text as "Request for the proposal") does not set the obligation for Sponsor to sign any formal contracts.

III.7 It is not possible to make and offer for part of the order.

III.8 For the avoidance of doubt, the selection of the best proposal and the winning Bidder does not constitute a contract or an order to perform any services or any deliveries. The contract for the Project will be concluded in writing during separate procedure.

IV. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS AND A DESCRIPTION OF THE MANNER OF ASSESSING THE FULFILMENT OF THOSE CONDITIONS

IV.1 The Request for the Proposal relates to potential contractors whose scope of business activity is in full compliance with the subject of this Request (hereinafter referred to, depending on the stage whether the reference in the Request for Proposals is to the entity that submits the tender or signed the contract, as "**Bidder**" or "**Contractor**").

IV.2 The offers may be issued by Bidders who:

A) Have the necessary knowledge and experience to perform the Project:

(i) have experience in providing services in the field of preparation and conduct of clinical trials of medicinal products in compliance with ICH GCP (International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice) and Declaration of Helsinki, including international multicentre trials of early phases (Phase I and II) carried out both in Europe and in the USA on behalf of study sponsor;

(ii) have experience in preparation and conducting full-service clinical trials in the area of rare or orphan diseases (have organized and conducted at least 5 such studies in the last 10 years - and if the business period is shorter - in that period);

(iii) have experience in rare indications, particularly in Pulmonary Sarcoidosis and/or Idiopathic Pulmonary Fibrosis (IPF), or in other types of sarcoidosis or fibrosis (i.e. Cystic Fibrosis, Lymph Nodes Sarcoidosis, Liver Sarcoidosis) and have performed at least 1 full-service clinical trial in such an indication;

(iv) have experience in submission of clinical trials applications in European countries, including Regulatory submission under the EU Clinical Trials Information System (CTIS) (have performed at least 1 application under the CTIS);

(v) have experience in investigational site feasibility, selection and contracting for clinical trials,

including the sites located in the USA and Europe;

(vi) have experience in preparation of key clinical trial documentation, including: Informed Consent Form (ICF) (core, country- and site-specific), Case Report Form (CRF) and Clinical Study Report (CSR);

(vii) have experience in selecting, contracting and cooperating with Third Party Vendors, including EDC, IRT, Central Reading for PET-CT scans, Central Reading for ECG Holter and Central Laboratory (including Central Analytical Labs) in the implementation of clinical trials.

(viii) have experience in monitoring of clinical research using personnel in the USA.

B) Will engage the appropriate human resources capable for performing the Project. The Sponsor requires that the team, that will be involved in the delivery of the Project, is qualified by education, training and experience to perform their respective task(s).

The qualifications and professional experience (necessary to perform the Project) of the specified members of the team listed out below must be clearly documented in a CV, i.e. the CV must contain information such as: name of school or university and year of graduation, name of the company in which the person worked/works, name of the position and the scope of duties and period of work in a given position. The period of experience will be calculated by number of worked months (i.e. 1 year = 12 months). Relevant training certificates or training records (e.g. GCP, GCLP training) need to be documented in the CV or attached to the CV.

C) The Sponsor requires that the Bidder employs (subcontracting acceptable) an appropriate team for the performance of the Project, in particular:

(i) **Regulatory Specialist** with a minimum of three years' experience in coordinating the regulatory aspects of international multicentre clinical studies (in particular in rare and orphan diseases) by providing regulatory consultancy, and establishing regulatory applications, responses, and amendment strategies, including local expertise to coordinate the CA submissions, as well as the EC/ IRB submissions for the planned countries to meet project milestones;

(ii) **Project Manager (PM)** who will be responsible for the comprehensive management and supervision of the implementation of the clinical trial as well as communication with Vendors and the Ordering Party, who has at least five years of documented experience in management of clinical trials, including rare and orphan disease and early phase clinical trials;

(iii) **Pharmacovigilance (PV) and Drug Safety Lead,** with a minimum of three years of experience in safety management and monitoring, who will be responsible for management of safety surveillance activities, including safety database set-up and maintenance, and safety reporting to competent Regulatory Authorities, Ethics Committees and Investigators per national and regional legislation. The PV Lead needs to be authorized to use the EudraVigilance database;

(iv) **Medical Monitor** with at least 5-year experience in medical review of clinical data and experience in international multicentre early phase studies (Phase I and II) in the therapeutic area of rare/ orphan diseases and/or respiratory diseases;

(v) **Clinical Research Associates (CRAs)** who have at least two years of professional experience in the field of on-site clinical trials monitoring and will be based in the same

country as the study site(s); experience in monitoring of early phase trials or trials in rare diseases will be an advantage (however, it is not an obligatory requirement);

(vi) **Data Management Lead** with at least three years' experience in leading and coordinating all data management functions for the project to meet project timelines;

(vii) **Biostatistician** with at least three years' experience in biostatistical analysis of clinical trials results, including early phase clinical trials.

The Ordering Party does not allow the same person to hold more than one of the roles listed above in the bid and/or during the performance of the Project.

D) Have the technical and logistic potential and relevant certifications, approvals and authorizations required by international and local law to perform the Project. In regards to study sites personnel, the Sponsor requires that members of the Site Investigational Team involved in the study are adequately educated, trained and have required professional experience necessary to perform the study in strict accordance with applicable regulations (including ICH GCP and local regulations) and bioethical standards. The education and professional experience of site staff will be confirmed in the CV or by separate training certificates and professional licences.

E) The Sponsor requires the Bidder to have a Standard Operating Procedures (SOPs), necessary to conduct the study in accordance with ICH GCP. The Sponsor reserves the right to access the SOPs at every stage of the Project conduct.

F) The Sponsor requires the Bidder to carry out itself or to engage third party vendors (Sponsor's approval is required) in order to deliver the Project:

- **Central Laboratory for Biomarker Testing Services,** which will be properly equipped and certified to complete the relevant part of the Project within agreed timelines. The Central Laboratory needs to have in place quality control measures for each and every step of the process, all in accordance with their strict standard operating procedures (SOPs). The Laboratory must ensure that the documentation prepared and provided by them during and after the analysis is in compliance with regulatory requirements.

- **Central Bioanalytical Laboratory for PK and PD Analysis,** properly equipped and certified to complete the relevant part of the Project within agreed timelines. The Bioanalytical Laboratory needs to have in place quality control measures for each and every step of the process, all in accordance with their strict standard operating procedures (SOPs). Additionally, the Sponsor requires the Bioanalytical Lab has experience in development and validation of bioanalytical methods for clinical trials, as well as experience in preparation of regulatory bioanalytical documentation and reports as per Food and Drug Administration (FDA) and European Medicines Agency (EMA) requirements. In addition, the Sponsor requires the Central PK Laboratory to have validated software for calculating pharmacokinetic parameters.

- **Central PET-CT Reading,** adequately certified and experienced (having at least 5 years of experience in medical imaging expertise), having qualified specialists highly familiar with PET-CT analysis and interpretation.

- **Central ECG Holter Reading**, adequately certified and experienced, having qualified specialists highly familiar with ECG analysis and interpretation, having flexible technology to support home ECG collection.
- **Clinical Trial Supplies Vendor**, adequately certified and experienced in order to complete Investigational Medicinal Product (IMP) packing, labelling, certifications (including EU Qualified Person services) and clinical logistics in compliance with Good Manufacturing Practice (GMP) regulations. The Clinical Trial Supplies Vendor needs to have in place quality control measures for each and every step of the process, all in accordance with their strict standard operating procedures (SOPs).

G) Will be able to constantly supervise and manage the study at the investigational sites in all the countries where the clinical trial will be conducted;

H) Will guarantee the personal data protection of the study participants in line with the General Data Protection Regulation (GDPR) and other applicable laws and perseverance of the intellectual property of the Sponsor by implementation of respective measures as required by applicable laws and contracts that are to be concluded with the Bidder by in particular guarantying restricted access to electronic systems and paper files where the confidential and sensitive personal data will be stored;

I) Are in a good economic and financial standing, which assures proper execution of the project;

J) Will be able to start the Project activities immediately after contract signature.

In order to prove the above requirements, the Sponsor requires that the Bidder submits, along with the proposal, a Statement about fulfilling the requirements for participation in the bid procedure (the Statement is attached as Appendix No.2) and attaches the CV along with relevant certificates or training records of the team planned to be involved in the Project (as listed in section IV.2 C). The Sponsor allows submission of blinded CVs at this stage and delivery of the unblinded CVs only after the winning Bidder will be chosen (by winning Bidder only).

IV.3 Excluded from the proceedings shall be those Bidders who are related to the Sponsor by either personal or equity connections. Equity or personal relationship is understood as relations between the Sponsor or individuals authorized to take commitments on behalf of the Sponsor or those acting on behalf of the Sponsor in order to prepare and implement the winning Bidder selection procedure and the Bidder, including in particular:

A) participation in the company, in a civil or limited partnership; holding at least 10% (or less if so prescribed by the respective provisions of applicable law) shares or interests; serving a function of a member of the supervisory organ, a member of the management organ, holder of commercial power of attorney or other proxy;

B) having family ties, such as by marriage, by lineage at first or second degree, by adoption, guardianship or custody, staying in cohabitation with the Bidder, the Bidder's deputy legal entities or members of management or supervisory bodies of Bidders applying for the contract award;

C) being in such a legal or factual relationship with the Bidder that it may give raise to justified doubts as to the impartiality or independence in connection with the procurement procedure.

As a proof of the above the Sponsor requires that the Bidder submits, along with the Proposal, a statement about

not being related to the Sponsor (Appendix No. 3).

IV.4 Issuing the offer represents the full acceptance of the rules set in this Request and in particular the essential terms of the contract. Sponsor reserves that the contract that will be concluded with the Bidder shall include the provisions on the transfer of the entirety of intellectual property generated in the course of execution of the Project.

V. DESCRIPTION OF THE PROJECT

The scope of the Project includes preparation and comprehensive execution of the phase II, Proof-of-Concept, clinical trial in order to assess efficacy, pharmacokinetics, pharmacodynamics and safety of chitinase inhibitor OATD-01 in patients with active pulmonary sarcoidosis in compliance with ICH GCP (International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice), Declaration of Helsinki and all other applicable international and local regulations and in accordance with the study protocol and other study documents provided by the Sponsor.

In this clinical study OATD-01 will be administered for the first time to patients with active pulmonary sarcoidosis during a 12-week treatment period, to evaluate if such therapy is efficient. Clinical safety, pharmacodynamics (PD), and pharmacokinetics (PK) of OATD-01 will also be characterized. Type and number of planned study procedures have been described in the protocol Synopsis (Appendix No. 4, Confidential). The aim of the study is to enrol 90 patients in about 30 - 35 investigational sites both in Europe and in the USA. First Patient is expected to be enrolled at the end of **August 2023** and recruitment period is planned for 15 months. Detailed Assumptions and Timelines have been defined by the Sponsor in Appendix No. 5 (Confidential). The protocol Synopsis and the Study Assumptions and Timelines will be disclosed to Bidders after execution of CDA.

The handwritten original of the confidentiality agreement should be sent to the following address: Molecure S.A., ul. Żwirki I Wigury 101, 02-089 Warsaw.

The Sponsor has the right to change the initial study design. The final study Protocol will be approved after reviewing all preclinical study data and following the recommendations of the regulator's scientific advice. The final Project schedule and timelines will be agreed with the selected Contractor during a 'kick-off meeting'.

Table 1. Detailed scope of the Project

Item	Task
1.0	**Study oversight management**
1.1	Oversight Management - Startup
1.2	Oversight Management - Conduct
1.3	Oversight Management - Closeout
1.4	Sponsor Teleconferences
1.5	Project Manager / Safety Review Committee Meetings
1.6	Internal Team Teleconferences

2.0	**Vendor selection, contracting and management during the study**
2.1	PET-CT Scan Central Reading
2.2	Electronic Data Capture (EDC) Vendor
2.3	IRT/ IWRS Vendor
2.4	Central Laboratory, including Analytical labs
2.5	Holter ECG Central Reading
2.6	Vendor Management
3.0	**Study Initiation Activities**
3.1	Prepare for and Conduct Internal Kickoff Meeting
3.2	Prepare for and Conduct Sponsor Kickoff Meeting
3.3	Create Core Study Plans, including: Project Management Plan including Communication Rules, Start-Up Plan, Risk Management Plan & Risk Log, IMP Management and Supply Plan, Protocol Deviations Management Plan, List of SOP Plan, Clinical Monitoring Plan, Site Initiation Plan, PSV/SIV Slides, Site Pharmacy Manual, Medical Monitoring Plan, Safety Management Plan.
3.4	Patient Questionnaire licensing and translations
3.5	Prepare Patient Card and Patient Diary
3.6	Conduct Team Training Activities- Initial
3.7	Conduct Team Training Activities- Ongoing
4.0	**Protocol Amendment Implementation**
4.1	Manage Protocol Amendment Activities
4.2	Amendment - Regulatory Submission (CTA in Europe)
4.3	Amendment - IRB/EC Submission
4.4	Amendment - Informed Consent Forms update (core, country and site ICFs)
4.5	Amendment - Clinical Site Agreements update
4.6	Amendment - EDC and Related Tools
5.0	**Trial Master File ("TMF")**
5.1	Conduct TMF Maintenance and QC
6.0	**Regulatory and IEC / IRB Applications**
6.1	Perform Regulatory Submission and Obtain Clinical Trial Application ("CTA") Decision in Europe
6.2	Perform EU-CTR Modification Part 1
6.3	Perform EU-CTR Modification Part 2
6.4	Perform Regulatory Maintenance Submissions
6.5	Perform National Registry Submissions Application
6.6	Initial Central EC and IRB Submissions
6.7	Initial Local EC and IRB Submissions
6.8	Annual EC & IRB Maintenance Submissions
6.9	Develop Country Product Labels (for each country)
6.10	Regulatory Meetings and Communications
6.11	Perform Data Protection Application
6.12	Translations
6.13	End of Trial Notifications
7.0	**Site Identification and Initiation**
7.1	Perform Country Feasibility and Selection
7.2	Perform Site Feasibility and Site Selection for Qualification
7.3	Conduct On-Site Qualification Visits / Pre-Study Visits
7.4	Develop Contract Strategy & Templates
7.5	Site Contract Negotiation
7.6	Collect and Approve Site Regulatory Package Documents
7.7	Core Informed Consent Form ("ICF")
7.8	Country-Specific ICFs
7.9	Site-Specific ICFs
7.10	Organize, Prepare and Conduct Investigator Meetings
7.11	Initiation Visits

8.0	**Clinical Monitoring (100% SDV) and Site Management**
8.1	Conduct Site Management & Contacts
8.2	Conduct On-Site Monitoring Visits - One Day
8.3	Conduct On-Site Monitoring Visits - Two Day
8.4	Conduct Remote Monitoring Visits
8.5	Conduct On-Site Termination Visits
8.6	Clinical Meetings and Communications
8.7	Investigator Site Files management
9.0	**Investigator Payments**
9.1	Administer Investigator Payments
9.2	Conduct Transparency Reporting Activities (if applicable)
9.3	Patient Travel Costs management
10.0	**Central Lab Setup and Maintenance**
10.1	Central Lab Setup, Maintenance and Closure
11.0	**Clinical Data Management**
11.1	Develop Data Management Plan and Guidelines
11.2	Develop EDC Database & Related Tools
11.3	Develop Offline Listings
11.4	Conduct Data Cleaning Activities
11.5	Validation of Electronic Data
11.6	Coding Setup and Maintenance
11.7	Perform Final Database Lock Activities
11.8	Conduct EDC Archiving Activities
11.9	Clinical Data Management Meetings and Communications
11.10	Local Lab Data Management
11.11	Perform EDC Version Update - if applicable
11.12	DSMB Activities
11.13	Interim Analysis
12.0	**Biostatistics and Statistical Programming**
12.1	Develop Statistical Analysis Plan ("SAP")
12.2	Program Tables, Listings, & Figures ("TLF")
12.3	Program Datasets
12.4	Perform Statistical Analysis Dry Run 1
12.5	Run Final TLFs
12.6	Conduct Stats Archiving Activities
12.7	Biostatistics and Statistical Programming Meetings and Communications
12.8	In-text TLF Development/Pre-Programming & Program/QC In-Text Table
12.9	Interim Analysis
13.0	**Data Surveillance**
13.1	Data Surveillance Plan & System Setup
13.2	Conduct Data Surveillance Activities
14.0	**Protocol Deviations**
14.1	Program Protocol Deviation Specification
14.2	Conduct Protocol Deviation Review
15.0	**Medical Monitoring**
15.1	Medical Monitoring Set-Up
15.2	After-Hours Medical Monitoring
15.3	Medical Interaction with Sponsor
15.4	Medical Review of Listings
15.5	Medical Meetings and Communications

16.0	**Pharmacovigilance ("PV")**
16.1	Safety Database Set-Up and Maintenance
16.2	Serious Adverse Event ("SAE") Processing
16.3	Safety Information System Site Reporting
16.4	Set Up and Conduct Reporting Activities
16.5	Pharmacovigilance Meetings and Communications
16.6	Line Listings
16.7	Eudravigilence
17.0	**Clinical Study Report ("CSR") Development**
17.1	Develop CSR
17.2	Develop Subject Narratives for CSR
17.3	Develop CSR Appendices
18.0	**Medical Writing**
18.1	Drug Safety Update Report (DSUR)
19.0	**Patient Recruitment and Retention ("PRR")**
19.1	Perform Patient Recruitment and Retention Services
19.2	Perform Patient Comms Initial Development and Translation Activities
19.3	Patient Concierge
20.0	**Data Transfer Activities**
20.1	Conduct Data Transfer Programming Activities
20.2	Transfer Data
21.0	**Quality Assurance**
21.1	Quality Assurance activities
22.0	**IMP Management**
22.1	Packing and Labeling
22.2	Batch Certification & QP Release
22.3	Clinical Supply Management (Storage, Distribution, Return, Destruction)
23.0	**Other Charges** Please take into account all costs for subcontractors related to the conduct of a clinical trial not listed above (e.g., all license fees - if applicable, etc.). All other necessary costs, expenses related to office and administrative activities should also be taken into account.

The scope of the order may change as a result of circumstances that the Ordering Party could not objectively foresee at the time of concluding the contract, or circumstances resulting from the implementation and conduct of a clinical trial in accordance with the current regulations.

The Ordering Party reserves the right to terminate the contract with the Contractor in the absence of a positive, opinion issued by the competent bioethical commission / obtaining consent to commence a clinical trial from the relevant agency. The Ordering Party reserves the right to terminate the contract with the Contractor also if, for scientific or business reasons, the work related to the OATD-01 molecule or the chitinase program developed by the Sponsor is stopped or suspended. The contract will regulate mutual settlements between the Sponsor and the Contractor in such cases.

VI. EVALUATION OF SUBMITTED OFFERS AND SELECTION CRITERIA

VI.1 **Quote Net** – weight:60% (60 pts.)

In this criterion points will be calculated (with accuracy to two decimal places) according to the formula:

$$Pc = \frac{C_{min}}{C_{evaluated}} x60$$

Pc – Points received

C_{min} – The smallest Net price out of the submitted offers that are not subject to rejection

$C_{evaluated}$ – Net price of the offer being evaluated

VI.2 **First patient Enrolled* date** - Weight: 20% (20 pts.)

In this criterion, points will be awarded according to the formula:

- 20 points – when first patient is enrolled no later than 8 weeks since the full approval of the study (Regulatory and Ethics) is in place
- 10 points - when first patient is enrolled no later than 12 weeks since the full approval of the study (Regulatory and Ethics) is in place
- 0 points - when first patient is enrolled later than 12 weeks since the full approval of the study (Regulatory and Ethics) is in place

* Enrollment - the process of registering or entering a patient into a clinical trial. Once a patient has been enrolled, the participant would then follow the clinical trial protocol.

VI.3 **Current experience in Pulmonary Sarcoidosis or Idiopathic Pulmonary Fibrosis (IPF) clinical trials** – Weight: 20% (20 pts.)

In this criterion, points will be awarded according to the formula:

- 20 points – if the Bidder has conducted Pulmonary Sarcoidosis or IPF trial(s) within last 2 years
- 0 points - if the Bidder conducted Pulmonary Sarcoidosis or IPF trial(s) more than 2 years ago.

VI.4 In the case of two or more tenders with equal number of points awarded, the Ordering Party shall call Contractors who submitted equally evaluated offers to submit, within the period specified, additional offers. For any of the evaluation criteria, the additional offer may not be less favorable than the one submitted in response to the Request for offers (i.e. in the first offer).

VII. HOW TO PREPARE AND SUBMIT THE OFFER

VII.1 The offer must be signed by the person authorized to represent the Bidder. Scans of handwritten documents or electronically signed documents shall be accepted.

VII.2 Each Bidder may submit only one offer.

VII.3 Costs of the offer preparation shall be incurred by the Bidder.

VII.4 **Offers must be submitted in English no later than: 10 February 2023 23:59:59 CET using the form available in Appendix No.6.**

VII.5 Offers shall be issued via email to: k.aranowska@molecure.com

VII.6 The receipt of the offer via electronic means indicated in point VII.5 shall be considered as a date of submitting the offer.

VII.7 Offers that do not meet the deadline, are incomplete (despite a request for supplementation, if such a request was possible and in accordance with the regulations) or sent to the wrong email address will not be taken into consideration.

VII.8 Any questions concerning the Object of the tender should be addressed to: k.aranowska@molecure.com no later than **09/02/2023 12:00 PM (CET).** Contact person is Katarzyna Aranowska.

VII.9 Any questions concerning the formal issues of the tender should be addressed to: k.kazimierczak@molecure.com no later than **09/02/2023 12:00 PM (CET).** Contact person is Kinga Kazimierczak.

VII.10 The offer should include the validity date (at least 30 days from the submission deadline).

VII.11 The price should be set in both Net (not including VAT) and Gross.

VII.12 The values in the offer (Net amount and Gross amount) should be rounded to two decimals with the mathematical rule of rounding the numbers.

VII.13 The offer price should include VAT. The correct determination of VAT is responsibility of the Bidder – in accordance with the provisions of the Act of 11 March 2004 on Goods and Services Tax (Journal of Laws of 2021 item 685 as mentioned) if applicable.

VII.14 The offer shall not be prepared in price variants.

VII.15 The financial settlements between the Ordering Party and the Bidder may be made in PLN, EUR, USD or GBP.

VIII. TENDER RESULTS

Bidder will be informed about choosing his offer via email. Formal results will be also published on the Ordering Party's website https://molecure.com/pl/zamowienia/

IX. IMPORTANT PROVISIONS OF THE FUTURE AGREEMENT

IX.1 Bidder will be obligated to enter into the agreement including all conditions presented in the Request and in the offer.

IX.2 Sponsor provides the possibility of submitting a supplementary order consistent with the subject of the basic contract in the amount not exceeding 50% of the order value specified in the contract concluded with the Bidder.

IX.3 It is not possible to introduce significant changes to the content of the agreement in relation to the content of the offer, which was the base for the Bidder selection, unless:

A. The amendments concern performing additional supplies or services by the Bidder, not covered by the basic contract, provided they are necessary and the following conditions are met:
   i. The change of the Bidder cannot be made due to the economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of basic contract,
   ii. The change of the Bidder would cause significant inconvenience or substantial cost increase to the Ordering Party,
   iii. The value of any subsequent changes do not exceed 50% of the basic contract value.

IX.4 Any contract amendment must be done in writing, otherwise will not be valid.

IX.5 Information regarding contractual penalties:
Sponsor will require the Bidder to constitute particular pledges, in particular contractual penalties.

X. LIST OF APPENDICES

Appendix 1. CDA template

Appendix 2. Statement concerning fulfilment of the requirements set out in point IV.2

Appendix 3. Statement regarding personal and capital connections with the Sponsor

Appendix 4. CONFIDENTIAL Protocol Synopsis

Appendix 5. CONFIDENTIAL Study Assumptions and Timelines

Appendix 6. The Proposal form

Appendix 7. Declaration of compliance with the information obligations provided for in Article 13 or Article 14 of the GDPR

The budget will be assessed only on the basis of Appendix No. 6 submitted by the Bidder.

Please do not send any additional documents than required by this Request.