Rzeczpospolita Polska

Warsaw, 10/02/2023

REQUEST FOR PROPOSAL No. 04/2023-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

Providing that the Sponsor plans to initiate and conduct Phase II international clinical study with the drug candidate OATD-01, and one of the countries where the study will be conducted is the USA, the Sponsor is posting this Request for Proposal. The scope of the Request includes providing professional advisory services in the field of regulatory affairs related to clinical development of a drug candidate (OATD-01) and preparation and submission of clinical trial application to the US regulatory bodies. The scope includes, but is not limited to the following deliverables:

1) Regulatory strategy for USA versus EU clinical development;
2) USA regulatory application authoring and preparation (with the Bidder as the primary author);
3) USA Investigational New Drug Application (IND) and subsequent submissions, including Development Safety Update Report (DSUR);
4) Regulatory project management, including regulatory contact (as the US agent);
5) Ad-hoc consulting – covering all other related items;

for total study duration until Clinical Study Report (CSR) submission ("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 personalized 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 performing regulatory services related to **early clinical development** of investigational medicinal products;

(ii) have experience in providing services in the field of authoring, preparation and filing of clinical trial applications, including US IND, in compliance with ICH GCP (International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice) and Code of Federal Regulations;

(iii) have authored and submitted at least 5 successful orphan or rare disease drug applications to the US FDA (Food and Drug Administration) of which at least 1 application have been

successfully submitted within the recent 3 years;

B) Will engage the appropriate human resources experienced and capable for performing the Project;

C) Will guarantee the perseverance of the intellectual property of the Sponsor by in particular guarantying restricted access to electronic systems and paper files where the confidential data will be stored;

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

E) Will be able to start the Project activities immediately after contract signature;

F) Will be able to perform IND submission within maximally 8 working days from delivery of complete study documentation by the Sponsor.

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).

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

Providing that the Sponsor plans to initiate and conduct Phase II international clinical study with the drug candidate OATD-01, and one of the countries where the study will be conducted is the USA, the Sponsor is posting

this Request for Proposal. The scope of the Request includes providing professional advisory services in the field of regulatory affairs related to clinical development of a drug candidate (OATD-01) and preparation and submission of clinical trial application to the US regulatory bodies. The scope includes, but is not limited to the following deliverables:

1) Regulatory strategy for USA versus EU clinical development;
2) USA regulatory application authoring and preparation (with the Bidder as the primary author);
3) USA Investigational New Drug Application (IND) and subsequent submissions, including Development Safety Update Report (DSUR);
4) Regulatory project management, including regulatory contact (as the US agent);
5) Ad-hoc consulting – covering all other related items;

for total study duration until Clinical Study Report (CSR) submission ("Project").

The Sponsor plans to initiate Phase II clinical trial in which 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 and safe. The aim of the study is to enrol 90 patients in about 30 - 35 investigational sites both in Europe and in the USA, while activation of 5-7 sites in the USA is the Sponsor's requirement. The list of European countries planned for study conduct will be provided at later stage, after country selection. US IND submission is expected **by end of April 2023, but not later than by 31 May 2023**, and final Clinical Study Report is expected in June 2025. The Study design and main assumptions have been described in the protocol Synopsis (Appendix No. 4, Confidential) and in the Appendix No.5 - Study Assumptions and Timelines (Confidential). The Confidential Appendices No. 4 and 5 will be disclosed to Bidder 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 Bidder during a 'kick-off meeting'.

Table 1. Detailed scope of the Project

Item	Task
1.	Regulatory Strategy Advice (strategy for USA versus EU clinical development)
2.	US regulatory application authoring and preparation (with the Bidder as the primary author)
3.	US IND application and subsequent submissions, including DSUR and CSR
4.	Regulatory project management, including regulatory contact (as the US agent)
5.	Ad-Hoc Consulting and covering all other related items

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

For evaluation purposes only, the offers submitted in currency other than polish zloty (PLN) will be converted into PLN using the NBP (central bank of the Republic of Poland) rate of exchange in effect on the date the Request For Proposal is published.

VI.2 **IND submission date** - Weight: 20% (20 pts.)

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

- 20 points – when IND submission is performed within maximally 4 working days from delivery of complete study documentation by the Sponsor
- 10 points - when IND submission is performed within 5 or 6 working days from delivery of complete study documentation by the Sponsor
- 0 points - when IND submission is performed within 7 or 8 working days from delivery of complete study documentation by the Sponsor

VI.3 **Number of orphan or rare disease drug applications authored by the Bidder successfully submitted to the FDA** - Weight: 20% (20 pts.)

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

- 20 points – for at least 20 orphan or rare disease drug applications authored by the Bidder successfully submitted to the FDA, of which at least 1 application have been successfully submitted within the recent 3 years;
- 10 points – for at least 10 orphan or rare disease drug applications authored by the Bidder successfully submitted to the FDA, of which at least 1 application have been successfully submitted within the recent 3 years;

- 0 points – for at least 5 orphan or rare disease drug applications authored by the Bidder successfully submitted to the FDA, of which at least 1 application have been successfully submitted within the recent 3 years.

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: 17 February 2023 23:59:59 CET using the form available in Appendix No.6.**

VII.5 Offers shall be issued via emails 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 **16/02/2023 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 **16/02/2023 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.