Ryvu Therapeutics S.A.
2 Sternbacha Street, 30-394 Krakow, Poland
registered in the District Court for the Krakow-Srodmiescie
in Krakow XI Division of the National Court Register
KRS number: 0000367359
VAT ID: PL6792942955

MEDICAL RESEARCH AGENCY

Update 3rd November 2023
Update 31th October 2023
Krakow, 19th October 2023

REQUEST FOR PROPOSAL No. ABM-19102023A

In connection with the implementation by Ryvu Therapeutics S.A. of the project "The conduct of a phase II, multicentre, open-label clinical trial (RIVER-81) evaluating the safety and efficacy of RVU120 in combination with venetoclax in patients with relapsed/refractory acute myeloid leukemia who have failed prior therapy with venetoclax and a hypomethylating agent" no. 2022/ABM/06/00002/P/02 (hereinafter: "Project") co-financed from the state budget by the Medical Research Agency under the Competition: Development of targeted or personalized medicine based on therapeutic products based on nucleic acids and small-molecule compounds no. ABM/2022/6, Ryvu Therapeutics S.A. invites proposals for the execution of the following defined description of the order.

I. ORDERING PARTY, SPONSOR:

Ryvu Therapeutics S.A.
Sternbacha 2, 30-394 Krakow, Poland
EU VAT PL6792942955

II. DESCRIPTION OF THE ORDER:

This order concerns the validation of **the flow cytometry method** that will be implemented in the RIVER-81 clinical study. The method will assess levels of intracellular proteins (MCL-1, BCL-XL, BCL-2) in the subpopulation of AML cells from the bone marrow or peripheral blood cells of patients, defined by using appropriate surface markers and gating strategy (eg. CD45, CD34, CD14 and CD64).

Due to the need to protect business secrets, the description of the order (subject of the request) is made available to Bidders who undertake to maintain confidentiality. To tenders@ryvu.com must be sent the electronically signed CDA or information about CDA currently in force. The CDA template is attached as Appendix 03. The title of the message must contain the reference number of the RFP (ABM-19102023A).

III. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS:

Bidders that fulfill the following requirements are invited to submit the proposals:

- Bidders able to demonstrate compliance with international quality standards required for the handling and analysis of human biological samples from clinical trials:
  - ~~ISO 15189 and ISO17025 / CLIA; or equivalent~~
  - GCP environment/ Systems in compliance with FDA 21CFR part 11; or equivalent.
  - ~~Proficiency Testing Programmes.~~
- Bidders with documented experience in performing validation of flow cytometry methods.

These conditions to be confirmed in Appendix 01 – Proposal form. The assessment of the conditions will be made using the system: meet/do not meet.

Access to the bone marrow and peripheral blood samples from AML patients will be an asset. Please select the proper box in Appendix 01.

IV. PLACE, DATE, AND PROCEDURE OF SUBMISSION OF PROPOSALS:

IV.1. The proposal must be submitted by: ~~31th October 3rd November~~ 8th November 2023 at 23.59 CET.

IV.2. The proposal must be sent via e-mail to the following address: tenders@ryvu.com. The message with the offer should refer to the RFP number indicated on the first page: **ABM-19102023A**.

IV.3. The proposal and its attachments should be prepared in English.

IV.4. The proposal must be prepared in accordance with the form constituting Appendix 01 to this RFP and must include the following information: Start-up timelines, Turnaround time for each part of the validation, and information about deliverables, data, and material handling, project management and the validity period (minimum by 30th November 2023). The Ordering Party may require Bidders to agree to an extension of the proposal validity period for the period of up to next 30 calendar days.

V. CRITERIA FOR EVALUATION OF PROPOSALS:

V.1. Offers that comply with the description of the order set out in section II. and with conditions for participation in the proceedings set out in section III and are prepared according to the procedure set out in section IV. will be accepted for the evaluation of offers. Offers that do not meet the requirements will be rejected.

- Criterion 1: Net price ("C") – max. 8,00 points.

Net price ("C") is considered as the total price for the execution of the order (all activities including all associated costs related to kits, reagents, consumables, management, and other resources and operations needed to execute contracted work). The quote must include prices given in EUR or USD.

In order to compare the offers they shall be converted into PLN at the average exchange rate of the National Bank of Poland (NBP) prevailing on the day of closing the tender procedure indicated in section IV.1

In the Net Price criterion, points will be awarded (to two decimal places) according to the formula:

$$\text{Criterion Net price "C"} = \frac{\text{the lowest net price offered among the bids submitted}}{\text{net price of the examined offer}} \times 8{,}00 \text{ points}$$

- Criterion 2: Total project duration offered ("T") considered as the turnaround time given in calendar days; max. 2,00 points according to the criteria given below:
  - Over 240 calendar days – 0,00 points;
  - 240 – 221 calendar days – 0,50 point;
  - 220 – 201 calendar days – 1,00 point;
  - 200 – 180 calendar days – 1,50 points;
  - below 180 calendar days – 2,00 points

V.2. The Ordering Party will select the most advantageous offer that obtains the highest number of points.

V.3. Having to choose between quotations scored in the same number of points, the Ordering Party will call Bidders to re-present the prices.

VI. ADDITIONAL INFORMATION

VI.1. The Ordering Party allows for the possibility of awarding to the Contractor supplementary orders, in an amount not exceeding 50% of the value of the contract specified in the agreement concluded with the contractor, while such orders are consistent with the subject of the basic contract.

VI.2. The terms and conditions of the agreement may change during the course of the agreement (Ordering Party reserves the right to amend the agreement):

- in terms of the timelines and term of the agreement – following changes in the scope of the study and Project (extension of the duration of the Project, extension of appropriate stages of the Project, change of research plans);
- the number of individual units/components of the clinical trial may be changed or introduction of new units not covered by the basic order may occur, if the changes are necessary to achieve the intended overarching objective of the trial, and the necessity for their introduction is directly related to the results obtained during the conduct of the trial and were impossible to foresee at an earlier stage,
- in terms of the number of patients and number and types of countries and sites – which is directly related to the conduct of a particular type of study involving oncology patients and the fact that special circumstances/ events may arise during the course of the study that could not have been foreseen earlier,
- in the event of force majeure as an event which is externally impossible to foresee and which could not have been prevented and whose consequences and effects could not have been prevented.
- The Ordering Party reserves the right to make changes to the final order / contract based on the requirements of the study protocol.

VI.3. The Bidders may ask the Ordering Party to clarify the content of this RFP. If the request for clarification of the content of the RFP was received later than by the end of **27rd October 2023**, the Ordering Party may provide explanations or leave the application unexamined. Questions must be sent to the following e-mail address: tenders@ryvu.com.

VI.4. Due to the need to protect business secrets, in the event of questions requiring the disclosure of confidential data, the Ordering Party reserves the right to provide explanations after executing the Confidential Disclosure Agreement (CDA). It is allowed to use an electronic signature (including a qualified electronic signature) or a trusted signature (trusted profile).

VI.5. The Ordering Party reserves the right to change the content of the RFP, including changes in the terms of the procedure. Bidders will be informed.

VI.6. The Ordering Party reserves the right to ask the Bidders at any stage of the evaluation of offers for additional information, documents, additions, or explanations. The Ordering Party's contact with the Bidder will take place by e-mail indicated in the content of the offer sent by the Bidder.

VI.7. This RFP serves to estimate the market price of the contract. The Ordering Party reserves the right to enter into negotiations with Bidders who have submitted an offer and meets the conditions for participating in the proceedings. Arrangements regarding the date of negotiations will be carried out by e-mail. The modified offer may not contain conditions less favorable than the original proposal.

VI.8. This RFP does not oblige the Ordering Party to conclude a contract.

VI.9. For more information, please contact Anna Dziedzicka or Aleksandra Mazgała at the following email address: tenders@ryvu.com.

ATTACHMENTS

Appendix 01 – Proposal Form;

Appendix 02 – Description of the order;

Appendix 03 – Mutual Confidentiality Agreement.