Ryvu Therapeutics S.A.,
2 Sternbacha Street, 30-394 Krakow, is registered in the District Court for the Krakow-Srodmiescie in Krakow XI Division of the National Court Register

KRS number: 0000367359
Reg. No. 120515330
VAT ID: PL6792942955
Share capital: PLN 9,248,059.20 (paid in full)

Krakow, 29th May 2023

REQUEST FOR PROPOSAL No. ABM-29052023CRO

In connection with the planned 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' ('Project') under the Competition: Development of targeted or personalized medicine based on therapeutic products based on nucleic acids and small-molecule compounds ABM/2022/6 organized by the Medical Research Agency, Ryvu Therapeutics S.A. invites quotes for the execution of the following defined subject of the request.

I. ORDERING PARTY/SPONSOR

Ryvu Therapeutics S.A.
Sternbacha 2, 30-394 Krakow, Poland
EU VAT PL6792942955
in the further content of the RFP, hereinafter referred to as the 'Ordering Party' or 'Sponsor'.

II. SUBJECT OF THE REQUEST

This subject of the request concerns operational execution of the maintenance part of a phase II clinical study of a study drug in combination with a market drug in patients with AML/HR-MDS.

Due to the need to protect business secrets the subject of the request (Appendix 02 to this RFP) will be sent upon request to all Bidders whom the Ordering Party have executed Confidential Disclosure Agreement or to who sign and send to tenders@ryvu.com the electronically signed CDA. The CDA template is attached as Appendix 01 – Mutual Confidentiality Agreement. The title of the message must contain the reference number of the RFP, which is RFP no. ABM-29052023CRO.

III. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS

Bidders that fulfill the following are invited to submit a proposal:

- Bidders with operational readiness to activate sites in time to allow FPI by 1st of September 2023.
- Bidders with Phase II hematology clinical studies experienced team (permanent employees only, no subcontractors or freelance accepted) in the countries selected by the Sponsor.
- Bidders who are engaged in activities consistent with the subject of the request and who have experience in the field of Phase II hematologic clinical studies – at least 5 global phase II studies started for different sponsors in the last 3 years counted up to the date of publication of this RFP, and if the period of doing business is shorter during this period.
- Bidders with CRO's permanent employees that will be dedicated for the study:
  - Project Manager with min. 5 years of professional experience as Project Manager of Phase I/II hematology clinical studies,
  - Medical Monitor with min. 5 years of experience as independent Medical Monitor of Phase I/II oncology clinical studies,
  - Clinical Trial Manager with min. 2 years of professional experience as Clinical Trial Manager of hematology clinical studies,
  - Clinical Research Associate (in all the countries selected by the Sponsor) with min. 2 years of professional experience as Clinical Research Associate of hematology clinical studies,

The period of professional experience required in this section should be counted up to the date of publication of this RFP. Bidders are obliged to submit resumes (CVs) of the above-mentioned people. The proposed Project Manager, Clinical Trial Manager and Clinical Research Associate must be finally approved by Ryvu.
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.

IV. PLACE, DATE PLACE, DATE AND PROCEDURE OF SUBMISSION OF QUOTES

IV.1. The proposal must be submitted by: **12th June 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-29052023CRO.**

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

IV.4. The proposal should be prepared in an accordance with the form constituting Appendix 03 to this RFP and must include the following information:

- detailed description of the work given in the CRO budget grid as a unitized budget. Units` composition should be provided (number of hours and resource allocation per unit); provided in an MS Excel file, prices given in EUR, cost has to be grouped with functional areas in accordance with Table 02 of Appendix 02 – Subject of the request. Any cost not covered is to be added as an additional cost group 'Other necessary to perform'. (Time and Material costing is acceptable). A final list of deliverables, roles and responsibilities and project timelines will be agreed in the course of signing the agreement and described in the assigned Work Oder (or equivalent) as an alternative scenario a fix price budget may be provided in addition to a unitized one.
- current reporting (frequency and way of updates/meetings, data format, documentation, etc.) during the course of the service, a list of all study manuals, plans, guidelines and trackers that will be generated for this study, a description of team structure (organizational chart), project management, process overview, and communication/escalation plan, metrics used by a CRO and provided to the study sponsor on performance and compliance verification.
- if the services offered are provided by direct employees of the CRO, freelance contractors, or other form of sub-vendor(s).
- a description of CRO's experience in the field of hematology, Phase I/II clinical studies in the last 5 years.

It is also advisable to include all other relevant background information and strategic approaches presenting CRO's eligibility to execute the studies.

IV.5. **The Bidders must provide the total price for the execution of the order (total fees including direct, indirect and pass throughs costs) consisted with the subject of the request. The proposal must include prices given in EUR.**

V. ADDITIONAL INFORMATION

V.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 meeting the following conditions: such orders are consistent with the subject of the basic contract, the possibility of awarding such an order was provided for in the request for proposals and in the contract with the contractor, the total value of the supplementary order was taken into account when calculating the value of the basic order. [….]

V.2. During the course of the agreement, the conditions and terms of the agreement may change:

- in terms of the term of the agreement – following changes in the scope of the Project (extension of the duration of the Project, extension of appropriate stages of the Project, change of research plans);
- 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.

V.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 6th June 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.

V.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 signing and sending by e-mail by the Bidder the Confidential Disclosure Agreement (CDA). It is allowed to use an electronic signature (including a qualified electronic signature), a trusted signature (trusted profile). The CDA template is attached as Appendix 01 – Mutual

Confidentiality Agreement. Completed and signed CDA should be sent to the indicated e-mail address: tenders@ryvu.com.

V.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.

V.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.

V.7. This RFP does not oblige the Ordering Party to conclude a contract.

V.8. For more information, please contact Aleksandra Mazgała or Anna Dziedzicka at the following email address: tenders@ryvu.com.

ATTACHMENTS

Appendix 01 – Mutual Confidentiality Agreement,

Appendix 02 – Subject of the Request - provided at the Bidder's request after the Mutual Confidentiality Agreement is concluded.

Appendix 03 – Proposal Form - provided at the Bidder's request after the Mutual Confidentiality Agreement is concluded.