



Ryvu Therapeutics S.A.  
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MEDICAL  
RESEARCH  
AGENCY

Krakow, 24<sup>th</sup> July 2023

## REQUEST FOR PROPOSAL No. ABM-24072023PK

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

in the further content of the RFP, hereinafter referred to as the ‘Ordering Party’ or ‘Sponsor’.

### II. DESCRIPTION OF THE ORDER

This order concerns the execution of PK samples analysis and reporting in the phase II clinical study of a study drug in combination with a market drug in patients with AML.

**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](mailto:tenders@ryvu.com) must be sent information about CDA currently in force or the electronically signed CDA. The CDA template is attached as Appendix 03. The title of the message must contain the reference number of the RFP (ABM-24072023PK).**

### III. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS

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

- Bidders capable of setting up the service (PK samples analysis process and reporting) by 1<sup>st</sup> October 2023.
- Bidders who possess the following are invited to submit quotations: an experienced team, as evidenced by the Laboratory Head's Curriculum Vitae; experience in working with small and medium-sized European biotech companies.
- Bidders who are invited to submit quotations must be engaged in activities consistent with the subject of the request and possess experience in the field of PK samples analysis and reporting.

- Bidders who possess the following are invited to submit quotations:
  - Must have formal qualifications required by the law to perform specific activities or actions.
  - Must be engaged in activities consistent with the description of the contract.
  - Must be able to turnaround with analysis in 24 hours on request.
  - Must have experience in AML human plasma samples analysis.
  - Must use available on the market integrated tools for data processing, graphing & charting, report generation, and compliance create an efficient, all-in-one collaboration workbench. The statement with the name of the tool must be attached to the offer.
  - Must have the necessary knowledge, experience, technical potential, and personnel capable of performing the contract. This includes a Project Manager who will be appointed to take care of the project with a minimum 2 years of professional experience, Laboratory Head with a minimum of 5 years of professional experience and Bioanalytical Support with a minimum 2 years of professional experience (a resume/CV must be attached to the offer). The period of professional experience required for this section should be counted up to the date of publication of this RFP.
  - Must be in a sound economic and financial condition to ensure the performance of the contract.
  - Must not be in liquidation or declared bankrupt.
  - Must not be in arrears with payment of public and legal charges, taxes, or social or health insurance contributions.

**These conditions are 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 AND PROCEDURE OF SUBMISSION OF QUOTES**

**V.1.** The proposal must be submitted by: **3<sup>rd</sup> August 2023 at 23.59 CET.**

**V.2.** The proposal must be sent via e-mail to the following address: [tenders@ryvu.com](mailto:tenders@ryvu.com). The message with the offer should refer to the RFP number indicated on the first page: **ABM-24072023PK.**

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

**V.4.** The proposal should be prepared in an accordance with the form constituting Appendix 01 to this RFP and should include the following information:

- A detailed description of the work including the analysis of High sensitivity (Hs) method used, details of procedures followed, reagents (including catalog numbers) and quality controls.
- 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, project management, process overview, and communication/escalation plan and detailed Budget grid.

**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**

**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.** 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 study and 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.

**VI.3.** When pricing the service, it should be taken into account that the following changes may occur during the service:

- the term of completion – The targeted enrollment completion date was set on 1st October 2025. Sponsor reserves the right to change the expected date of completion following changes in the scope of the signed contract for co-financing 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,
- the number of patients, 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; Sponsor reserves the right to change the number of patients and number and types of countries and sites.

**VI.4.** 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 31<sup>st</sup> July 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](mailto:tenders@ryvu.com).

**VI.5.** 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) or a trusted signature (trusted profile).

**VI.6.** 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.7.** 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.8.** 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 quotation.

**VI.9.** This RFP does not oblige the Ordering Party to conclude a contract.

**VI.10.** For more information, please contact Aleksandra Mazgała or Anna Dziejzicka at the following email address: [tenders@ryvu.com](mailto:tenders@ryvu.com).

#### **ATTACHMENTS**

Appendix 01 – Proposal Form

Appendix 02 – The description of the order,

Appendix 03 – Mutual Confidentiality Agreement.