

REQUEST FOR PROPOSAL No. AMB-17072023K

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 building and delivery of Central Lab Kits as well as biological samples logistics and central labs shipments tracking 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 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 (AMB-17072023K).

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 (the building and delivery of Central Lab Kits as well as biological samples logistics and central labs shipments tracking) by 1st October 2023.

Bidders who possess the following are invited to submit quotations:

- Must have experience in working with small and medium-sized European biotech companies.
- 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 order.
- Must have the necessary knowledge, experience, technical potential, and personnel capable of performing the contract.
- Must have a Quality Assurance Department, QMS, Quality Manual, Quality Policy, a comprehensive CAPA policy, Disaster Recovery Program, Change Control Process and Risk Assessment Policy.

- Must use an established network of qualified local service providers to support the provision of specialist transport and logistics services when necessary, including airlines, customs brokers, and specialist local providers (as applicable).
- Must have at least one kit production facility in Europe.
- Must have its own proprietary system for real-time shipment tracking and booking.
- Must have global presence with its entities located in the Americas, Europe, and the Asia Pacific.
- Must be in a sound economic and financial condition to ensure the performance of the order.
- 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 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: **31st July 2023 at 23.59 CET.**
- V.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: **AMB-17072023K.**
- 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 building and delivery of Central Lab Kits as well as biological samples logistics and central labs shipments tracking.
 - 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.

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 such orders are consistent with the subject of the basic contract.
- V.2.** During the course of the agreement, the conditions and terms of the agreement may change:
 - 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.

- 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.
- Sponsor reserves the right to make changes to the final order / contract based on the requirements of the study protocol. These changes may include, but are not limited to, the following factors: dose and quantity of the drug, study timelines, number of patients, countries where the study will be conducted.

- 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 26th 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.
- 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) or a trusted signature (trusted profile).
- 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 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.
- V.8.** This RFP does not oblige the Ordering Party to conclude a contract.
- V.9.** 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.10.** The Ordering Party reserves the right to enter into negotiations with Bidders who have submitted an offer and meet 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.
- V.11.** This RFP does not oblige the Ordering Party to conclude a contract.
- V.12.** For more information, please contact Aleksandra Mazgała or Anna Dziedzicka at the following email address: tenders@ryvu.com.

ATTACHMENTS

Appendix 01 – Proposal Form

Appendix 02 – The description of the order,

Appendix 03 – Mutual Confidentiality Agreement.