

Krakow, 28.02.2025

REQUEST FOR PROPOSAL no. ABM-28022025A

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 execution of **clinical monitoring** (site management and monitoring) services (including CRAs' performance oversight) under a Functional Service Provider (FSP) model for Clinical Research Associates (CRAs) 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) and offer form are made available to Bidders who undertake to maintain confidentiality. Electronically signed CDA or information about CDA currently in force must be sent to vendors.clinical@ryvu.com. The CDA template is attached as Appendix 03. The title of the message must contain the reference number of the RFP (ABM-29022025A).

III. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS

Bidders meeting the following criteria are invited to submit a proposal:

- To ensure the participation of bidders with the necessary knowledge, experience, and technical capability to perform the contract, the Contractor must have been in business performing activities corresponding with the description of the order for at least **five years**. The required period of experience will be calculated up to the date of publication of this RFP.
- Clinical Research Associates (CRAs) assigned to the project must have **oncology experience**, meaning they have previously conducted clinical monitoring for at least two oncology studies. **Senior CRA (Sr. CRA) designation is a requirement.**
- To ensure timely project implementation, the assigned CRAs must have a valid contract in place with **Contractor's** at the time the service commences.
- **Payment schedule:** Payment to be made based on monthly invoices issued by the Contractor. Invoices should reflect the actual hours worked and costs incurred in relation to the services performed for the Ordering Party (Pass-Through Costs).

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

The Ordering Party reserves the right to ask bidders to provide additional documentation at the stage of offer verification, to confirm the accuracy of the proposal/offer form. This may include but is not limited to a detailed price calculation, more information on the bidder's experience, anonymized CVs of individual SrCRAs, and any additional documents confirming their qualifications and experience.

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

- IV.1.** The proposal must be submitted by: **7th March 2025 at 23.59 CET.**
- IV.2.** The proposal must be sent via e-mail to the following address: vendors.clinical@ryvu.com. The message with the offer should refer to the RFP number indicated on the first page: **ABM-28022025A.**
- IV.3.** The proposal must be prepared in English.
- IV.4.** The proposal should be prepared in an accordance with the form constituting Appendix 01 to this RFP and must include the following information:
- **an hourly rate:** The work of CRAs will be billed on an hourly basis, based on the actual number of hours invested and not on units completed.
 - an estimated **FTE** for the CRAs based on the assumptions provided in the order.
 - a precise **contract value calculation** taking into account the assumptions for its execution.

The Bidders must provide the total estimated contract value for the execution of the order (total estimated fees including direct and pass-through costs) consistent with the subject of the request. The proposal must include prices given in EUR. The assumptions for determining the total price are indicated in the Description of the Order.

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.** The terms and conditions of the agreement may be subject to changes during its term (the Ordering Party reserves the right to amend the agreement) in the following cases:
- in terms of the timelines and term of the agreement – following changes in the scope of the study and the Project (extension of the duration of the Project, extension of appropriate stages of the Project, modifications of the research plans),
 - the number of countries, sites, monitoring frequencies, hours per visit, estimated pass-through costs may be adjusted. Additionally, new services or costs not covered by the initial order may be introduced. Such changes may occur if deemed necessary to achieve the trial's overarching objectives, provided that the need for these changes arises directly from the trial's results and could not have been foreseen at an earlier stage;
 - in terms of the number and types of countries and sites – this flexibility is essential due to the specific nature of oncology studies, where unforeseen circumstances or events may arise during the study that could not have been anticipated in advance.,
 - in the event of force majeure as an event which is an unforeseeable event beyond external control that could not have been prevented, along with its consequences and effects.

Furthermore, the Ordering Party reserves the right to make changes to the final contract based on the requirements of the study protocol.

- V.3.** The Bidders may ask the Ordering Party to clarify the content of the RFP. If the request for clarification of the content of the RFP was received later than by the end of 5th March 2025, the Ordering Party may provide explanations or leave the application unexamined. Questions must be sent to the following e-mail address: vendors.clinical@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 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).

- 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.** For more information, please contact Anna Dziejzicka or Agata Marszał-Kłosowska at the following email address: vendors.clinical@ryvu.com.

ATTACHMENTS:

- Appendix 01 – Proposal Form;
- Appendix 02 – Description of the order;
- Appendix 03 – Mutual Confidentiality Agreement.