



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

Krakow, 13th August 2024

REQUEST FOR PROPOSAL No. ABM-13082024K Manufacturing of RVU120 Capsules for a Phase 2 Clinical Trial

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 is for the manufacture of RVU120 capsules for a Phase II clinical trial. The capsules will be used in the RIVER-81 clinical trial.

Due to the need to protect business secrets, the description of the order (subject of the request) will be made available to Bidders who undertake to maintain confidentiality. The Bidder must have a signed confidentiality agreement with the Ordering Party. If the agreement is not in force, an electronically signed CDA must be sent to tenders@ryvu.com. The CDA template is attached as Appendix 01. The title of the message must include the RFP reference number i.e. ABM-13082024K.

III. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS:

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

- A. Turnaround time: bidders applying for the contract must declare the expected bulk product Certificate of Analysis delivery time – not later than November 2024; the final QP release date is not expected in the offer as it depends on the Ryvu’s IMPD Substantial Modification EMA acceptance. However, the release should not take more than two (2) weeks from the date Ryvu provides all regulatory documents required for the QP release.
- B. Proposal validity period - minimum until 31st October 2024.
- C. Bidders applying for the contract must declare the possibility of reserving a development/manufacturing slot in advance, based on the letter of intent before the final contract is signed.
- D. Bidders able to demonstrate compliance of processes and procedures with EU-cGMP and show a valid and relevant authorization from the local regulatory authorities required for the manufacturing of the Investigational Medicinal Product.
- E. Bidders with documented experience in manufacturing of oral dosage forms for clinical trials with sound regulatory agencies inspection track record (EMA, FDA).

These conditions to be confirmed in Appendix 02 – 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 PROPOSALS:

- IV.1.** The proposal must be submitted by: **20th August 2024 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 proposal should refer to the RFP number indicated on the first page: **ABM-13082024K.**
- 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 02 to this RFP.

V. CRITERIA FOR EVALUATION OF PROPOSALS:

- V.1.** Proposals 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 proposals. Proposals that do not meet the requirements will be rejected.

❖ Criterion 1: Net price ("C") – max. 10,00 points.

The Net price ("C") is the total price for the execution of the order (sum of the prices for manufacturing of the capsules, fields A + B in the Proposal Form (Appendix 02)). The quote must contain prices given in EUR or USD.

In order to compare the proposals 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:

$$\text{Criterion Net price "C"} = \frac{\text{the lowest net price offered among the bids submitted}}{\text{net price of the examined offer}} \times 10,00 \text{ points}$$

- V.2.** The Ordering Party will select the most advantageous offer that obtains the highest number of points.
- V.3.** Having to choose between proposals 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 placing additional orders (supplementary orders) with the selected Contractor for an amount not exceeding 50% of the value of the contract concluded with the Contractor, provided that 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 relation to the timelines and duration of the agreement – following changes in the scope of the study and Project (e.g. extension of the Project duration, extension of appropriate Project stages, change in research plans);
 - with regard to the number and size of capsules – following changes in the scope of the study and the Project,
 - in relation to the turnaround time/bulk product Certificate of Analysis delivery time - a change arising from random events/reasons beyond the control of the Ordering Party and the Contractor must be previously agreed and approved between both parties;
 - 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 **16th August 2024**, 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 proposals 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 proposal sent by the Bidder.
- VI.7.** The Ordering Party reserves the right to enter into price negotiations with Bidders who have submitted the proposals and meets the conditions for participating in the proceedings. Arrangements regarding the date of negotiations will be carried out by e-mail. The modified proposal 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 Dziejzicka or Aleksandra Mazgała at the following email address: tenders@ryvu.com.

ATTACHMENTS:

Appendix 01 – Mutual Confidentiality Agreement

Appendix 02 – Proposal Form

Appendix 03 – Description of the order