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

Krakow, 12th July 2023
updated on 1st August 2023

REQUEST FOR PROPOSAL No. ABM-12072023IMP

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 the RVU120 Investigational Medicinal Product management 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 (ABM-12072023IMP).

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 RVU120 Investigational Medicinal Product management the RVU120 Investigational Medicinal Product management (as described in the description of the order, including project management, distribution management, label generation, secondary production, re-labelling, de-labelling, storage, data services, supply chain management system, QP services.
- Bidders engaged in activities consistent with the description of the order and possessing experience in the field of IMP management.
- Bidders with formal qualifications required by the law to perform specific activities and actions as described in the description of the order.
- Bidders with proven experience of working with small and medium-sized European biotechnology companies.
- Bidders are required to provide a Clinical Supplies Management team. The assigned team will have proven experience of handling the drug and clinical trial type.
- Bidders are required to provide a Project Liaison Manager, who's primary role is to onboard the Sponsor to ensure there is efficient and timely integration of the two teams.
- Bidders with ability to offer QP study lead at the start of the study.

- Bidders with the ability to support challenges across any country mentioned in study assumption section of the RFP.
- Bidders declaring EU site shipment deliveries within 2 – 3 days (due to unforeseen circumstances, if there will be situations where the delivery time need to be extended beyond the initial estimate, it is acceptable to extend the delivery time).
- Bidders offering a web-based system designed patient assignments capable of handling small to medium sized studies. Minimum functionality of the web-based system functionalities:
  - an integrated user interface,
  - browser compatibility,
  - is optimized for mobile devices,
  - provides reporting modules that can be filtered according to the specific needs,
  - offers a simplified resupply and site management capability,
  - provides screening, resupply, and discontinuation; real-time reports and visibility of supplies;
  - automates drug ordering, and generation of shipments.
- Bidders confirming they have the required country-specific regulatory agency license/permit required for storage, packaging/labelling, release for clinical use, distribution, import from third countries, destruction of investigational medicinal products, documents confirming of having passed the current audits, documented experience in managing investigational drug, including appropriate storage conditions with monitoring and accounting system. These apply to the pre-selected countries, excluding countries listed as "to be considered" (South Korea and Australia). The Ordering Party reserves the right to review the above-mentioned documents.

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: **4th August 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-12072023IMP.**

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 01 to this RFP and must include the following information:
  - a detailed description of the work,
  - 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 a 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:
  - in terms of the timelines and 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.
- 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 the RFP. If the request for clarification of the content of the RFP was received later than by the end of 2nd August, 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 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 Aleksandra Mazgała or Anna Dziedzicka at the following email address: tenders@ryvu.com.

ATTACHMENTS

Appendix 01 – Proposal Form;

Appendix 02 – Description of the order;

Appendix 03 – Mutual Confidentiality Agreement.