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, 6th July 2023 UPDATE

REQUEST FOR PROPOSAL No. ABM-03072023V

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 support of the Venetoclax supply chain (management, purchasing, storage, supply, labelling, QP release, status monitoring, return, and destruction) in 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-03072023V).

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 (support of the Venetoclax supply chain: management, purchasing, storage, supply, labelling, QP release, status monitoring, return, and destruction) by 1st October 2023.
- Bidders with permanent employees that will be dedicated to the study:
  - Project Manager with at least 2 years of professional experience as a project manager and with 10 years of experience in logistics and/or in supply unit.
  - Associate Project Manager with at least 2 years of professional experience including experience in logistics and/or in supply unit.

  The period of professional experience required in this section should be counted up to the date of publication of this RFP. Bidders are obliged to submit resumes (CVs) of the above-mentioned people.
- Bidders whose activities are consistent with the description of the order and who have experience in at least 15 clinical trials requiring Venetoclax management.
- Bidders with a quality management system that guarantees the quality and conformity of the services provided and the documentation produced, appropriate to the scope set out in the description of the order.

- Bidders with a global depot and supplier network present in each of the countries listed in the description of the order.
- Bidders who can demonstrate that their warehouses, couriers and other sub-contractors have passed the current audits required by EU and UK GMP and GDP (e.g. licenses, certificates issued by the relevant competent authority).
- Bidders with a valid insurance policy covering the import/export, inland transits, storage (extended to cover loss of or damage to the insured goods whilst stored on the premises outside the normal course of transit) of pharmaceutical medical devices and related products. The valid insurance policy must be attached to the proposal.

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: **13th July 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-03072023V.**

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,
- a list of plans, guidelines and trackers that will be generated for this study, a description of team structure, project management, process overview, and communication/escalation plan, provider's experience in Venetoclax management 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:

- 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.
- Ryvu Therpeutics 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 10th 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 does not oblige the Ordering Party to conclude a contract.

V.8. 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 - provided at the Bidder's request after the Mutual Confidentiality Agreement is concluded.

Appendix 03 – Mutual Confidentiality Agreement.