**CURRENT REPORT 14/2024**
**March 28, 2024**

## Conclusion of an agreement in the area of operational execution of RVU120 Phase II clinical trial in myelofibrosis

The Management Board of Ryvu Therapeutics S.A. with its registered office in Krakow, Poland ("Company", "Ryvu") informs that on March 28, 2024, the Company concluded an agreement with Fortrea Inc., headquartered in North Carolina, US ("Fortrea"), covering the operational execution of the POTAMI-61 clinical study ("Agreement"). The conclusion of the Agreement marks another step in the implementation of the RVU120 development plan ("Development Plan"), as announced by the Company in the current report 45/2023 on October 23, 2023.

The subject of the Agreement is the operational execution of the POTAMI-61 clinical study – a global, multicenter, Phase II study investigating RVU120 as a monotherapy and in combination with ruxolitinib for the treatment of patients with intermediate or high-risk, primary or secondary myelofibrosis. Services provided under the Agreement will encompass various aspects of clinical study execution, including clinical project management, medical and safety monitoring, as well as clinical site management and monitoring.

The POTAMI-61 study consists of two parts. Part A is designed to evaluate the safety and anti-tumor activity of RVU120 as a monotherapy and in combination with ruxolitinib in a group of approximately 20 patients. Based on the outcomes of Part A, Part B will further assess safety, tolerability, and anti-tumor activity in a larger cohort, totalling up to approx. 230 patients for both Part A and Part B combined.

Following the RVU120 Development Plan, the Management Board intends to proceed with the execution of Part A of the POTAMI-61 study, as described above. The estimated cost for all study start-up activities and the execution of Part A under the Agreement is approx. EUR 3 million. This includes all relevant services, as well as fees for investigators and clinical sites-related procedures.

The total value of the Agreement, if the Management Board decides to proceed with Part B of the study (enrolling up to approx. 230 patients), will amount to approx. EUR 16.4 million. Further decisions regarding prioritizations within the RVU120 Development Plan, including a decision on the potential initiation of Part B of the POTAMI-61 study, are scheduled to be made in Q1 2025.

The initiation of the POTAMI-61 study is scheduled for mid-2024, with start-up activities already underway. Initially, Part A of the study is set to commence at clinical sites in Poland and Italy. If Management Board decide that Part B is initiated, the study will expand to include additional sites both in EU and non-EU countries, totalling approximately 50 clinical sites worldwide. Fortrea will continue to provide support across all study locations.

Currently, two Phase II clinical studies of RVU120 are ongoing: (i) RIVER-52 study, investigating RVU120 as a monotherapy for the treatment of patients with relapsed/refractory acute myeloid leukemia (r/r AML) and high-risk myelodysplastic syndromes (HR-MDS), as well as RIVER-81 study investigating RVU120 in combination with venetoclax for the treatment of patients with r/r AML. Expanding the clinical development with the POTAMI-61 study is part of the planned broad clinical development of RVU120 in multiple hematology indications and various treatment settings (monotherapy and combination therapy), aiming at maximizing the potential of RVU120 and diversifying the risks associated with further clinical development.

Fortrea is a global provider of clinical development and patient access solutions to the life sciences industry. Fortrea provides phase I-IV clinical trial management, clinical pharmacology, differentiated technology-enabled trial solutions and post-approval services.

The Agreement meets the criteria of a significant agreement due to its importance for the further development of the RVU120 clinical program. The terms of the Agreement do not deviate from the conditions customarily accepted for this type of agreements.

*Disclaimer: This English language translation has been prepared solely for the convenience of English-speaking readers. Despite all the efforts devoted to this translation, certain discrepancies, omissions or approximations may exist. In case of any differences between the Polish and the English versions, the Polish version shall prevail. Ryvu Therapeutics S.A., its representatives and employees decline all responsibility in this regard.*

**Legal basis:** Article 17.1 of MAR

**Representatives of the Issuer:**

- Hendrik Nogai – Member of the Management Board
- Kamil Sitarz – Member of the Management Board