CURRENT REPORT 37/2024

December 5, 2024

Dosing of the first patient in the POTAMI-61 Phase II Study of RVU120 for the Treatment of Patients with Myelofibrosis (MF)

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków ("Ryvu", the "Company"), announces that on December 4, 2024 the first patient has been dosed in the POTAMI-61 study ("POTAMI-61 Study"), a Phase II clinical trial investigating RVU120 as a monotherapy for the treatment of patients with myelofibrosis (MF). The study is being conducted by Fortrea Inc., headquartered in North Carolina, US ("Fortrea"), as announced by the Company in current report 28/2004 dated March 28, 2024.

POTAMI-61 Study is an open-label, multicenter Phase II study of RVU120, a novel small-molecule cyclin-dependent kinase (CDK) 8/19 inhibitor, to treat patients with MF. In POTAMI-61 Study, RVU120 is being explored as a single agent for the treatment of patients with primary or secondary MF previously treated with or ineligible for JAK inhibitor e.g. ruxolitinib (RUX) or in combination with RUX for patients with suboptimal response to JAK inhibitor.

In the POTAMI-61 Study, patients will receive RVU120 until disease progression, withdrawal of consent or other reasons specified in the study protocol. The POTAMI-61 Study consists of two parts. Part A of the study with a planned enrollment of approximately 20 patients will comprise two cohorts: 1) single-agent therapy with RVU120 in patients resistant or refractory to prior JAK inhibitor treatment or ineligible for JAK inhibitor treatment, and 2) RVU120 in combination with RUX in patients who experience a suboptimal response to prior JAK inhibitor treatment. Depending on results from Part A, cohorts 1 and/or 2 could be expanded in Part B which will further assess safety, tolerability, and antitumor activity in a larger cohort, totaling up to approximately 230 patients for both Part A and Part B combined. RVU120 could also be investigated in a frontline setting in cohort 3. Ryvu will initially proceed with the execution of Part A of the study, while the decision on the potential initiation of Part B will be based on the outcomes of Part A.

Initially, Part A of the study will enroll patients at clinical sites in Poland and Italy. If the Ryvu Management Board decides to initiate Part B, the POTAMI-61 Study will expand to include additional sites both in the EU and non-EU countries, totaling approximately 50 clinical sites worldwide.

POTAMI-61 Study represents the fourth planned RVU120 Phase II clinical study launched in 2024. Ryvu has already started patient treatment in the RIVER-81 study (r/r AML; RVU120 in combination with venetoclax), RIVER-52 study (r/r AML and HR-MDS; RVU120 as

monotherapy) and in the REMARK study for the treatment of patients with lower-risk myelodysplastic syndromes (LR-MDS) as reported by Ryvu in the current report 5/2024 dated January 31, 2024, the current report 10/2024 dated February 14, 2024 and the current report 29/2024 dated September 19, 2024 respectively.

The POTAMI-61 Study is part of RVU120 Development Plans communicated in current report no 45/2023 on October 23, 2023 and aligns with the Company's cash runway.

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