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Dosing of the first patient in the REMARK Phase II Study of RVU120 for the Treatment of Anemia in Patients with Lower-Risk Myelodysplastic Syndromes (LR-MDS)

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków ("Ryvu", the "Company"), announces that on September 18, 2024 the first patient has been dosed in the REMARK study ("REMARK Study"), a Phase II clinical trial investigating RVU120 as a monotherapy for the treatment of patients with lower-risk myelodysplastic syndrome (LR-MDS).

REMARK Study is an open-label, multicenter Phase II study of RVU120, a novel small-molecule cyclin-dependent kinase (CDK) 8/19 inhibitor; the study aims to treat anemia in patients with LR-MDS. In REMARK Study, RVU120 is being explored as a single agent in patients with LR-MDS who have exhausted available treatment options.

The REMARK Study is being conducted as an investigator-initiated study through the EMSCO network with Prof. Uwe Platzbecker, a globally renowned expert in the field of LR-MDS, as the Coordinating Principal Investigator.

REMARK Study represents the third of four planned RVU120 Phase II clinical studies scheduled for launch in 2024. Ryvu has already started patient treatment in the RIVER-81 (r/r AML; RVU120 in combination with venetoclax) and RIVER-52 (r/r AML and HR-MDS; RVU120 as monotherapy) studies, as reported by Ryvu in current report 5/2024 dated January 31, 2024, and current report 10/2024 dated February 14, 2024 respectively. In the near future, the Company also plans to begin patient recruitment for the POTAMI-61 study, evaluating RVU120 both as a monotherapy and in combination therapy for the treatment of patients with myelofibrosis (MF).

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