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Dosing of the first patient in the RIVER-52 Phase II Study of RVU 120 as a monotherapy for the treatment of patients with relapsed/refractory AML and HR-MDS

The Management Board of Ryvu Therapeutics S.A., with its registered office in Krakow, Poland (the "Issuer", "Ryvu"), announces that the first patient has been dosed with the study drug in a Phase II clinical trial 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) – the RIVER-52 study (the "Study").

The primary goal of the RIVER-52 study will be to evaluate safety and efficacy of RVU120 in a larger population of patients with genetically defined subtypes of AML, including NPM1 mutations, as well as with HR-MDS. The evaluation will be conducted at the dose level of 250 mg served EOD (Every Other Day), identified in the Phase Ib clinical study, where numerous signs of clinical activity have been observed.

The RIVER-52 study is initially launching at clinical sites in Poland and Italy. Ultimately, the Study will expand to other EU and non-EU countries, covering up to 80 clinical sites globally. According to the Management Board of the Issuer the planned overall enrollment is up to approx. 140 patients.

The Study is divided into two parts. Part 1 aims to assess the level of anti-tumor activity in patients with genetically defined subtypes of AML, including NPM1 mutations, and in patients with HR-MDS. Based on the outcomes of Part 1, Part 2 will further evaluate the safety, tolerability, and anti-tumor activity in a larger group of patients within the subtypes that exhibit the highest sensitivity to RVU120.

The Study has received approval from the Competent Authorities in Poland and Italy following a clinical trial application under the European Union Clinical Trial Regulation (EU-CTR) 536/2014, as well as positive opinions from the respective Ethics Committees, enabling patient enrollment in both countries. Start-up activities in other EU and non-EU countries are currently in progress.

RIVER-52 represents the second of the four planned RVU120 Phase II clinical studies scheduled for launch in H1 2024. In addition to RIVER-52, Ryvu has already started patient treatment in the RIVER-81 study (evaluating RVU120 in combination with venetoclax for treating r/r AML patients), communicated in current report no. 5/2024 on January 31, 2024. Upcoming plans also include the initiation of the REMARK study (conducted as an investigator-initiated trial, exploring RVU120 as a monotherapy for the treatment of patients with low-risk myelodysplastic syndromes; LR-MDS) and the POTAMI-61 study (evaluating both monotherapy and combination therapy for the treatment of patients with myelofibrosis; MF).

The Study is part of RVU120 Development Plan communicated in current report no 45/2023 on October 23, 2023.

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Legal basis: Article 17.1 MAR

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