

## CURRENT REPORT 20/2023

May 11<sup>th</sup>, 2022

### New clinical and preclinical data on RVU120 to be presented at the upcoming 2023 European Hematology Association Congress

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków ("Company") hereby announces that updated safety and efficacy data from the Phase 1b dose-escalation study of RVU120 in patients with Acute Myeloid Leukemia (AML) and High-Risk Myelodysplastic Syndromes (HR-MDS) and nonclinical data of RVU120 in combination with JAK1/2 inhibitor Ruxolitinib (RUX) in myeloproliferative neoplasms will be presented at the Annual European Hematology Association (EHA) 2023 Hybrid Congress, taking place June 8-11, 2023 in Frankfurt, Germany.

Until February 2023, treatment with single-agent RVU120 has led to complete remission in one patient, an increase of hemoglobin and platelets in four patients, and bone marrow blast reduction in five patients, including in a patient with TP53 double-hit. Based on these encouraging clinical benefits, favorable safety, and no dose-limiting toxicities, the Company's Management Board plans to continue the dose escalation phase, expecting further increases in RVU120's anti-leukemic and erythroid-stimulating activity at increased doses.

The data suggest synergistic effects between RVU120 and RUX in myelofibrosis by demonstrating a significant reduction of disease manifestation in vivo. In the opinion of the Company's Management Board, these data reinforce the potential emerging role of targeting both CDK8/19 and JAK1/2 in myeloproliferative neoplasms.

Details of poster presentations are as follows:

**Abstract Title:** *"Preclinical and Clinical Signs of RVU120 Efficacy, a Specific CDK8/19 Inhibitor in DNMT3A Mutation Positive AML and HR-MDS"*

**Abstract Number:** #P450

**Session date and time:** Friday, June 9, 18:00 - 19:00 CEST

The clinical abstract presents updated safety and efficacy results from the ongoing Phase 1b dose escalation study of RVU120 for relapsed/refractory AML and high-risk MDS ([NCT04021368](#)). Results from patients dosed up to 110 mg have shown a favorable safety profile of RVU120. At the data cut-off of February 28, 2023, 22 patients have been enrolled, and 10 out of 19 evaluable patients showed clinical benefit: 1 patient with AML treated at 75 mg with CR, 3 patients with AML treated at 100 mg, and 1 patient with HR-MDS at 75 mg with a significant increase of hemoglobin and platelets, 4 patients with adverse risk cytogenetics treated between 10 and 100 mg with a BM blast reduction and 1 patient with AML, dosed at 110 mg, showing a BM blast reduction of 70% at the beginning of cycle 4. No DLTs

were observed, and no study drug interruptions due to adverse drug reactions occurred. The data warrant further exploration of RVU120 in AML and HR-MDS, and enrollment is ongoing at 135 mg.

**Abstract Title:** “*Combination JAK1/2 and CDK8/19 inhibition demonstrates enhanced efficacy in myeloproliferative neoplasms*”

**Abstract Number:** #P986

**Session date and time:** Friday, June 9, 18:00 - 19:00 CEST

The presentation, prepared in collaboration with Prof. Raajit Rampal’s group from Memorial Sloan Kettering Cancer Center, includes the assessment of RVU120, a highly selective and potent CDK8/19 inhibitor in monotherapy and combination with Ruxolitinib (RUX), a JAK1/2 inhibitor for the treatment of myeloproliferative neoplasms (MPN). Treatment with RVU120 demonstrated single agent efficacy that could be further enhanced by a synergistic combination with RUX in MPN models, both *in vitro* and *in vivo*. In the opinion of the Company’s Management Board, these data nominate CDK8/19 inhibition in combination with JAK1/2 inhibition as a potential novel therapeutic strategy in MPNs.

All abstracts are now available online and can be obtained from the conference site: <https://ehaweb.org/>

The EHA conference is considered one of the most important scientific events, gathering researchers, as well as potential clients and business partners - biotechnology and pharmaceutical companies and industry investors.

**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