

## CURRENT REPORT 16/2024

May 14, 2024

### Preclinical and clinical data on RVU120 to be presented at the 2024 European Hematology Association Congress

The Management Board of Ryvu Therapeutics S.A. with its registered office in Krakow, Poland ("Company", "Ryvu") announces that it will present clinical and preclinical data from RVU120 at the 2024 European Hematology Association Congress (EHA), June 13-16, Madrid, Spain.

#### Details on the poster presentations are as follows:

**Abstract Title:** RVU120, a first-in-class CDK8 inhibitor for the treatment of relapsed/refractory AML and high-risk MDS: preliminary results from two ongoing studies.

**Abstract Number:** 6466

**Session date and time:** Friday, June 14 (18:00-19:00 CEST)

*The abstract includes data on 29 evaluable patients out of 38 total dosed patients.*

In the Phase I trial CLI120-001, RVU120 shows promising clinical activity in patients with AML or HR-MDS. 15 out of 38 patients experienced clinical benefit with RBC transfusion independence and/or blast reduction. A complete remission (CR) was achieved in a patient with NPM1 and DNMT3A mutations as well 3 marrow CRs in patients with HR-MDS. Relevant target inhibition was achieved at a dose of 110 mg or higher, supporting a recommended Phase II dose (RP2D) of 250mg. The follow-on Phase II RIVER-52 study investigates RVU120 as a monotherapy in patients with genetically defined AML or HR-MDS and is currently recruiting.

**Abstract Title:** Synergistic potential of RVU120, a first-in-class CDK8/CDK19 inhibitor, with venetoclax in AML: preclinical and initial clinical insights.

**Abstract Number:** 6720

**Session date and time:** Friday, June 14 (18:00-19:00 CEST)

The abstract presents updated preclinical data supporting the synergistic combination of RVU120 and venetoclax in AML, including RVU120's potential to overcome resistance to

venetoclax treatment. Ongoing preclinical research and an ongoing Phase II clinical study seek to refine patient stratification and enhance therapeutic outcomes, with initial safety profiles appearing favorable. The Phase II RIVER-81 study is investigating RVU120 in combination with venetoclax in patients with AML and is currently recruiting.

**Abstract Title:** CDK8/19 Inhibition: A Promising Therapeutic Strategy in Myeloproliferative Neoplasms.

**Poster Number:** P1018

**Session date and time:** Friday, June 14 (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 as a monotherapy and in combination with JAK inhibitors, and other drug candidates for the treatment of myeloproliferative neoplasms (MPN). Analysis of the effects from combinations of RVU120 with other compounds *in vitro* has revealed potentially new therapeutic options for patients with MPN sensitivity and resistance to ruxolitinib (RUX). *In vivo* data further support CDK8 inhibition as a potential novel therapeutic strategy in MPNs. Additional mechanistic work will potentially elucidate disease mechanisms and therapeutic action independent of JAK-STAT attenuation. This work has led to a Phase II clinical study (POTAMI-61) for RVU120 as a monotherapy in patients with myelofibrosis patients not eligible for RUX or in combination with RUX for those patients with myelofibrosis and suboptimal RUX response.

**Investor Event:**

Ryvu will host a webinar on Friday, May 17, at 3:00 PM CET with Professor Raajit Rampal, who will present the myelofibrosis landscape, the latest data and the potential of RVU120 in MF.

To join the webcast, please register here: <https://ryvu.clickmeeting.com/pre-eha2024-webinar-rvu120-progress-and-opportunity-in-mf/register>

*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:**

- Paweł Przewięźlikowski – President of the Management Board
- Hendrik Nogai – Member of the Management Board