

## CURRENT REPORT 35/2023

July 14, 2023

### Conclusion of two agreements in the area of data management and biostatistics for RVU120 Phase II clinical trials in hematology

The Management Board of Ryvu Therapeutics S.A. with its registered office in Krakow, Poland ("Company", "Ryvu") informs that on July 13, 2023, two agreements were concluded with Clinscience Sp. z o.o., part of the NEUCA Group, with its registered office in Warsaw ("Clinscience"), in the area of providing data management and biostatistics-related services for RIVER-52 ("Agreement 1") and RIVER-81 ("Agreement 2") clinical trials (jointly the "Agreements"). The conclusion of the Agreements serves the implementation of the goals indicated in the "Development Plans for 2022-2024" ("Development Plans"), as announced by the Company in the current report 16/2022 on August 19, 2022.

Agreement 1: The subject of the agreement is to provide clinical data management and biostatistics services, including building and hosting of an Electronic Data Capture (EDC) system, in the RIVER-52 clinical study i.e., Phase II study of RVU120 as monotherapy in the treatment of acute myeloid leukemia/high-risk myelodysplastic syndrome (AML/HR-MDS). The total value of Agreement 1 will amount to approximately EUR 1.33 million.

Agreement 2: The scope of the agreement is to provide clinical data management and biostatistics services, including the EDC system building and hosting, in the RIVER-81 clinical study i.e., Phase II study of RVU120 in combination therapy with venetoclax in the treatment of AML/HR-MDS. The total value of the Agreement 2 will amount to approximately EUR 1.26 million. The costs associated with the implementation of the Agreement 2 will be co-financed by the Medical Research Agency ("ABM") from the state budget, in the framework of a competition for the development of targeted or personalized medicine based on nucleic acid-based medicinal products and small molecule compounds, in which the Company has been selected as one of the beneficiaries as informed in the current report no. 29/2023 on June 13, 2023, provided that an agreement is signed with ABM.

RVU120 is a selective, first-in-class dual CDK8/CDK19 kinase inhibitor that has shown signs of clinical activity in treated patients, as well as efficacy in numerous *in vitro* and *in vivo* models of hematologic malignancies and solid tumors.

Currently, two dose escalation clinical studies of RVU120 are ongoing in patients with AML/HR-MDS and solid tumors.

Expanding the clinical development in AML/HR-MDS through the initiation of Phase II clinical trials is part of the planned broad clinical development of RVU120 in multiple indications (hematology and solid tumors) and various treatment options (monotherapy

and combination therapy), aiming to maximize the potential of RVU120 and diversify the risks associated with further clinical development.

The initiation of Phase II clinical trials of RVU120 in hematologic indications (including the RIVER-52 and RIVER-81 studies) as well as solid tumors is planned for the second half of 2023.

Clinscience, part of the NEUCA Group, is a global contract research organization (CRO) distinguished by its specialization in immuno-oncology (including cell therapy), as well as data management and biostatistics capabilities. Clinscience provides strategic, full-service custom solutions, from protocol development to the final clinical study report, tailored to the needs of global pharmaceutical and biotech companies.

The Agreements meet the criteria of significant agreements due to their importance for the further development of the RVU120 clinical program and constitute an element of the implementation of the Development Plans. The terms of the Agreements do not deviate from the conditions customarily accepted for this type of agreements.

*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:** 17.1 MAR

**Representatives of the Issuer:**

- Paweł Przewięźlikowski – President of the Management Board
- Kamil Sitarz – Member of the Management Board