CURRENT REPORT 34/2023

July 6, 2023

Conclusion of two agreements with Zakłady Farmaceutyczne Polpharma S.A. in the area of RVU120 active substance (API) production for Phase II clinical trials

The Management Board of Ryvu Therapeutics S.A. with its registered office in Krakow, Poland ("Company", "Ryvu") informs that on July 5, 2023, two agreements were concluded with Zakłady Farmaceutyczne Polpharma S.A, with its registered office in Starogard Gdański, ("Polpharma"), in the area of RVU120 active substance (Active Pharmaceutical Ingredient, API) production (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 the execution of the API manufacturing campaign for RVU120 in the registration cGMP (current Good Manufacturing Practice) standard – a key element in the preparation for the potential fast-to-market strategy, possible in case of the RIVER-52 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 remuneration under the Agreement, including the estimated cost of materials, will amount to approximately EUR 0.89 million.

Agreement 2: The subject of the agreement is the development and optimization of the production process, as well as RVU120 API manufacturing in accordance with cGMP requirements for the RIVER-81 study, i.e., Phase II study of RVU120 in combination therapy with venetoclax in the treatment of AML/HR-MDS. The total remuneration under the Agreement, including the estimated cost of materials, will amount to approximately EUR 0.77 million. The costs associated with the implementation of the Agreement 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.

Zakłady Farmaceutyczne Polpharma S.A. is one of the largest pharmaceutical manufacturers in the Central and Eastern Europe region. Polpharma is part of an international pharmaceutical group that offers modern drugs, active substances, and innovative solutions for patients and business partners. Polpharma CDMO provides development and contract manufacturing services for active substances to partners worldwide.

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