

CURRENT REPORT 44/2023

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Conclusion of a Clinical Trial Financial Support agreement for an investigator-initiated Phase II RVU120 study in Low-Risk Myelodysplastic Syndromes

The Management Board of Ryvu Therapeutics S.A. with its registered office in Krakow, Poland ("Company", "RyvU"), announces that on October 19, 2023, the Company concluded a Clinical Trial Financial Support ("CTFS") agreement with GCP-Service International West GmbH with its registered office in Siegburg, Germany ("GCPS") and Prof. Dr. med. Uwe Platzbecker ("Coordinating Principal Investigator" or "CPI"), for financing REMARK study ("Study", "REMARK") i.e. an investigator-initiated Phase II RVU120 study in low-risk myelodysplastic syndromes ("LR-MDS") conducted through European Myelodysplastic Neoplasms Cooperative Group ("EMSCO") network ("Agreement"). The conclusion of the Agreement 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.

REMARK will be an Investigator Initiated Trial ("IIT"), and the Agreement involves three parties:

- Prof. Uwe Platzbecker – Coordinating Principal Investigator;
- GCP Service International West GmbH – Contract-Research Organization responsible for conducting the Study;
- Ryvu – Financier of the study; Ryvu is also going to provide the study drug – RVU120.

The Study aims at the development of RVU120 as a monotherapy for the treatment of patients with LR-MDS. The Study will be conducted through the European Myelodysplastic Neoplasms Cooperative Group (EMSCO) network in cooperation with GCPS. EMSCO was founded in 2012 by Prof. Uwe Platzbecker and Prof. Pierre Fenaux. Since then, the EMSCO network has been extended to other European countries and has carried out 9 common trials in MDS, of which 3 are currently ongoing. Ryvu will retain full ownership of RVU120.

As an Investigator Initiated Trial, REMARK will be a study with scientific and medical merit, developed and coordinated by the CPI. The estimated Company's financial contribution to REMARK study is approx. EUR 4 million.

REMARK is planned to take place at approx. 25 clinical sites in the EU, with the primary goal of enrolling about 40 patients to generate exploratory clinical data that will allow a decision to be made on the further development of RVU120 in this therapeutic indication. Start-up activities for the study are scheduled to commence later this year, and patient enrollment is planned for the first half of 2024.

Prof. Platzbecker is the Director of the Department for Hematology, Cellular Therapy, Hemostaseology and Infectious Diseases at the University Hospital Leipzig, Germany. He is the co-founder and chairman of EMSCO and co-chairman of the European Hematology Association Scientific Working Group on

MDS. Prof. Platzbecker's research interests primarily focus on myelodysplastic syndromes (MDS) and its treatment. Specifically, Prof. Platzbecker's team has worked on trials assessing luspatercept (Reblozyl) and imetelstat in patients with low-risk MDS.

The Agreement meets the criteria of a significant agreement due to its importance for the further clinical development of the RVU120 program and constitutes an element of the Development Plans implementation.

The Company informs that a webinar will be held on Monday, October 23, 2023 at 9:00 a.m. to discuss further development plans for RVU120. The meeting will be available via the link: <https://ryvu.clickmeeting.com/ryvu-esmo-2023-results-ryvu120-development-plans/register>

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Legal basis: 17.1 MAR

Representatives of the Issuer:

- Hendrik Nogai – Member of the Management Board
- Kamil Sitarz – Member of the Management Board