CURRENT REPORT 14/2023

March 2nd, 2023

Conclusion of an agreement concerning the operational execution of Phase II of Phase I/II clinical trial of RVU120 in Patients with Relapsed/Refractory Solid Tumors

The Management Board of Ryvu Therapeutics S.A. ("Company", "Ryvu") informs that on March 2nd, 2023 it entered into an agreement with Labcorp Drug Development Inc. ("LabCorp Drug Development"), based in New Jersey, USA to conduct Phase II of Phase I/II of a clinical study to determine the safety and efficacy profile of RVU120 in patients with relapsed/refractory metastatic or advanced solid tumors (the "Agreement").

The Phase I clinical study of RVU120 began on August 13th, 2021. Labcorp Drug Development (then known as Covance Inc.) has cooperated with Ryvu in the operational execution of the Phase I clinical trial of RVU120 in solid tumors under the contract about which the Company informed in the current report 5/2021 of March 8th, 2021.

The primary objective of the Phase I/II study is to evaluate the anti-tumor activity of RVU120 as a single agent in patients with selected tumor types and to further evaluate the safety and tolerability profile of RVU120. Phase II will be conducted at selected clinical investigational sites in Europe and will start after the selection of the recommended Phase II dose based on Phase I results.

Labcorp Drug Development will be responsible for the operational execution of the Phase II clinical study. The estimated cost of the Agreement is EUR 3,872,088.22 (PLN 18,102,012.43 converted at the average exchange rate of the National Bank of Poland of March 2nd, 2023, EUR 1 = PLN 4,6750) and will be co-financed by the European Regional Development Fund and the Government of Poland as part of the project titled "Clinical development of an innovative drug candidate in solid tumors" within the Smart Growth Operational Programme 2014-2020, measure 1.1.1. "Fast Track". The value of the Agreement may change in the event of extending the scope of the order.

Labcorp Drug Development is a leading global life sciences company with 25 years of experience in conducting clinical trials to support drug development. Labcorp Drug Development has a long track record of global clinical experience in conducting oncology trials, with solid tumors being one of Labcorp Drug Development's key areas of expertise. Over the past five years, Labcorp Drug Development has conducted more than 1 000 clinical studies in Oncology, with Phase I/II studies being the most common.

RVU120 is a clinical-stage, selective, first-in-class dual inhibitor of CDK8 and CDK19 kinases. RVU120 has demonstrated efficacy in a number of solid tumors and hematologic malignancies in in vitro and in vivo models. The Phase I clinical study in solid tumors is currently enrolling at five investigational sites in Poland and Spain.

The Agreement meets the criteria of a significant agreement due to its value and importance for the further development of the RVU120 program. In particular, Ryvu points out that extension of the clinical development of the RVU120 compound by initiating a phase II clinical trial in selected solid tumor indications was one of the goals indicated in the Development Plans for 2022-2024, which the Company announced in the current report 16/2022 on August 19th, 2022. The terms of the Agreement do not differ from those customary for this type of contract.

Legal basis: art. 19.3 of MAR

Representatives of the Company:

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