CURRENT REPORT 5/2021

Conclusion of an agreement concerning operational execution of Phase I clinical trial of RVU120 (SEL120) in solid tumors

Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków ("Issuer") informs that on March 8, 2021, an agreement was concluded with Covance Inc. based in New Jersey, USA ("Covance"), to conduct a Phase I (dose escalation) part of a Phase I / II clinical study – aimed at determining the safety and efficacy profile of RVU120 (SEL120) in patients with relapsed / refractory metastatic or advanced solid tumors.

Covance Inc., is a leading global drug development service company with 25-years of experience in running clinical trials. The company has a long track record of global clinical experience in executing Oncology trials, with solid tumors being amongst the top indications in terms of Covance's expertise. In the past five years, Covance has run over 1000 clinical studies in Oncology, with Phase I studies being the most often executed ones.

In January 2021, Ryvu Therapeutics has submitted a Clinical Trial Application (CTA), seeking approval to commence a Phase I/II trial, investigating the safety and efficacy of RVU120 (SEL120) in patients with relapsed / refractory metastatic or advanced solid tumors.

The main objective of the Phase I study will be to assess the safety and tolerability, pharmacokinetics (PK), pharmacodynamics (PD), initial antitumor activity of RVU120 (SEL120) in dose escalation cohorts, as well as determining Phase II recommended dose. Phase I part will be conducted in selected clinical investigational sites in Europe, then in Phase II, the study is planned to be extended to additional locations.

Covance will be responsible for operational execution of Phase I clinical study (dose escalation). The estimated cost of the Agreement is EUR 2,223,529 (PLN 10,206,665 converted at the average exchange rate of the National Bank of Poland of March 8, 2021, EUR 1 = PLN 4.5903) 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 contract may change in the event of extending the scope of the order.

RVU120 (SEL120) is a selective CDK8/19 inhibitor, which has demonstrated efficacy in a number of solid tumor models in vitro and in vivo as well as in onco-hematological malignancies. The first-in-human (FIH) phase I study of RVU120 (SEL120) in relapsed or refractory AML or high-risk myelodysplastic syndromes (HRMDS), is currently enrolling patients in 6 investigational sites in USA (https://clinicaltrials.gov/ct2/show/NCT04021368).

The Agreement meets the criteria of a significant agreement due to its value and importance for the further development of the RVU120 (SEL120) program. In particular, the Issuer points out that extension of the clinical development of RVU120 (SEL120) compound by launching a new phase I clinical trial in selected solid tumor indications was one of the goals indicated by the Issuer in the strategy for 2020-2022. The terms of the contract do not differ from those commonly used for this type of contract.

Company representatives:

- Kamil Sitarz – Management Board Member
- Tomasz Nocuń – Proxy