CURRENT REPORT 17/2021
May, 28 2021

Ryvu Therapeutics got full approval to conduct Phase I/II study of RVU120 (SEL120) in patients with relapsed/refractory metastatic or advanced solid tumors in Poland

The Management Board of Ryvu Therapeutics S.A. ("Company"), with reference to the current report no. 1/2021 dated January 4, 2021, hereby announces that its Clinical Trial Application (CTA) to commence a single-agent, open-label Phase I/II trial, investigating the safety and efficacy of RVU120 (SEL120) in patients with relapsed/refractory metastatic or advanced solid tumors in Poland, has been fully approved by the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, and the respective Central Ethics Committee.

The study is designed in two phases. Phase I part has the key objectives of assessing safety and tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary anti-tumor activity of RVU120 (SEL120) during dose escalating cohorts, and determination of the recommended phase II dose (RP2D). Phase II part will include patients with specific tumor indications, enrolled at distinct study groups, such as triple negative breast cancer (TNBC).

Following the above-mentioned approvals, the Company will be able to initiate a clinical study and start enrolling patients in Poland. Clinical Trial Applications in other European countries will be submitted over the coming months.

Legal basis: Article 17.1 of MAR

Representatives of the Company:

- Paweł Przewięźlikowski – President of the Management Board
- Setareh Shamsili – Vice President of the Management Board