

## **CURRENT REPORT 30/2021**

**August 25, 2021**

### **First Patient Dosed in Phase I/II Study of RVU120 (SEL120) in Patients with Relapsed/Refractory Metastatic or Advanced Solid Tumors**

The Management Board of Ryvu Therapeutics S.A. with its registered offices in Krakow ("Company" or "Ryvu") hereby informs, with reference to the current report no. 17/2021 dated 28th of May 2021 on the approval of Clinical Trial Application 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 ("Study"), by the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, and the respective Central Ethics Committee, that today the first patient enrolled in the Study, has received the first dose of the study drug.

RVU120 is a highly selective first-in-class CDK8/CDK19 inhibitor, which has demonstrated efficacy in a number of solid tumors in in vitro and in vivo models as well as in hematologic malignancies.

The Study is designed in two parts. The Phase I part will assess safety and tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary anti-tumor activity of RVU120 in dose escalation cohorts, as well as determine the recommended Phase II dose (RP2D). The subsequent Phase II part will include specific tumor indications, enrolled in distinct study cohorts.

The solid tumor study is the second trial Ryvu is conducting with RVU120, in parallel to the ongoing Phase I in patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) in the US in which the drug has demonstrated initial signs of single agent efficacy.

The Management Board informs also that a clinical trial application submission process for the study of RVU120 in patients with relapsed/refractory metastatic or advanced solid tumors has already been initiated in Spain as well, aiming to start enrollment in Q4 2021.

**Legal basis:** Article 17(1) of the Market Abuse Regulation (MAR) – confidential information.

#### **Representatives of the Company:**

- Paweł Przewięźlikowski – President of the Management Board
- Kamil Sitarz – Member of the Management Board