

## **CURRENT REPORT 1/2021**

**January 4, 2021**

### **The new Clinical Trial Application for the conduct of a Phase I/II study of RVU120 (SEL120) in patients with solid tumors submitted by Ryvu Therapeutics S.A.**

The Management Board of Ryvu Therapeutics S.A. („Company“) hereby announces that it has submitted a new 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 CTA has been submitted to the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and to the study Central Ethics Committee.

The study is designed in 2 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), and the phase II part, subsequently will include specific tumor indications, enrolled at distinct study groups, such as Triple Negative Breast Cancer (TNBC). The study will start in selected investigational sites in Europe, and later on at start of phase II, will expand also to other regions.

RVU120 (SEL120) is a selective CDK8/19 inhibitor, which has demonstrated efficacy in a number of solid tumor types in *in vitro* and *in vivo* models as well as in onco-hematological malignancies. The first-in-human (FIH) phase I study with 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>).

Following the approval of the CTA, expected in H1 2021, Company will be able to activate the selected clinical sites in Poland and start enrolling patients.

**Legal basis:**

Article 17.1 of the Market Abuse Regulation

**Representatives of the Company:**

- Paweł Przewięźlikowski – President of the Management Board
- Krzysztof Brzózka – Vice President of the Management Board