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

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków, Poland ("Company"), in connection with the current stock report 30/2021 dated 25th August 2021, hereby announces that the Clinical Trial Application ("CTA") to commence a single-agent, open-label Phase I/II trial investigating safety and efficacy of RVU120 (SEL120) in patients with relapse/refractory metastatic or advanced solid tumors in Spain, has been fully approved by the Spanish Agency for Medicine and Medical Devices (AEMPS), and the respective Ethics Committee. The above approval allows to expand the study of RVU120 in relapsed/refractory metastatic or advanced solid tumors beyond Poland, where active enrollment is on-going.

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 RVU120 study in solid tumors 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 on-going Phase Ib study in patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (HR-MDS) in which the drug has demonstrated initial signs of single agent efficacy. RVU120 AML/HR-MDS study is conducted in the clinical sites in the US and Poland.

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