CURRENT REPORT 25/2021
July 14, 2021

FDA lifts partial clinical hold on RVU120 (SEL120) Phase Ib study in acute myeloid leukemia and myelodysplastic syndrome

The Management Board of Ryvu Therapeutics S.A. ("Company" or "Ryvu") hereby informs, in connection with the current report no 9/2021 dated April 8, 2021, that the U.S. Food and Drug Administration ("FDA" or "Agency"), has lifted a partial clinical hold, on the first-in-human phase Ib, dose escalation clinical trial of RVU120 (also known as SEL120) in patients with relapsed/refractory (R/R) AML and high-risk MDS, which is conducted in the United States.

The partial clinical hold was issued following Ryvu's report to the FDA of a serious adverse event involving a patient death that might have possibly been related to RVU120. Study enrollment was suspended but patients already on treatment could continue treatment. As of July 14, 2021 one patient still remains on RVU120 treatment.

Based on the recommendations from the FDA, the study will resume enrollment at the 75mg dose (Every Other Day - EOD) in a standard 3+3 design, according to a revised protocol intended to increase patients' safety. Protocol amendment covers modified exclusion criteria, scope of monitoring and frequency of laboratory testing. Following the completion of 75mg cohort, the data generated will be reviewed by the Agency and a further dose escalation strategy will be established. Additionally, Ryvu plans to use 75mg dose as the starting dose for the single-agent, open-label Phase I/II trial, investigating the safety and efficacy of RVU120 in patients with relapsed/refractory metastatic or advanced solid tumors, which shall commence patient enrollment of in Q3 this year. The Company has informed about the conclusion of an agreement concerning operational execution of Phase I clinical trial of RVU120 in solid tumors in the current stock report no 5/2021 dated March 18, 2021.

The initial safety and efficacy data from the first four cohorts in the trial were presented at the Virtual EHA Congress on June 11, 2021 (Company has informed about it in the current stock no 12/2021 dated May 12, 2021). RVU120 demonstrated acceptable safety profile and two clinically relevant responses were observed in the first five AML and high risk MDS patients treated: one complete response (CR) and one erythroid response.

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