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Ryvu Therapeutics Presents Clinical and Translational Data Updates at the 63rd American Society of Hematology (ASH) Annual Meeting and the 44th San Antonio Breast Cancer Symposium

The Management Board of Ryvu Therapeutics S.A. ("Company", "Ryvu") hereby informs that the Company presented positive clinical and preclinical data demonstrating the single-agent activity of Ryvu's two lead oncology drug candidates, RVU120 and SEL24 (MEN1703) at the 63rd American Society of Hematology Annual Meeting, as well as at the 44th Annual San Antonio Breast Cancer Symposium (SABCS).

Presented data included updated clinical results for RVU120, a selective CDK8/19 inhibitor being developed for the treatment of hematological malignancies and solid tumors. RVU 120 has thus far demonstrated an acceptable safety profile and preliminary signs of efficacy. The RVU120 inhibitor is currently in the first-in-human (FIH) Phase 1b dose-escalation trial (CLI120-001), which is currently enrolling patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (HR-MDS).

With a data cutoff of November 16, 2021, data highlights include:

- A Complete Remission (CR) in an AML patient harboring mutations in DNMT3A and NPM1. Supportive translational data were also presented demonstrating the anti-leukemic activity of RVU120 in PDX AML models bearing DNMT3A and NPM1 mutations;
- An erythroid response (ER) in a HR-MDS patient who had relapsed after several lines of previous treatment; as of the data cutoff, this patient remains on study treatment with stable disease for more than 15 months. Supportive translational data were also presented demonstrating that RVU120 induces erythroid differentiation in (Lin-) CD34+ cells;
- Acceptable safety profile in 6 patients completing safety evaluations for cycle 1. None of these patients experienced dose-limiting toxicity (DLT). A total of 12 serious adverse events (SAEs) have been reported – none were deemed to be related to the study drug.

Moreover, Ryvu's global partner Menarini Group, which is currently developing SEL24 (MEN1703) on the basis of an exclusive licence agreement concluded with the Company, presented updated Phase 2 data for SEL24 (MEN1703) (DIAMOND-01, ClinicalTrials.gov identifier: NCT03008187), showing pharmacodynamics (PD) and genomic profiling.

DIAMOND-01 is the First-in-Human, Phase I/II dose escalation and cohort expansion trial of SEL24 (MEN1703) for patients with relapsed or refractory AML and previously untreated patients unsuitable for chemotherapy.

Posters presented At the 63rd ASH Annual Meeting & Exposition included:

- CLI120-001 Phase Ib Study of RVU120 (SEL120) in Patients with AML and High-Risk MDS: Updated Safety/Efficacy Results from Initial Dose Escalation (Publication Number: 3418),
- RVU120 (SEL120) CDK8/19 Inhibitor - a Drug Candidate for the Treatment of MDS Can Induce Erythroid Differentiation (Publication Number: 1518),
- Inhibition of Cyclin Dependent Kinase 8 (CDK8): A Novel Approach to Target the Leukemia Initiating Cells (LICs) in T-Cell Acute Lymphoblastic Leukemia (T-ALL) (Publication Number: 2250),
- Preclinical and Clinical Signs of Efficacy of RVU120 (SEL120), a Specific CDK8/19 Inhibitor in DNMT3A-Mutated AML (Publication Number: 2371),
- SEL24 (MEN1703) Inhibits PIM/FLT3 Downstream Target in Acute Myeloid Leukemia (AML) Patients: Results of the Pharmacodynamics (PD) Assay and Genomic Profiling in the First-in-Human Diamond-01 Trial (Publication Number: 3436).

An additional poster on the potential efficacy of RVU120 in hormone-negative breast cancer models was presented at the 2021 San Antonio Breast Cancer Symposium, which showed that oral administration of RVU120 demonstrated strong anticancer activity in a TNBC xenograft model:

- Selective CDK8/CDK19 inhibitor RVU120 demonstrates efficacy against hormone-independent breast cancer cells in vitro and in vivo (#1766).

Both the ASH conference and the San Antonio Breast Cancer Symposium are considered to be one of the most important scientific events, gathering researchers, as well as potential clients and business partners - biotechnology and pharmaceutical companies from all over the world and industry investors.

All of the posters are available online at Ryvu's website:
https://ryvu.com/investors-media/publications/

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

Representatives of the Company:

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