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Ryvu's partner Menarini Group receives FDA Orphan Drug Designation for SEL24 (MEN1703) for the Treatment of Acute Myeloid Leukemia

The Management Board of Ryvu Therapeutics S.A. ("Company") hereby announces that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation ("ODD") to SEL24/MEN1703 for the treatment of Acute Myeloid Leukemia (AML). SEL24/MEN1703 is a first-in-class, orally available, dual PIM/FLT3 inhibitor, in-licensed by Menarini Group from the Company.

ODD is granted by the FDA to therapies intended for the treatment of conditions that impact fewer than 200,000 people in the US and provides companies with several incentives to support the development of therapeutics and diagnostics for rare diseases. ODD does not supersede the process of regulatory approval and drugs for rare diseases are required to undergo the same rigorous scientific review process as any other drug. However, obtaining ODD status allows use of FDA's scientific support and advice to further the process of clinical trials and can significantly shorten the subsequent stages of studies by simplified drug evaluation and registration procedures.

Currently SEL24/MEN1703 is being examined as part of the DIAMOND-01 trial as a single agent for the treatment of patients with Acute Myeloid Leukemia (AML). DIAMOND-01 is a First-in-Human, Phase I/II, dose escalation and cohort expansion trial of SEL24/MEN1703, investigated as a single agent for the treatment of patients with AML.

In the dose escalation part of the DIAMOND-01 trial, SEL24/MEN1703 has demonstrated a manageable safety profile up to the recommended dose (RD) of 125 mg/day, along with initial evidence of anti-leukemic activity as single agent. This evidence has been confirmed in the cohort expansion part of the study, which also showed preliminary single agent efficacy in relapsed/refractory AML, particularly in patients with IDH mutant disease, either naïve - or previously exposed - to IDH inhibitors.

The trial is currently recruiting AML patients bearing IDH1 or IDH2 mutation, to further investigate the activity of SEL24/MEN1703 in this molecularly defined sub-population of patients.

Legal basis: art. 17 ust. 1 MAR

Representatives of the Company:

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