

## CURRENT REPORT 8/2025 March 26, 2025

## Dosing of the first patient in the JASPIS-01 phase II study of dapolsertib (MEN1703/SEL24) for the treatment of patients with relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL)

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków (the "Company", "Ryvu", "Issuer"), announces that on March 26, 2025 the first patient has been dosed of dapolsertib (MEN1703/SEL24) in the JASPIS-01 study ("JASPIS-01 Study") for the treatment of patients with relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL). The JASPIS-01 Study is being conducted by Syneos Health, LLC, a Delaware limited liability company with principal offices located in the United States at 1030 Sync Street, Morrisville, North Carolina 27560, together with Syneos Health UK Limited, a company with principal offices located at Farnborough Business Park, 1 Pinehurst Road, Farnborough, Hampshire, GU14 7BF, England, Europe, as announced by the Company in current report no. 31/2024 dated October 18, 2024.

The JASPIS-01 Study is an open-label, Phase II clinical trial investigating dapolsertib as a monotherapy and in combination with glofitamab for the treatment of patients with relapsed/refractory (r/r) DLBCL. It comprises three parts: Part 1 focuses on evaluating safety and preliminary anti-tumor activity in approximately 18 patients; Part 2 will assess, based on the results of Part 1, anti-tumor activity as a primary objective in a larger group of patients, as well as safety and tolerability; and Part 3 will offer an optional randomized comparison to show the contribution of dapolsertib and glofitamab over glofitamab alone. The JASPIS-01 Study is registered on ClinicalTrials.gov under NCT06534437. The JASPIS-01 Study was initiated at clinical sites in Poland, with plans to expand to additional EU and non-EU countries.

Dapolsertib hydrochloride is the new International Nonproprietary Name (INN) for MEN1703 (SEL24) as accepted by the World Health Organization (WHO). Dapolsertib is a selective, small-molecule, dual inhibitor of PIM and FLT3 kinases, two enzymes strongly implicated in the malignant transformation of hematopoietic cells and lymphomagenesis. The compound has been discovered by the Company, and is currently in clinical development in collaboration with Menarini (as defined below) as a therapeutic option for various cancers.

The license agreement with Berlin-Chemie AG, headquartered in Berlin, Germany, a part of the Italian Menarini Group ("Menarini"), was signed on March 28, 2017, as previously reported by the Company in current report no. 4/2017. Menarini holds global development and commercial rights to dapolsertib. Initially, dapolsertib was developed as a potential



treatment for patients with relapsed/refractory (r/r) acute myeloid leukemia (AML). More details on the completed Phase I/II clinical study can be found at ClinicalTrials.gov under NCT03008187. Data from this study was presented at multiple scientific conferences and symposia.

Encouraged by promising results from translational research, Menarini decided to continue the development of dapolsertib by initiating a new Phase II study in patients with r/r DLBCL – the JASPIS-01 study. Menarini fully funds all study activities, while the Company is the operational partner for executing the JASPIS-01 Study on behalf of Menarini as announced by the Issuer in the current report no. 40/2023 dated September 14, 2023.

Disclaimer: This English language translation has been prepared solely for the convenience of English-speaking readers. Despite all the efforts devoted to this translation, certain discrepancies, omissions or approximations may exist. In case of any differences between the Polish and the English versions, the Polish version shall prevail. Ryvu Therapeutics S.A., its representatives and employees decline all responsibility in this regard.

## **Legal basis:** Article 17.1 of MAR **Representatives of the Issuer:**

- Hendrik Nogai Member of the Management Board
- Kamil Sitarz Member of the Management Board