

CURRENT REPORT 31/2024

October 18, 2024

Conclusion of an agreement in the area of operational execution of MEN1703 (SEL24) Phase II clinical trial in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

The Management Board of Ryvu Therapeutics S.A. with its registered office in Kraków ("Ryvu", the "Company"), informs that on October 18, 2024, the Company concluded an agreement with 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 ("Syneos"), covering the operational execution of the JASPIS-01 clinical study ("Agreement").

The JASPIS-01 study is an open-label, Phase II clinical trial investigating MEN1703 (SEL24) as a monotherapy and in combination with glofitamab for patients with relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL). It comprises three parts: Part 1 focuses on evaluating safety and preliminary anti-lymphoma activity in approximately 18 patients; Part 2, based on Part 1 results, will assess 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.

The initiation of the JASPIS-01 study is scheduled for Q4 2024, with start-up activities already underway. Initially, the study is set to commence at clinical sites in Poland, with the plan to expand to additional EU and non-EU countries still within Part 1. The study is registered on ClinicalTrials.gov under NCT06534437.

The subject of the Agreement is the operational execution of Part 1 of the JASPIS-01 study. It includes services related to clinical study execution, such as clinical project management, medical and safety monitoring and clinical site management.

The total cost of the Agreement i.e. €3,821,572.99, includes all the relevant services, as well as fees for investigators and clinical sites-related procedures. Additionally, costs associated with the study start-up activities already performed by Syneos under the Initial Service Agreement ("ISA") are also included in the total amount of the Agreement. All costs of the Agreement will be fully reimbursed by the Company's partner, Menarini Group (as defined below). This reimbursement is in line with an agreement concluded between the Company and Berlin-Chemie AG with its registered office in Berlin, Germany, part of the

Italian Menarini Group ("Menarini Group"), as reported by the Issuer in current report no. 40/2023 dated September 14, 2023.

Syneos Health is a contract research organization (CRO) that provides comprehensive services for drug development. It supports pharmaceutical and biotechnology companies through all phases of clinical trials, offering expertise in areas like regulatory affairs, patient recruitment, and data management to facilitate the efficient delivery of new therapies.

The Agreement meets the criteria of a significant agreement due to its importance for the further development of the MEN1703 clinical program. The terms of the Agreement do not deviate from the conditions customarily accepted for this type of agreements.

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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