# Rallybio Presents Phase 1 Single Ascending Dose Data for RLYB116, an Innovative Subcutaneously Injected Inhibitor of Complement Component 5

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*-- First-In-Human Single Ascending Dose Clinical Data for RLYB116 Demonstrated a Reduction in Free C5 Greater than 99% at 24 Hours for the 100 mg dose and at 12, 24, and 72 Hours for the 300 mg dose in Healthy Participants --*

*-- Mean Estimated Elimination Half-Life for RLYB116 was > 300 Hours --*

*-- No Severe or Serious Adverse Events with Single-Dose Administration of RLYB116 --*

*-- Phase 1 Multiple Ascending Dose Study of RLYB116 Ongoing; Preliminary Safety, PK, and PD Data Expected in 4Q 2023 --*

NEW HAVEN, Conn.--(BUSINESS WIRE)--Sep. 3, 2023-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases, today presented clinical data in a poster from the Phase 1 first-in-human single ascending dose (SAD) clinical study in healthy participants of RLYB116. RLYB116 is an innovative potentially long-acting, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-mediated diseases. The poster presentation took place at the 29th International Complement Workshop (ICW), in Newcastle, UK.

The data demonstrated that single-dose administration of RLYB116 at the two higher doses of 100 mg and 300 mg resulted in maximum exposures of greater than 1 µM and 3 µM, respectively, and greater than 99% reductions in free C5 concentrations. Subcutaneously administered RLYB116 was observed to be generally well-tolerated as a single 100 mg or 300 mg dose, with mild to moderate adverse events and no drug-related serious adverse events.

“The results presented today at ICW continue to support our belief in the potential use of RLYB116 for the treatment of a broad range of complement-mediated diseases. These single-dose data suggest that RLYB116 could be a highly innovative C5 inhibitor with the potential to address significant unmet medical need for patients,” commented Eric Watsky, M.D., Rallybio RLYB116 Program Lead. “We remain on track to report initial data from the Phase 1 multiple ascending dose study of RLYB116 and disclosing our indication strategy in the fourth quarter of 2023.”

The poster can be viewed on the Publications & Presentations page of the company’s website: https://rallybio.com/publications-presentations/

Additional information about ICW 2023 is available at: https://icw2023newcastle.co.uk/.

**About Rallybio**

Rallybio (NASDAQ: RLYB) is a clinical-stage biotechnology company with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Rallybio has built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. The Company has two clinical stage programs: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT) and RLYB116, an inhibitor of complement component 5 (C5), with the potential to treat several diseases of complement dysregulation, as well as additional programs in preclinical development.

Rallybio is headquartered in New Haven, Connecticut with an additional facility at the University of Connecticut’s Technology Incubation Program in Farmington, Connecticut. For more information, please visit www.rallybio.com and follow us on LinkedIn and Twitter.

**Forward-Looking Statements**

This press release contains forward-looking statements that are based on our management’s beliefs and assumptions and on currently available information. All statements, other than statements of historical facts contained in this press release are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements concerning results from the Phase 1 first-in-human single ascending dose clinical study of RLYB116, and statements concerning the expected progress, results and plans for RLYB116, the timing of the availability of data from the Phase 1 multiple ascending dose (MAD) study of RLYB116, our expectations regarding reporting of data from the MAD study, our expectations regarding the usefulness of such data and the data from the Phase 1 first-in-human single ascending dose study, the timing of disclosure of our indication strategy for RLYB116, and the likelihood that Rallybio will be successful in developing RLYB116. The forward-looking statements in this press release are only predictions and are based largely on management’s current expectations and projections about future events and financial trends that management believes may affect Rallybio’s business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our ability to successfully initiate and conduct our planned clinical studies, and complete such clinical studies and obtain results on our expected timelines, or at all, whether our cash resources will be sufficient to fund our operating expenses and capital expenditure requirements and whether we will be successful raising additional capital, our ability to enter into strategic partnerships or other arrangements, competition from other biotechnology and pharmaceutical companies, and those risks and uncertainties described in Rallybio’s filings with the U.S. Securities and Exchange Commission (SEC), including Rallybio’s Quarterly Report on Form 10-Q for the period ended June 30, 2023, and subsequent filings with the SEC. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we are not obligated to publicly update or revise any

forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise.

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