Rallybio Announces Positive Data for RLYB116 Phase 1 Study Demonstrating Complete and Sustained Inhibition of Terminal Complement

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– Data Support the Study of RLYB116 as a Potential Best-In-Class Therapeutic for Multiple Complement Mediated Diseases –

– Initiation of RLYB116 Phase 2 Clinical Trial in Immune Platelet Transfusion Refractoriness Currently Planned for 2H 2026 with Potential for Topline Data in 2027 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Feb. 17, 2026-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today announced positive results from its Phase 1 confirmatory pharmacokinetic/pharmacodynamic (PK/PD) clinical trial evaluating RLYB116, the Company's innovative, once-weekly, small volume, subcutaneously injected C5 inhibitor, in development for patients with complement-mediated diseases with its initial focus on immune platelet transfusion refractoriness (PTR) and refractory antiphospholipid syndrome (APS).

"The results from our Phase 1 study of RLYB116 are both validating and highly encouraging, reinforcing our belief that this program has the potential to be a best-in-class therapeutic. At the 300 mg dose, we achieved complete and sustained inhibition of terminal complement with a safety profile consistent with other subcutaneous biologics," stated Stephen Uden, M.D., Co-Founder and Chief Executive Officer of Rallybio. "These data underscore the potential of RLYB116 to deliver rapid onset, durable activity, and patient-friendly administration through a small volume, off-the-shelf autoinjector—features that could transform care for individuals living with complement-mediated diseases such as immune platelet transfusion refractoriness and antiphospholipid syndrome."

The single-blind multiple ascending dose Phase 1 confirmatory PK/PD study of RLYB116 (NCT06797375) was designed to demonstrate complete and sustained complement inhibition with favorable tolerability in healthy volunteers. The study evaluated a 4-week treatment duration that included two cohorts of eight participants each, randomized 3-to-1 to receive either RLYB116 or placebo once weekly. Cohort 1 evaluated dosing of 150 mg and Cohort 2 evaluated dosing of 300 mg. The study included a 10-week follow-up period after the conclusion of treatment.

"With these results in hand, we have the potential to move into a Phase 2 proof of concept study in immune PTR, in 2H 2026. We remain steadfast in our belief that RLYB116 has significant value as a potential best-in-class therapy for patients with high unmet need," concluded Dr. Uden.

The data demonstrated the following:

- A 300 mg once-a-week dose of subcutaneously administered RLYB116 achieved complete and sustained inhibition of terminal complement.
- Complete and sustained inhibition of ex-vivo hemolytic activity demonstrates clinically effective blockade of terminal complement.
- RLYB116 administered as a 150 mg and 300 mg once-a-week dose was well tolerated with no gastrointestinal side effects reported among participants. The most common adverse events in both cohorts were mild-to-moderate injection site reactions, consistent with other subcutaneously administered biologics. None were severe or caused discontinuation of study drug. These results further validate the manufacturing process enhancements designed to improve the tolerability profile of RLYB116.

"Based on our prior clinical experience, the Phase 1 results are compelling and provide strong corroboration for our scientific and clinical rationale. The data demonstrate the potential for rapid onset and sustained activity, offering clinical benefit and flexibility for a convenient dosing regimen that addresses a significant unmet need for patients with immune PTR, APS and other complement mediated diseases," said Steven Ryder, M.D., Chief Medical Officer of Rallybio.

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 pipeline of promising product candidates aimed at addressing diseases with unmet medical need in areas of complement dysregulation and hematology. The Company's lead program, RLYB116, is a differentiated C5 inhibitor with the potential to treat diseases of complement dysregulation, with an initial focus on immune platelet transfusion refractoriness and refractory antiphospholipid syndrome. Rallybio's pipeline also includes RLYB332, a preclinical long-acting matriptase-2 antibody for the treatment of diseases of iron overload. Rallybio is headquartered in New Haven, Connecticut. For more information, please visit www.rallybio.com and follow us on LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements that are based on our management's beliefs and assumptions and 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 the timing to initiate and have topline data from a Phase 2 clinical trial of RLYB116, the potential for RLYB116 to be a best-in-class therapeutic, and the potential of RLYB116 to transform care for individuals living with complement-mediated diseases. 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 conduct the RLYB116 Phase 2 clinical trial and complete such study and obtain results on our expected timelines, or at all, the potential result of such clinical trials and those risks and uncertainties described in Rallybio's filings with the U.S. Securities and Exchange Commission (SEC), including the Quarterly Report on Form 10-Q for the period ended September 30, 2025, 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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