Rallybio Announces Positive Phase 1 Single Ascending Dose Results for RLYB116, an Innovative Subcutaneously Injected Inhibitor of Complement Component 5

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-- 100 mg Results Demonstrated a Reduction of >99% in Free C5 with the Potential for Weekly or Less Frequent Self-Administered Dosing --
-- RLYB116 Administered as a Single 100 mg dose was Generally Well-Tolerated --
-- Phase 1 Multiple Ascending Dose Study Expected to Commence in 1Q 2023 --

NEW HAVEN, Conn.--(BUSINESS WIRE)--Nov. 7, 2022-- Rallybio Corporation (Nasdaq: RLYB) today announced positive topline results from its Phase 1 single ascending dose (SAD) study in healthy participants of RLYB116, an innovative potentially long-acting, subcutaneously injected inhibitor of complement component 5 (C5), in development for the treatment of patients with complement-mediated diseases.

In the ongoing Phase 1 study, all study participants that were administered a single 1 mL subcutaneous injection of 100 mg of RLYB116 (n=6) demonstrated a reduction in free C5 greater than 99% within 24 hours of dosing. The terminal elimination half-life of RLYB116 was greater than 300 hours.

“We are excited by these positive data which suggest the potential for rapid and complete functional blockade of terminal complement activity with a patient-convenient, self-administered 1 mL injection of RLYB116. Pharmacokinetic modeling of these single dose data support the potential for sustained complement inhibition with once-a-week or less frequent dosing, and we believe the possibility of an improved quality of life for patients. We believe that these preliminary results validate RLYB116 as a highly innovative C5 inhibitor with the potential to address significant unmet need for patients with a broad range of complement-mediated diseases,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio.

Eric Watsky, M.D., Rallybio’s RLYB116 Program Lead added, “The results from this ongoing Phase 1 study support the further development of RLYB116 in patients with a broad range of complement-mediated diseases, with a long half-life and the potential to fully inhibit C5 with a small volume subcutaneous injection. We currently expect to initiate the multiple ascending dose Phase 1 study of RLYB116 in the first quarter of 2023.”

Subcutaneously administered RLYB116 was observed to be generally well-tolerated at the 100 mg dose, with mild or moderate adverse events and no drug-related serious adverse events reported.

About the RLYB116 Phase 1 Study

RLYB116 is an innovative, potentially long-acting, subcutaneously injected inhibitor of C5. The ongoing RLYB116 single-blind, placebo-controlled dose escalation study was initiated in February 2022 and is designed to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of single subcutaneous dose RLYB116 in healthy participants and includes five dose cohorts (2, 10, 30, 100, 300 mg RLYB116) with each enrolling 8 participants. Post-treatment / study follow-up is expected to continue for 10 weeks.

About Rallybio

Rallybio is a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases. Since its launch in January 2018, Rallybio has built a portfolio of promising product candidates, which are now in development to address rare diseases in the areas of hematology, immuno-inflammation, maternal fetal health, and metabolic disorders. The Company’s mission is being advanced by a team of highly experienced biopharma industry leaders with extensive research, development, and rare disease expertise. 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**.

Forward-Looking Statements

This press release contains forward-looking statements that are based on our management’s beliefs and assumptions and on information currently available to management. 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 results from the Phase 1 study of RLYB116, the potential clinical effects of RLYB116, the potential benefits, safety and efficacy of RLYB116, including compared to other C5 inhibitors, the clinical development program for RLYB116, the timing of the initiation of the multiple ascending dose study for RLYB116, and our research and development program for the treatment of 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 initiate and conduct our planned clinical trials, including the multiple ascending dose study for RLYB116, and complete such clinical trials 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, 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, 2022, 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. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. 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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