Rallybio Highlights Portfolio Advances and Outlines Expected Milestones in 2023

January 5, 2023

-- Phase 1b Proof-of-Concept Data for RLYB212 on track for 1Q 2023 --

-- Initiated Phase 1 Multiple Ascending Dose Study of RLYB116 in 4Q 2022; Safety, PK and PD Data Expected in 2H 2023 --

-- Cash Runway Extended into 1Q 2025 following November 2022 Follow-On Offering --

NEW HAVEN, Conn.--(BUSINESS WIRE)--Jan. 5, 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 provided an update on recent accomplishments and announced expected 2023 clinical milestones. The Company will present these updates at the 41st Annual J.P. Morgan Health Care Conference in San Francisco, California on Tuesday, January 10, 2023, at 3:45 p.m. PT (6:45 p.m. ET).

“In 2022, Rallybio's first full year as a public company, we made significant progress in our mission to develop transformative therapeutics for rare diseases with severe unmet needs,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. “Over the past 12 months, we announced encouraging preliminary data for our two lead assets, RLYB212, for the prevention of FNAIT, and RLYB116, our C5 inhibitor. We also significantly expanded our earlier-stage pipeline through strategic business development efforts.”

Dr. Mackay continued, “We are excited to build on this progress in 2023. We remain on track to announce Phase 1b proof-of-concept data for RLYB212 in the first quarter and, following the initiation of the multiple ascending dose Phase 1 study of RLYB116 in the fourth quarter of 2022, expect to report initial data in the second half of 2023. In parallel, we continue to seek transformative assets and partners globally in order to address substantial unmet needs and deliver improved outcomes to many more people around the world.”

Recent Portfolio Milestones and Expected Upcoming Milestones

Maternal Fetal Blood Disorders

Rallybio expects to announce Phase 1b proof-of-concept data for RLYB212, a novel human monoclonal anti-HPA-1a antibody in development for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), in the first quarter of 2023. The Company commenced dosing under an amended protocol of this ongoing study to evaluate a higher dose of RLYB212 in September 2022. The Company expects the broad range of pharmacokinetic and pharmacodynamic data from this study to enable substantive modeling of the concentration-effect relationship and further inform dosing for a future registrational study of RLYB212.

In addition, Rallybio is advancing its FNAIT natural history alloimmunization study. This non-interventional study is designed to provide key information on the frequency of women at higher risk for FNAIT across a broad population of pregnant women of different racial and ethnic characteristics, and the occurrence of HPA-1a alloimmunization in these women. The Company expects that the data from this study will contribute to a control dataset for a future, single-armed registration trial for RLYB212.

Complement Dysregulation

Rallybio announced today that it initiated dosing in the first multiple ascending dose cohort of a Phase 1 study of RLYB116 in the fourth quarter of 2022. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement component 5, or C5, in development for the treatment of patients with complement-related diseases. The single-blind, dose escalation, placebo-controlled study is designed to evaluate the safety, pharmacokinetics, and pharmacodynamics of RLYB116 in healthy participants. Initial data are expected in the second half of 2023.

Rallybio also continues to advance the development of RLYB114, formulated for intravitreal injection, for the treatment of ophthalmic disorders.

Hematological Disorders

Rallybio continues to conduct investigational new drug (IND)-enabling activities for RLYB331, a preclinical, potentially first-in-class therapeutic monoclonal antibody that inhibits Matriptase-2 (MTP-2), to support the transition of this asset into clinical development.

Metabolic Disorders

Rallybio, together with its partner Exscientia, continues to work toward the selection of a small molecule development candidate to advance into the clinic targeting ENPP1 for the treatment of patients with hypophosphatasia (HPP). *In vivo* efficacy data are expected in the second half of 2023. Following those results, the companies expect to commence IND-enabling studies.

In December 2022, Rallybio announced a strategic alliance with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. Under the terms of the agreement, AbCellera and Rallybio will co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies. The partnership’s first program will focus on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Financial Update

In November 2022, Rallybio announced the pricing of a follow-on offering of approximately $55 million in gross proceeds. J.P. Morgan, Cowen and Evercore ISI acted as joint lead book-running managers for the offering.

Cash, cash equivalents, and marketable securities were $132.4 million as of September 30, 2022, and with the November 2022 follow-on offering, the Company currently expects its cash runway to extend into the first quarter of 2025.

Webcast of Presentation at the 41st Annual J.P. Morgan Health Care Conference

Rallybio is scheduled to present at the 41st Annual J.P. Morgan Health Care Conference on Tuesday, January 10, 2023, at 3:45 p.m. PT (6:45 p.m. ET). A live webcast of the presentation and subsequent question and answer session will be accessible through the Events and Presentations section of Rallybio's website. An archived replay of the webcast will be available for 30 days following the presentation.

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 timing of our planned studies for RLYB212 and RLYB116, and the timing of the availability of data from such studies, including proof-of-concept data for the Phase 1b RLYB212 clinical study, the initiation and timing of our pre-IND enabling studies for our ENPP1 inhibitor, and the timing of the availability of data from such studies, our ability to transition RLYB331 into clinical development, and our projected financing needs. 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 September 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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