Rallybio Announces Portfolio Prioritization and Provides Corporate Update

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– Prioritization of Phase 2-ready clinical-stage programs: RLYB212 for the prevention of FNAIT and RLYB116, a C5 inhibitor for the treatment of patients with complement-mediated diseases –

– Anticipated cost savings, including a 45% workforce reduction, extends cash runway into mid-2026 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Feb. 6, 2024-- Rallybio Corporation (Nasdaq: RLYB) today announced the prioritization of its portfolio and a 45% workforce reduction to focus resources on its Phase 2-ready clinical stage programs, RLYB212 and RLYB116. RLYB212 is a novel human monoclonal anti-HPA-1a antibody in development for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), and RLYB116 is a once-weekly, low volume subcutaneously injected inhibitor of complement component 5 (C5) in development for patients with complement-mediated diseases. With these changes, Rallybio expects to extend its cash runway into mid-2026.

“Following a thorough review of our business, we have made the decision to prioritize our portfolio. We believe that these difficult but necessary decisions to streamline our operations and align resources are critical to extend our cash runway, support the advancement of our two clinical-stage programs, and put us on a path toward long-term success,” said Stephen Uden, M.D. Chief Executive Officer of Rallybio.

“I would like to personally thank our departing employees for their countless contributions and tireless commitment to our mission,” Dr. Uden continued. “It is incredibly difficult to part ways with these talented members of the Rallybio team who have demonstrated such dedication to bringing transformative therapies to patients in need.”

Key Elements of Portfolio Prioritization and Corporate Update

Prioritization of Clinical-Stage Programs

RLYB212

- The Company plans to provide an update on Phase 2 discussions for RLYB212 with the European Medicines Agency (EMA) in the first half of 2024.
- Rallybio continues to expect to initiate a Phase 2 dose confirmation study for RLYB212 in pregnant women at higher risk of FNAIT in the second half of 2024.
- The Company continues to screen mothers in the FNAIT natural history alloimmunization study, a non-interventional study designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population. Rallybio expects to provide an update on screening numbers in its full-year earnings release in March 2024.

RLYB116

- Manufacturing work announced in December 2023 is progressing, and Rallybio is encouraged by data indicating the potential to achieve improved tolerability at higher doses of RLYB116.
- While the exposure levels of RLYB116 demonstrated in the Phase 1 study are expected to be suitable for the treatment of patients with generalized myasthenia gravis, the Company believes the ongoing enhancements will enable higher exposure to RLYB116, supporting the treatment of patients with a broader range of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria and antiphospholipid syndrome.
- Rallybio continues to expect to complete this manufacturing work and provide an update on the development plan for RLYB116 in the second half of 2024.

Preclinical Program Update
The Company continues to believe that its preclinical programs have the potential to address significant existing unmet needs for patients and caregivers and bring meaningful value to stakeholders. The revised operating plan will fund preclinical program activities to important 2024 milestones, as described below. Beyond achievement of these milestones, Rallybio will seek alternative options to further advance these programs, including additional partnerships and other forms of non-dilutive financing.

- **RLYB331, Matriptase-2 (MTP-2) Inhibitor:** Completion of the ongoing preclinical activities, with data expected in the first half of 2024.
- **ENPP1 Inhibitor, Exscientia Partnership:** Lead AI-designed compounds enter candidate selection process in the second half of 2024.
- **AbCellera Partnership:** Advancement of discovery efforts to the next research milestone in the second half of 2024.
- **RLYB114, EyePoint Collaboration:** The evaluation of Rallybio’s C5 inhibitor using EyePoint’s proprietary technology for sustained intraocular drug delivery is ongoing. An update is expected in the first half of 2024.

Workforce Reduction

The Company will implement a 45% workforce reduction, representing 19 positions, which will be substantially complete by the end of the first quarter of 2024. Rallybio estimates that the workforce reduction will result in aggregate charges of approximately $3.3 million, primarily for one-time employee severance and benefit costs and excluding share-based compensation expense.

Based on the above actions, Rallybio's cash, cash equivalents and marketable securities of approximately $109.9 million (unaudited) as of December 31, 2023, are now expected to fund its revised operating plan into mid-2026.

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. 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 the timing of initiation of the Phase 2 dose confirmation study for RLYB212, the release of screening numbers of women in the natural history study, whether the results of the natural history study and the planned Phase 2 dose confirmation study will be sufficient to support design and implementation of a Phase 3 registrational study for RLYB212, whether the manufacturing work for RLYB116 will be timely completed or successful, our expectations regarding the usefulness of data from our clinical studies, the timing of achieving milestones in 2024 for our preclinical programs, the likelihood that Rallybio will be successful in developing RLYB212, RLYB116, or any of our other product candidates, our ability to successfully identify and implement alternative and acceptable options to further advance our programs, expected costs related to the workforce reduction and related charges, including the timing of such charges, the expected use of operating cost savings associated with the updated operating plan and the timing, and our cash runway. 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 September 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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