Rallybio Announces Publication of RLYB212 Phase 1 Proof-of-Concept Study Results in Thrombosis and Haemostasis

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– Study Demonstrates that RLYB212 Rapidly Clears HPA-1a Positive Platelets, an Essential Step in Preventing Alloimmunization and FNAIT –

– Rallybio On Track to Initiate RLYB212 Phase 2 Dose Confirmation Trial in Pregnant Women at Higher Risk for FNAIT in 4Q 2024 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Aug. 29, 2024-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, announced today that data from the Phase 1 proof-of-concept study of RLYB212, a novel monoclonal anti-HPA-1a antibody in development for the prevention of maternal alloimmunization and fetal and neonatal alloimmune thrombocytopenia (FNAIT), were published in *Thrombosis and Haemostasis*. Top-line results from this study were previously presented at the 31st Congress of the International Society on Thrombosis and Haemostasis (ISTH) in 2023.

“These data were instrumental in our selection of the initial dose for the upcoming Phase 2 trial of RLYB212, which is on track for initiation in the fourth quarter of 2024,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio. “Our primary focus is to advance RLYB212 through development with a goal of bringing a new therapy to a completely underserved area of maternal fetal health.”

Data from the Phase 1 proof-of-concept study demonstrated that subcutaneous administration of RLYB212 produced a dose-dependent, rapid, and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both doses (0.09 mg and 0.29 mg) meeting the prespecified proof-of-concept criteria of ≥90% reduction in mean platelet elimination half-life as compared to placebo. These data along with a significant body of preclinical data generated to date were critical to the establishment of therapeutic exposure targets that Rallybio believes will safely and effectively prevent maternal alloimmunization to fetal antigen, the prerequisite event leading to FNAIT.

The bolus challenge of HPA-1a positive platelets was designed as a surrogate for a large 30 mL fetal-maternal hemorrhage. Platelet elimination profiles after subcutaneous administration of RLYB212 were consistent with those of Rhesus factor D (RhD)-positive erythrocytes after intramuscular administration of anti-RhD agents, which are well-established to safely and effectively prevent RhD alloimmunization during pregnancy. Consistent with previously reported data, RLYB212 was generally well-tolerated with no reports of serious or severe adverse events.

Rallybio is on track to initiate a Phase 2 dose confirmation trial in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT in the fourth quarter of 2024. The Company also continues to screen pregnant women in its ongoing FNAIT natural history study, which is designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population that can serve as a control arm for a planned Phase 3 trial.

About FNAIT
Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT) is a potentially life-threatening rare disease that can cause uncontrolled bleeding in fetuses and newborns. FNAIT can arise during pregnancy due to an immune incompatibility between an expectant mother and her fetus in a specific platelet antigen called human platelet antigen 1, or HPA-1.

There are two predominant forms of HPA-1, known as HPA-1a and HPA-1b, which are expressed on the surface of platelets. Individuals who are homozygous for HPA-1b, meaning that they have two copies of the HPA-1b allele and no copies of the HPA-1a allele, are also known as HPA-1a negative. Upon exposure to the HPA-1a antigen, these individuals can develop antibodies to that antigen in a process known as alloimmunization. In HPA-1a-negative expectant mothers bearing a HPA-1a-positive fetus, alloimmunization can occur upon mixing of fetal blood with maternal blood. When alloimmunization occurs in an expectant mother, the anti-HPA-1a antibodies that develop in the mother can cross the placenta and destroy platelets in the fetus. The destruction of platelets in the fetus can result in severely low platelet counts, or thrombocytopenia, and potentially lead to devastating consequences including miscarriage, stillbirth, death of the newborn, or severe lifelong neurological disability in those babies who survive. There is currently no approved therapy for the prevention or prenatal treatment of FNAIT.

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, our expectations regarding the usefulness of data from our clinical studies and the FNAIT natural history study, and the timing of publications relating to FNAIT and RLYB212. 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 FNAIT natural history study, and the Phase 2 clinical trial for RLYB212, 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, 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, 2024, 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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