Rallybio Announces Initiation of Dosing in RLYB212 Phase 2 Clinical Trial

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– Key Data Readouts from Sentinel Participant Expected in 2Q 2025 and 3Q 2025 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Feb. 11, 2025-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today announced that the first participant has been dosed in the Phase 2 trial investigating RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and fetal and neonatal alloimmune thrombocytopenia (FNAIT). Pharmacokinetic (PK) and safety data from the second trimester are expected in the second quarter of 2025, with PK and safety data at the time of delivery expected in the third quarter of 2025.

"Dosing the sentinel participant in our RLYB212 Phase 2 trial marks a significant milestone for our RLYB212 program and for Rallybio," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "In addition to the assessment of safety, we are looking for the PK profile in the sentinel participant to demonstrate the ability of RLYB212 to achieve and maintain target concentrations throughout pregnancy. We plan to provide an update in the second quarter, as we continue to advance our mission to deliver a safe and effective therapeutic to prevent maternal alloimmunization and the potentially catastrophic consequences of FNAIT."

The single-arm Phase 2 dose confirmation trial (2024-512651-20/NCT06435845) is designed to assess the PK and safety of RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT. Secondary objectives include assessments of pregnancy and neonatal/infant outcomes, and the occurrence of emergent HPA-1a alloimmunization. Subcutaneous administration of RLYB212 is to be initiated by Gestational Week 16 and continued every 4 weeks through parturition.

The Phase 2 trial is designed to enroll participants in three stages: first with a sentinel pregnant woman, followed by an initial cohort (Cohort 1) that will include three pregnant women, and then a second cohort (Cohort 2) that will include four pregnant women, for a total target enrollment of eight participants. A data review for participants and infants is planned prior to the initiation of each cohort. The trial will seek to enroll participants at sites in Europe.

About RLYB212
RLYB212 is a subcutaneously administered monoclonal anti-HPA-1a antibody in development for the prevention of HPA-1a alloimmunization in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT. RLYB212 is designed to rapidly eliminate HPA-1a positive fetal platelets from a pregnant woman's circulation, thereby preventing maternal HPA-1a alloimmunization. Prevention of maternal alloimmunization eliminates the risk of FNAIT in the fetus.

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 needs 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, a C5 inhibitor 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 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 disclosure of preliminary PK and safety data for the sentinel participant in the RLYB212 Phase 2 trial, and whether RLYB212 will be an effective therapeutic approach for FNAIT. 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 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 September 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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