Rallybio Announces Publication of Target-Mediated Drug Disposition Modeling and Simulations Informing the RLYB212 Dosing Regimen in Pregnant Women

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—Dosing Regimen to be Evaluated in Recently Initiated RLYB212 Phase 2 Clinical Trial —

NEW HAVEN, Conn.--(BUSINESS WIRE)--Nov. 27, 2024-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today announced the publication of a manuscript titled, "Informing Pregnancy Dose via Target-Mediated Drug Disposition Modeling and Simulations for a Recombinant Human Monoclonal Antibody," in a special pregnancy themed issue of *Clinical Pharmacology and Therapeutics: Pharmacometrics & Systems Pharmacology*.

"Selecting a dose to ensure the safety of participants in any clinical trial is paramount, and not least for pregnant women and their developing babies. However, pharmacological research in pregnant women is limited, and few clinical pharmacology models incorporate the dynamic physiological changes during pregnancy," said Steven Ryder, MD, Chief Medical Officer of Rallybio. "The dose regimen identified through the modeling and simulation collaboration between Rallybio and our partners at Certara USA will now be evaluated in our recently initiated RLYB212 Phase 2 dose confirmation trial. Furthermore, this work is a meaningful step forward in using model-informed approaches to support not only the advancement of our RLYB212 program for prevention of maternal alloimmunization and fetal and neonatal alloimmune thrombocytopenia, or FNAIT, but also the development of monoclonal antibodies for use in pregnancy more broadly."

The manuscript details the target-mediated drug disposition (TMDD) model, which simultaneously characterized the pharmacokinetics of RLYB212 and introduces a novel parameter to describe the pharmacodynamics of HPA-1a-positive platelet elimination. Prior to performing dose regimen simulations, additional model parameters related to clearance, volume and intercompartmental transfer rates were incorporated into the TMDD model to account for dynamic physiological changes associated with pregnancy. The model was then used to perform simulations to inform the dosing regimen for the RLYB212 Phase 2 dose confirmation trial in pregnant women at higher risk of HPA-1a alloimmunization and FNAIT. The complete article can be accessed here.

Rallybio is developing RLYB212, a novel human monoclonal anti-HPA-1a antibody, to prevent alloimmunization in pregnant women and thereby eliminate the risk of FNAIT and its potentially devastating consequences in their fetuses and newborns. Rallybio recently announced the initiation of screening in its Phase 2 dose confirmation trial in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT (2024-512651-20/NCT06435845). The Company is also conducting a non-interventional FNAIT natural history study that is designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population. As of November 1, 2024, more than 13,000 pregnant women had been screened in this ongoing study.

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, 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 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 rationale for dose selection for the RLYB212 Phase 2 trial, and whether the models used by the Company will accurately identify the actual dosing regimen for RLYB212, including for the Phase 2 trial. 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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