Rallybio Announces Approval of Clinical Trial Applications for Phase 2 Trial of RLYB212 in Pregnant Women at Higher Risk of Alloimmunization and FNAIT

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—First Ever Trial in Pregnant Women at Higher Risk of Alloimmunization and FNAIT —

—Screening in the Phase 2 Clinical Trial On Track to Initiate in 4Q 2024 —

NEW HAVEN, Conn.--(BUSINESS WIRE)--Oct. 29, 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 approval of its clinical trial applications (CTAs) for a Phase 2 clinical trial of RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and fetal and neonatal alloimmune thrombocytopenia (FNAIT). With these approvals from the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), Rallybio will begin to activate Phase 2 clinical sites and expects to initiate screening of participants in the fourth quarter of 2024.

"Securing these CTA approvals from European health authorities to advance RLYB212 into a Phase 2 trial is a significant achievement. These approvals are a testament to the dedication and innovation of our team and our partners as we advance this first ever program to prevent maternal alloimmunization and FNAIT," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "We are activating clinical sites and expect to initiate screening this quarter, which will mark another important step toward achieving our mission to prevent FNAIT and its potentially devastating consequences."

The single-arm Phase 2 dose confirmation trial (2024-512651-20/NCT06435845) will be conducted in Belgium, the Netherlands, Norway, Sweden, and the UK, and is designed to assess the pharmacokinetics (PK) and safety of RLYB212, a monoclonal anti-HPA-1a antibody, in a total of eight 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 will be initiated by Gestational Week 16 and will continue every 4 weeks through parturition.

"These approvals recognize Rallybio's commitment to safely and effectively progress a novel prophylactic approach for preventing alloimmunization in pregnant women at higher FNAIT risk," said Steven Ryder, M.D., Chief Medical Officer at Rallybio. "We are proud to be leaders in bringing much needed innovation to this area of women's health, which has gone unaddressed for far too long."

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 activating sites and initiating screening for the Phase 2 RLYB212 clinical trial, and statements concerning Rallybio's ability to successfully complete the Phase 2 trial, advance to a Phase 3 trial and obtain marketing approval of 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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