# Rallybio to Present Results of Epidemiological Analysis Demonstrating FNAIT Risk Across Racially and Ethnically Diverse Populations at the American Society of Human Genetics 2024 Annual Meeting

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*– Results Indicate that FNAIT Risk is More Prevalent Than Previously Estimated –*

NEW HAVEN, Conn.--(BUSINESS WIRE)--Sep. 23, 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 full data from an epidemiological analysis quantifying the proportion of women across diverse populations at higher risk of a fetal and neonatal alloimmune thrombocytopenia (FNAIT)-impacted pregnancy will be presented at the American Society of Human Genetics (ASHG) 2024 Annual Meeting to be held November 5 – 9, 2024 in Denver, CO.

"With our Phase 2 trial of RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT on track to initiate in the fourth quarter of 2024, we continue our efforts to raise awareness of FNAIT and broaden the understanding of the population at risk for this potentially devastating disease," said Stephen Uden, MD, Chief Executive Officer of Rallybio. Dr. Uden continued, "Data from this analysis provide the first clear evidence of the extent to which ancestries beyond the Caucasian population can carry a higher risk for FNAIT, underscoring the importance of screening all pregnant women for FNAIT risk as part of standard prenatal care. This would ensure that all women at higher risk for FNAIT could then be offered prophylactic treatment with RLYB212, if approved."

The ASHG abstract #7041T, which can be found **here**, details the high-level findings of the epidemiological analysis. In this analysis, women at higher risk for alloimmunization and FNAIT were defined as those having an HPA-1a negative and HLA-DRB3*01:01 positive genotype. Allele frequencies were obtained from gnomAD v4 for HPA-1a and the U.S. National Marrow Donor Registry (NMDR) for HLA-DRB3*01:01.

Proportions of women at risk of alloimmunizing were highest in Caucasian populations, with the highest proportions in the Ashkenazi Jewish population (2.36% and 0.65% of women at risk and at higher risk, respectively), followed by non-Finnish Europeans (2.34% and 0.64%), Middle Eastern (2.25% and 0.62%), Amish (2.25% and 0.62%), White Hispanic (2.25% and 0.59%) and Finnish (2.03% and 0.56%). Additionally, women in some non-Caucasian population groups were also found to be at risk including the Caribbean Hispanic population (1.48% and 0.33%), followed by African / African American (1.13% and 0.28%). Women of South Asian, East Asian and Amerindigenous ancestries were found to have lower risk (<1.0% and <0.1%).

Taken together, these data indicate that the proportion of pregnant women at higher risk for FNAIT annually has been significantly underestimated. For example, in key geographies of North America and major European countries, it is estimated that more than 30,000 pregnancies each year are at higher risk for FNAIT, representing a 40% increase from prior estimates and translating into a commercial opportunity of $1.6 billion.

This analysis was conducted by Rallybio in partnership with HealthLumen, a leader in epidemiological modeling of rare genetic diseases. The poster will be available in the Publications & Presentations section of Rallybio's website following the conclusion of the conference.

**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 diversity of ancestries that carry the genetic markers for FNAIT, the increase in the number of pregnancies estimated to be at high risk of FNAIT each year based on the epidemiological analysis and our estimates of the number of pregnancies at higher risk of FNAIT, our ability to identify the number of pregnant women at higher risk of FNAIT based on the results of the analysis, our ability to ensure routine prenatal screening, 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 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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