Fierce Names Rallybio to the 2024 Fierce 50 List as an Innovation Honoree

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NEW HAVEN, Conn.--(BUSINESS WIRE)--Sep. 9, 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 Fierce Life Sciences and Fierce Healthcare has named Rallybio an Innovation Honoree as part of the 2024 Fierce 50 list. The Fierce 50 showcases 50 individuals and companies driving advancements in medicine, fostering innovation, and shaping the future of biopharma and healthcare.

“The annual Fierce 50 special report highlights individuals and companies that are driving progress in the pharmaceutical, healthcare and biotechnology industries,” said Ayla Ellison, Editor-in-Chief of Fierce Life Sciences and Healthcare. “These 50 outstanding organizations and people demonstrate excellence in their fields, and their commitment to innovation, equity and improving lives is truly commendable. Congratulations to this year’s honorees.”

Rallybio was co-founded in January 2018 by Martin Mackay, PhD, Jeffrey Fryer, CPA, and Stephen Uden, MD, recognized leaders from the biopharma industry. Rallybio’s team is dedicated to developing life-transforming therapies for patients with severe and rare diseases, with an initial focus on maternal-fetal health as well as diseases of complement dysregulation. The Company’s lead program is RLYB212, an anti-HPA-1a monoclonal antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), a potentially devastating disease that threatens more than 30,000 pregnancies each year.

“It is an incredible honor for Rallybio to be recognized as part of this year’s Fierce 50. This award is a testament to the important work our team is doing to combat FNAIT and bring new therapies to underserved areas of medicine,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio. “We look forward to continuing to tackle medicine's toughest challenges with new solutions, and through our lead program, moving forward in our mission to eliminate FNAIT and its devastating consequences.”

Rallybio is on track to initiate a Phase 2 trial in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT in the fourth quarter of 2024. In addition, Rallybio is currently conducting an 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 the planned Phase 3 trial. Pregnant women at higher risk for FNAIT can be identified through currently available laboratory screening tests.

The Fierce 50 is a constellation of the most brilliant visionaries and trailblazers, handpicked by the discerning editors of Fierce Biotech, Fierce Pharma and Fierce Healthcare. These individuals and companies are a driving force in healthcare delivery, drug development, research, and more. For more information about the Fierce 50, visit https://fierce50.fiercelifesciences.com/.

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 the RLYB212 Phase 2 trial, whether regulators will agree that the FNAIT natural history study data will be an adequate control arm for a RLYB212 Phase 3 trial, and the potential success of our pipeline. 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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