Rallybio Announces Collaboration to Advance Therapeutic Solutions for Pregnant Individuals at Risk of Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT)

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- Rallybio to Receive Funding for FNAIT Awareness Initiative and Equity Investment from Johnson & Johnson -

NEW HAVEN, Conn.--(BUSINESS WIRE)--Apr. 10, 2024-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases, today announced a collaboration with Johnson & Johnson[1] to support the development of complementary therapeutic approaches aimed at reducing the risk of fetal and neonatal alloimmune thrombocytopenia (FNAIT). In addition, Rallybio received an equity investment of $6.6 million from Johnson & Johnson Innovation – JJDC, Inc.

Rallybio is developing RLYB212, a novel human monoclonal anti-HPA-1a antibody designed to prevent pregnant individuals from alloimmunizing[2], thereby eliminating the risk of FNAIT and its potentially devastating consequences in their fetuses and newborns. Rallybio is on track to initiate a Phase 2 dose confirmation study for RLYB212 in pregnant individuals at higher risk of alloimmunization and FNAIT in the second half of 2024.

Under this collaboration, Johnson & Johnson will provide funding for Rallybio to raise awareness of Johnson & Johnson's FNAIT clinical program in connection with Rallybio's ongoing FNAIT natural history study. Rallybio is also eligible to receive additional payments under the collaboration.

RLYB212 is the only investigational therapy currently reported to be in clinical development to address the needs of pregnant individuals at risk of FNAIT who have not alloimmunized[2]. Johnson & Johnson is conducting a Phase 3 study of nipocalimab, an investigational monoclonal antibody targeting FcRn, in pregnant individuals who are already alloimmunized. As these individuals have the alloantibodies that can cause FNAIT, preventative treatment with RLYB212 would not be appropriate.

"We are thrilled to be working with Johnson & Johnson on our mission to eliminate FNAIT," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Our complementary approaches, if successful, would ensure that pregnant individuals at risk of developing FNAIT have a potential treatment option – regardless of their alloimmunization status. Together, we can more effectively and expeditiously drive awareness of FNAIT, emphasize the importance of screening pregnant individuals for their risk of developing FNAIT, and advance our complementary therapeutic approaches."

Rallybio is currently conducting a natural history study designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population that is intended to support a future RLYB212 registration study. Pregnant individuals who are already alloimmunized are not eligible for inclusion in Rallybio's natural history study, nor for potential preventative treatment with Rallybio's investigational therapeutic, RLYB212.

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 platelet antigen. When alloimmunization occurs in an expectant mother, the 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 initiation of the Phase 2 dose confirmation study for RLYB212, the release of screening numbers of women in the natural history study, and whether the results of the natural history study and the planned Phase 2 dose confirmation study will be sufficient to support design and implementation of a Phase 3 registrational study for 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 studies, and complete such clinical studies 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 Annual Report on Form 10-K for the period ended December 31, 2023, 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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[1] FNAIT Collaboration Agreement between Momenta Pharmaceuticals, Inc., a Johnson & Johnson Company, and Rallybio IPA, LLC.

[2] Alloimmunizing: an immune response to foreign antigens upon exposure to genetically different cells or tissues

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