Rallybio Announces Publication of Data Highlighting the Ability of HPA-1a-Specific Antibodies to Prevent Alloimmunization in an Authentic Mouse Model of FNAIT

December 15, 2022 at 8:00 AM EST

-- Data Demonstrates that HPA-1a Alloimmunization can be Prevented with Prophylactic Administration of Low Levels of HPA-1a-specific Antibodies --

NEW HAVEN, Conn.--(BUSINESS WIRE)--Dec. 15, 2022-- Rallybio Corporation (Nasdaq: RLYB) today announced publication of preclinical study results for two human HPA-1a-specific antibodies in development for the prevention of FNAIT. The results demonstrate that low doses of the two HPA-1a-specific antibodies, the polyclonal candidate RLYB211 and the monoclonal candidate RLYB212, are equally effective at rapidly clearing HPA-1a-positive platelets from circulation and preventing alloimmunization to HPA-1a. As expected, prophylactically blocking HPA-1a alloimmunization prevented the onset of FNAIT. These results also establish the concentration-effect relationship and threshold exposure targets for effective prophylactic treatment with HPA-1a specific antibodies to prevent FNAIT. The findings were published in the journal *Blood*, the official journal of the *American Society of Hematology.*

FNAIT is a rare, life-threatening bleeding disorder where maternal alloantibodies cross the placenta and lead to depletion of fetal platelets. There are no currently approved therapies for the prevention of FNAIT. In this study, a novel alloantigen-specific mouse model developed by the senior author Dr. Peter J. Newman, Blood Research Institute at the Versiti Blood Center of Wisconsin, was used to examine the efficacy of prophylactic treatment regimens of RLYB211 and RLYB212, Rallybio's two therapeutic candidates for the prevention of FNAIT.

Results showed:

- Both RLYB211 and RLYB212 were equally effective at driving rapid and complete elimination of HPA-1a positive platelets from circulation and preventing the development of HPA-1a alloantibodies.
- HPA-1a negative female mice that were treated prophylactically with anti-HPA-1a antibody prior to exposure to HPA-1a positive platelets gave birth to HPA-1ab pups with significantly improved platelet counts and no bleeding symptoms.
- The threshold effect for rapid and complete elimination of HPA-1a positive platelets is achieved at circulating anti-HPA-1a antibody concentrations estimated to bind as little as ~10% of antigen, consistent with the clinical prophylactic treatment paradigm established for anti-Rhesus D (anti-RhD) to prevent Hemolytic Disease of the Fetus and Newborn (HDFN).

Rallybio also announced today the publication of an editorial in the same issue of *Blood*, "Protecting the fetus from FNAIT," by John W. Semple and Rick Kapur. The editorial compares FNAIT to HDFN, a disease which has drastically reduced in incidence following the introduction of prophylactic administration of anti-RhD, and suggests that the results reported by Zhi et al. provide proof-of-concept that prophylactic administration of HPA-1a-specific antibodies could be similarly effective at preventing anti-HPA-1a alloimmunization in pregnant women at risk for FNAIT.

"These preclinical results continue to support that administration of HPA-1a specific antibodies has the potential to effectively prevent HPA-1a alloimmunization in pregnant women who are at risk of developing fetal and neonatal alloimmune thrombocytopenia. We now look forward to discussing data from our Phase 1b proof-of-concept study for RLYB212, our monoclonal candidate, in the first quarter of 2023," said Róisín Armstrong, Ph.D., Rallybio's RLYB212 Program Lead.

"It is very gratifying to have this study featured in Blood with an accompanying commentary by leaders in the transfusion medicine community," added Peter J. Newman, Ph.D. "I believe our partnership with Rallybio has allowed us to advance our basic and translational studies into the clinic in a way that was previously not possible."

About Rallybio

Rallybio is a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases. Since its launch in January 2018, Rallybio has built a portfolio of promising product candidates, which are now in development to address rare diseases in the areas of hematology, immuno-inflammation, maternal fetal health, and metabolic disorders. The Company's mission is being advanced by a team of highly experienced biopharma industry leaders with extensive research, development, and rare disease expertise. Rallybio is headquartered in New Haven, Connecticut, with an additional facility at the University of Connecticut's Technology Incubation Program in Farmington, Connecticut. For more information, please visit **www.rallybio.com**.

Forward-Looking Statements

This press release contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to management. 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 ability of RLYB212 and RLYB211, and the prophylactic administration of HPA-1a-specific antibodies, to clear platelets and prevent alloimmunization in pregnant women, and the anticipated threshold effect for rapid and complete elimination of HPA-1a positive platelets compared to the clinical prophylactic treatment paradigm established for anti-RhD to prevent HDFN. 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 ongoing and future clinical trials for

RLYB212 for the prevention of FNAIT, 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, 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, 2022, 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. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20221214006018/en/

Investors
Ami Bavishi
Head of Investor Relations and Corporate Communications
475-47-RALLY (Ext. 282)
abavishi@rallybio.com

Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannah.deresiewicz@sternir.com

Media
Tara DiMilia
908-369-7168
Tara.dimilia@tmstrat.com

Source: Rallybio Corporation