Rallybio Announces In-Licensing of Potential First-In-Class Preclinical Antibody Candidate from Sanofi

May 10, 2022

--Expands pipeline focus on rare benign hematological disorders--

--Licensing agreement marks first business development transaction since IPO--

NEW HAVEN, Conn.--(BUSINESS WIRE)--May 10, 2022-- 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 that it has obtained worldwide exclusive rights to Sanofi's KY1066, which will be referred to as RLYB331 going forward, a preclinical potentially first-in-class antibody. RLYB331 has the potential to address a significant unmet need for patients with severe anemia with ineffective erythropoiesis and iron overload, such as beta thalassemia (BT) and a subset of myelodysplastic syndromes (MDS), amongst others. The transaction expands Rallybio's pipeline, is strategically consistent with Rallybio's existing focus on hematology, and aligns with its mission to accelerate the development of life-transforming therapies for patients with severe and rare disorders.

"With our strong focus on portfolio expansion, the in-licensing of RLYB331, our first as a public company, marks a pivotal moment for Rallybio. We believe RLYB331 is differentiated from all programs in clinical development based on its mechanism of action, with the potential to be first-in-class. We expect that RLYB331 may address a significant unmet need by correcting ineffective erythropoiesis, improving hemoglobin, reducing red blood cell transfusions and reducing iron overload in multiple hematological disorders such as beta thalassemia and myelodysplastic syndromes," said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. "This product candidate is a natural fit with our R&D expertise and our focus on hematological disorders. Along with our existing pipeline it provides an additional opportunity to leverage our deep expertise in rare diseases and to identify and accelerate the development of transformative therapies for patients with severe and rare diseases. We look forward to integrating RLYB331 into our portfolio and ultimately deliver this therapy to transform the treatment of patients with severe benign hematological disorders."

RLYB331 is a monoclonal antibody that inhibits Matriptase-2 (MTP-2). The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. The standard of care for many such hematological disorders leaves a significant unmet need in iron overload associated anemias with patients experiencing significant morbidity and consequent mortality.

Rallybio plans to prosecute preclinical activities for RLYB331 including CMC, and dose-range finding and toxicity studies, which will then support transition of the asset into clinical development.

Under the terms of the license agreement, Rallybio will make an upfront cash payment of $3 million to Sanofi, in addition to development and commercial milestones, and mid to high single digit royalties on net sales.

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 currently available information. 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 potential of RLYB331 to address an unmet need for patients with multiple iron overload associated severe anemias, our ability to successfully integrate RLYB331 into our portfolio, and whether our anticipated preclinical activities will support transition of RLYB331 to clinical development. 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 1 and 1b clinical trials for RLYB212 and the Phase 1 study for RLYB116, 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 identify new product candidates and successfully acquire such product candidates from third parties, 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, 2021, 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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