

NOVEMBER 2024

Rallybio Corporation

Rallybio

R

Forward-Looking Statements

This presentation contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this presentation are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "seek," "goal," "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 include, but are not limited to, statements concerning: the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding our clinical development plan for RLYB212; the timing of initiation and completion of our Phase 2 dose confirmation clinical trial for RLYB212, and the natural history study for our FNAIT prevention program, and the period during which the results of the trials will become available; the success, cost and timing of the clinical development of our product candidates; the potential clinical effects and benefits of RLYB212 and RLYB116; whether the results of the natural history study and the planned Phase 2 trial will be sufficient to support design and implementation of a Phase 3 registrational study for RLYB212; whether the manufacturing work for RLYB116 will result in the desired effects; our ability to more accurately identify the number of pregnant women at higher risk of FNAIT; the timing of publications relating to FNAIT and RLYB212; whether our conclusions from the RLYB116 biomarker work will be consistent with actual clinical results; the timing of achieving milestones in 2024 for our preclinical programs; our ability to compete with companies currently marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including FNAIT; our estimates of the market opportunity for RLYB212, and the size and growth potential of the markets for RLYB212 and RLYB116 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets; our ability to successfully develop screening tests for FNAIT, and whether such tests will be accepted in routine prenatal guidelines; our ability to retain and recruit key personnel; our expectations regarding government and third-party payor coverage and reimbursement; our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing; our ability to successfully identify and implement alternative and acceptable options to further advance our programs; the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships; and our cash runway and our financial performance. The forward-looking statements in this presentation are only predictions and are based largely on management's current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this presentation 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, competition from other biotechnology and pharmaceutical companies, and those risks and uncertainties described in our filings with the Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in our Form 10-Q for the period ending September 30, 2024, and any subsequent filings with the SEC.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. 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 herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Rallybio: Translating scientific advances into transformative therapies for patients with devastating rare diseases

Lead program aimed at preventing a devastating rare disease in babies

RLYB212 Phase 2 clinical trial initiated in 4Q 2024

Proven innovators in rare disease R&D

Track record of success in the global clinical development of therapies for patients with rare diseases

Strong financial position

\$75.1 million in cash and equivalents as of September 30, 2024, providing cash runway into mid-2026

Evaluating non-dilutive funding and partnering approaches for additional pipeline programs

Pipeline with significant potential for value creation

Molecule	Approach	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
RLYB212	Anti-HPA-1a Monoclonal Antibody	Prevention of FNAIT						
RLYB116	C5 Inhibitor Affibody®-ABD Fusion	Diseases of complement dysregulation						
RLYB114¹	C5 Inhibitor Pegylated Affibody®	Ophthalmological diseases of complement dysregulation						
RLYB332	Matriptase-2 Inhibitor Monoclonal Antibody	Diseases of iron overload and severe anemias						
ENPP1 Program	ENPP1 Inhibitor Small Molecule	Hypophosphatasia (HPP)						Partnership with Exscientia
Undisclosed		Undisclosed metabolic disease						Partnership with AbCellera

Seeking alternative options to further advance preclinical programs, including partnerships and other forms of non-dilutive financing

FNAIT: Fetal and neonatal alloimmune thrombocytopenia; **HPA-1a:** Human platelet antigen-1a; **C5:** Complement component 5; **ABD:** Albumin-binding domain; **ENPP1:** Ectonucleotide pyrophosphatase/phosphodiesterase 1

¹Rallybio and EyePoint Pharmaceuticals are conducting an evaluation to assess the viability of using EyePoint's delivery technology with Rallybio's C5 inhibitor

RLYB212

Anti-HPA-1a Antibody for
Prevention of Fetal and Neonatal
Alloimmune Thrombocytopenia
(FNAIT)



RLYB212 – The first potential therapy for the prevention of alloimmunization and FNAIT

Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT) is a rare condition in which a pregnant women's immune system attacks the platelets of her fetus, leading to potentially catastrophic outcomes in the baby

RLYB212, a monoclonal anti-HPA-1a antibody, is in clinical development as a subcutaneously (SC)-administered therapy to prevent the disease process in pregnant women that leads to FNAIT in the baby

Commercial market opportunity of \$1.6B+ in key markets, with >30,000 pregnancies estimated to be at higher risk of FNAIT each year

US and European Ob/Gyns and maternal-fetal specialists have:

- ✓ High awareness of FNAIT and its potentially catastrophic outcomes
 - ✓ High willingness to screen pregnant women for FNAIT risk
 - ✓ Strong interest in a preventative therapy
-

Collaboration with J&J to further raise awareness of FNAIT and J&J's complementary therapeutic approach aimed at mitigating FNAIT in pregnant women who are not eligible for preventative treatment with RLYB212



RLYB212 is designed to prevent pregnant women from alloimmunizing, thereby eliminating the risk of FNAIT in the baby

FNAIT is caused by a platelet antigen (HPA-1a) mismatch between the fetus and expectant mother

This can lead the mother to alloimmunize, i.e., develop antibodies to the fetal platelet antigen

These antibodies cross the placenta into the fetus and destroy platelets in the fetus

Destruction of fetal platelets can lead to intracranial hemorrhage (ICH) resulting in:

- Severe, life-long neurological disability
- Miscarriage or stillbirth
- Loss of the newborn

Pregnant women who are also HLA-DRB3*01:01 positive are at ~25-fold higher risk for alloimmunization



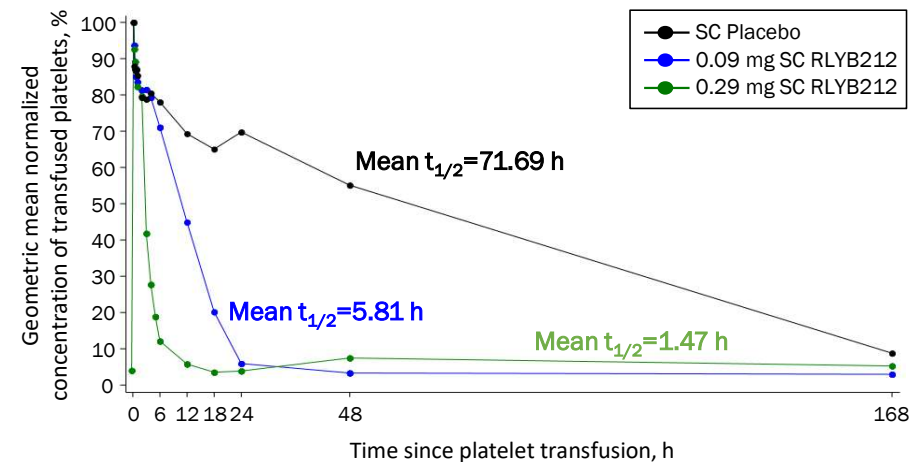
There are no approved therapies for the prevention or treatment of FNAIT and its potentially catastrophic consequences

RLYB212 is designed to prevent alloimmunization by rapidly eliminating mismatched fetal platelets from maternal circulation

PHASE 1b PROOF-OF-CONCEPT STUDY

- Eleven healthy HPA-1a-negative subjects randomized to receive RLYB212 0.09mg (n=4), RLYB212 0.29mg (n=5) or placebo (n=2) administered subcutaneously
- RLYB212 produced dose-dependent, rapid, and complete elimination of transfused HPA-1a positive platelets, achieving $\geq 90\%$ reduction in mean platelet elimination half-life in both dose groups vs. placebo
- RLYB212 was well-tolerated, with no reports of serious or severe adverse events
- Transfused platelet dose was designed to mirror a catastrophic bleed that could result in alloimmunization in pregnant women

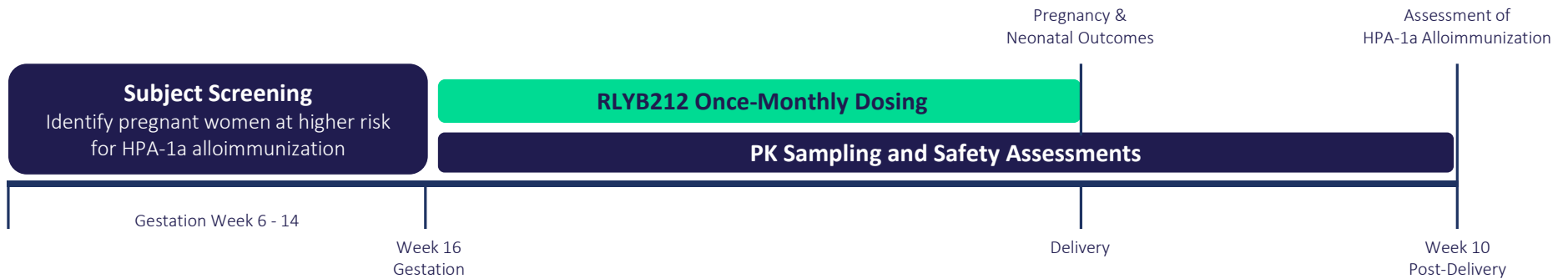
Platelet Elimination Through 7-Days Post-Transfusion



Platelet concentration was normalized at 100% for sample collected 10 minutes after platelet transfusion; SC, subcutaneous; $t_{1/2}$, platelet elimination half-life

RLYB212 demonstrated rapid and dose dependent elimination of transfused platelets

Phase 2 dose confirmation trial in pregnant women initiated in 4Q 2024



TRIAL DESIGN

- Phase 2 single-arm, open-label trial to assess the pharmacokinetics (PK) and safety of SC administered RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT¹ across sites in Europe
- Dosing initiated by Gestation Week 16 and continued at monthly intervals through delivery



PRIMARY OBJECTIVE

To assess the PK and safety of RLYB212



SECONDARY OBJECTIVES

To assess pregnancy outcomes, neonatal outcomes, and occurrence of emergent HPA-1a alloimmunization

¹Higher risk for alloimmunization and FNAIT defined as HPA-1a-negative, HLA-DRB3*01:01-positive pregnant women bearing an HPA-1a-positive fetus, with no existing alloimmunization

Ongoing natural history study is designed to increase our understanding of FNAIT and FNAIT risk



STUDY DESIGN

- Prospective, non-interventional, multinational natural history study across sites in US and Europe¹
- Screening pregnant women who present for Gestation Week 10 to 14 prenatal visit for higher risk of HPA-1a alloimmunization and FNAIT²

OBJECTIVES

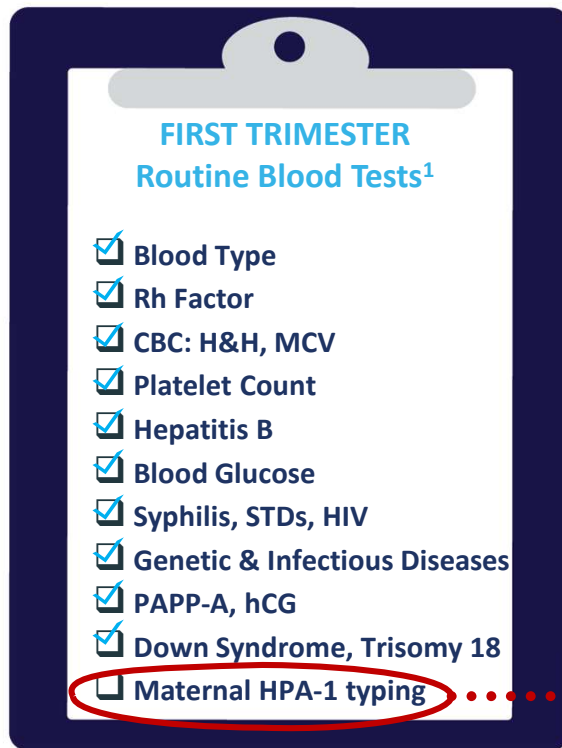
- Provide historical alloimmunization rate to serve as control dataset for planned single-arm Phase 3 registrational trial
- Obtain prevalence estimates of the FNAIT at-risk population, including racial and ethnic groups under-represented in published studies
- Establish operational scaffold for RLYB212 interventional studies, including implementation of lab tests to screen for higher FNAIT risk

Study is designed to provide a contemporary dataset for HPA-1a alloimmunization in a racially and ethnically diverse population

¹Targeting 20,000 – 30,000 pregnant women to be screened; ²Higher risk for alloimmunization and FNAIT defined as HPA-1a-negative, HLA-DRB3*01:01-positive pregnant women bearing an HPA-1a-positive fetus, with no existing alloimmunization

Screening tests to identify at-risk pregnant women can be integrated into routine prenatal care

Screening tests are already commercially available



**FIRST TRIMESTER
Routine Blood Tests¹**

- Blood Type
- Rh Factor
- CBC: H&H, MCV
- Platelet Count
- Hepatitis B
- Blood Glucose
- Syphilis, STDs, HIV
- Genetic & Infectious Diseases
- PAPP-A, hCG
- Down Syndrome, Trisomy 18
- Maternal HPA-1 typing



SCREENING PROCESS

- Low volume sample added to standard maternal blood typing panel
- Analyzed at reference labs and hospitals on existing equipment

If HPA-1a negative
(~2%² of pregnancies)

Additional testing to evaluate **HLA-DRB3*01:01 status**. If positive, referral to specialist as high-risk pregnancy³


¹ Summarized from ACOG Guidelines for Perinatal Care

² Estimate is based on a ~2% incidence of HPA-1a negative status

³ For pregnancies identified at higher FNAIT risk, physicians may conduct additional follow-up testing, e.g., maternal anti-HPA-1a antibody status, fetal HPA-1a genotype

Inclusion of screening in prenatal guidelines will facilitate the identification of at-risk pregnant women who can benefit from RLYB212

Criteria for Guideline Evaluations

 **Prevalence & Impact Data**

 **Preventive Therapeutic**

 **Validated Screen Test**

 **Cost Effectiveness Data**

Action Plan

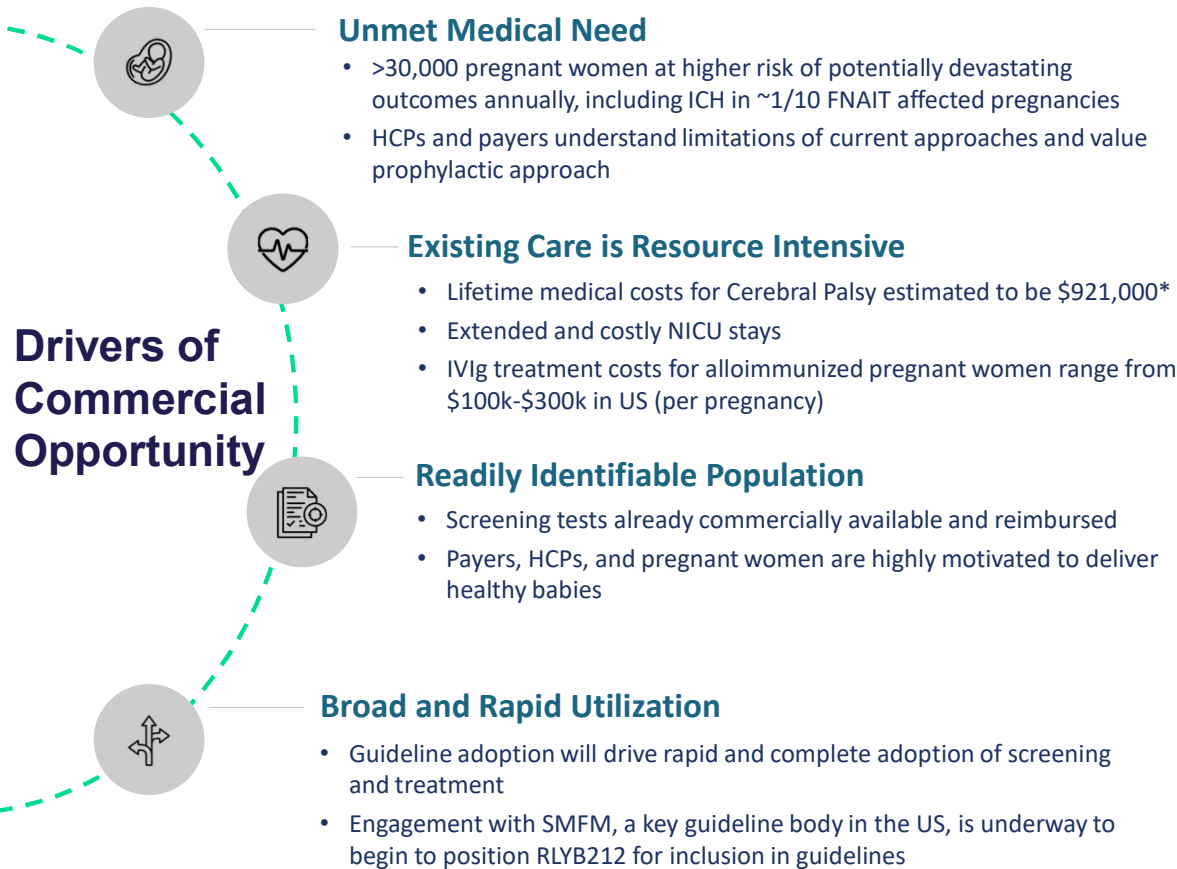
Natural History Study, Genomic Database Analysis

Phase 2 and Phase 3 Clinical Trial Data

Screen Test Readiness

HEOR Data Generation

RLYB212 represents a \$1.6B+ market opportunity



RLYB116

C5 Inhibitor for Treatment of
Complement-Mediated
Diseases



RLYB116 A novel, differentiated inhibitor of C5 for the treatment of complement-mediated diseases

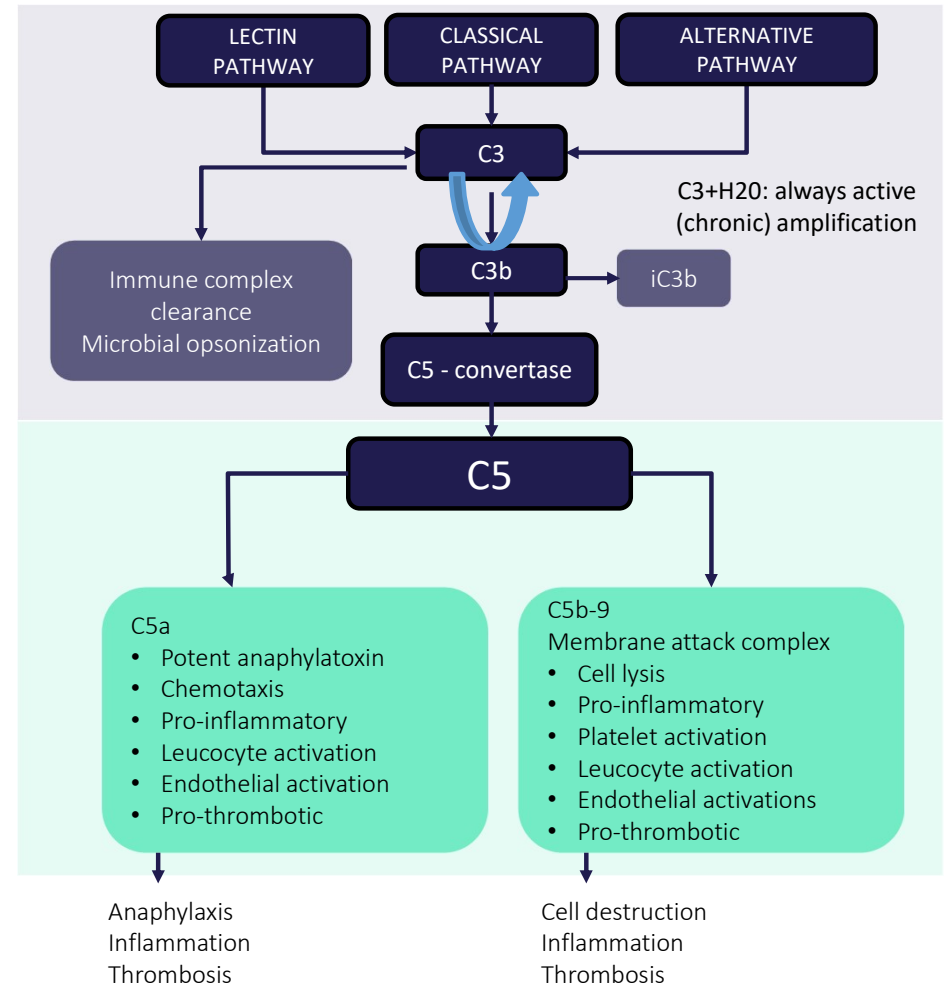
C5 is a proven therapeutic target with the potential to address a broad range of diseases

RLYB116 is an innovative therapeutic designed to meet patient demand for a once-weekly, self-administered, subcutaneously injected inhibitor of C5

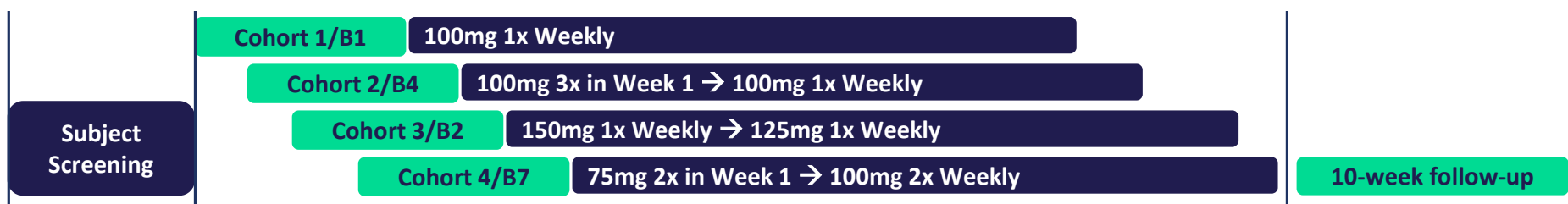
Phase 1 SAD/MAD data demonstrated significant reductions in free C5

RLYB116 can address significant unmet patient need in PNH, and APS, with a commercial potential of >\$4B in these two indications alone

Rallybio expects to provide updates on the manufacturing process enhancements and biomarker characterization as well as future plans for RLYB116 in December 2024



RLYB116 Phase 1 multiple ascending dose study designed to evaluate safety, tolerability, and free C5 inhibition



> STUDY DESIGN

Adaptive single-blind multiple ascending dose study evaluating a 4-week treatment duration, 5:1 assignment to RLYB116 or placebo, 12 participants in each of 4 cohorts, and a 10-week follow-up period

PRIMARY OBJECTIVE

To evaluate the safety and tolerability of RLYB116 in healthy participants following multiple dose administration

SECONDARY OBJECTIVES

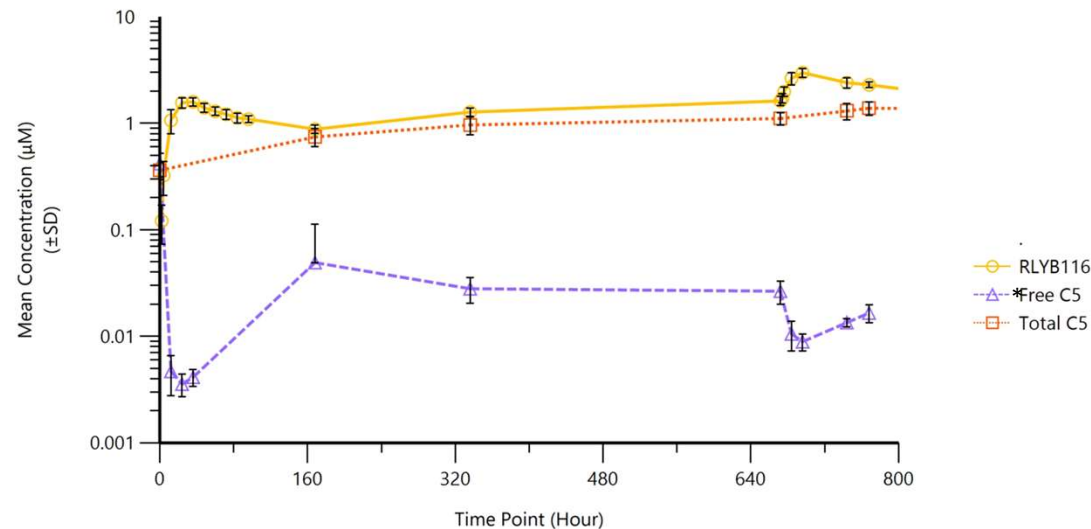
To characterize the pharmacodynamic, immunogenicity, and pharmacokinetic properties of RLYB116 following multiple dose administration

RLYB116 Phase 1 MAD data demonstrates significant free C5 reductions

PHASE 1 MULTIPLE ASCENDING DOSE STUDY

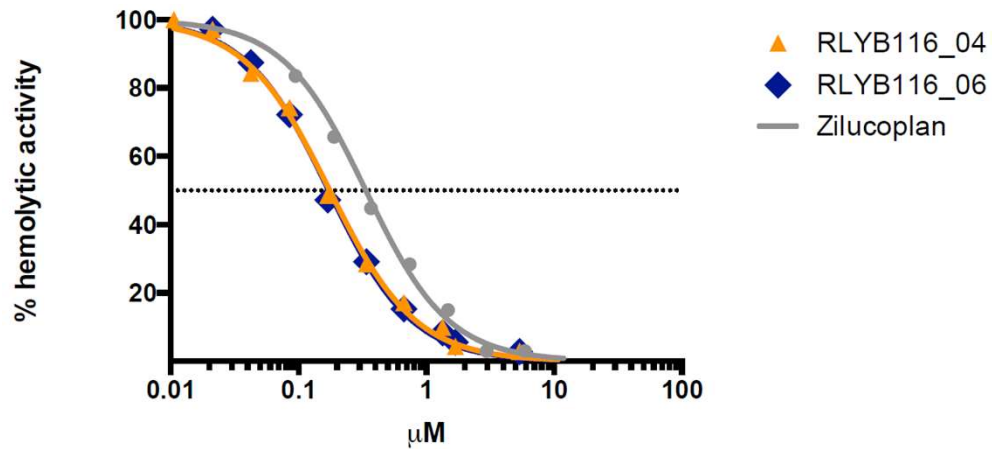
- RLYB116 administered at 100mg weekly SC resulted in free C5 reductions >99% at 24 hours and sustained reductions >93% at Day 29
- Increasing exposure to RLYB116 resulted in a higher ratio relative to total C5 and a greater reduction in free C5
- Achieved weekly doses of RLYB116 in excess of 100mg with mild adverse events
- No apparent impact of ADA formation on PK, PD, and safety data

Cohort 1 100mg Weekly Free C5 Reductions to Day 29



RLYB116 CH50 functional assay demonstrates lower IC50 than zilucoplan

Classical Complement Pathway Activity



	Zilucoplan	RLYB116_04	RLYB116_06
IC50	0.3368	0.1761	0.1722

- Study demonstrates that RLYB116 has similar effect to research-grade zilucoplan
- Conducted under matching conditions to zilucoplan published data (1% sera)¹

Preclinical Pipeline



Evaluating partnerships and other forms of non-dilutive financing to drive value for our preclinical pipeline

PROGRAM	RLYB114	RLYB332	ENPP1 INHIBITOR	UNDISCLOSED
	C5 Inhibitor for ophthalmic use	Long-acting MTP-2 inhibitor for treatment of diseases of iron overload and severe anemias	For treatment of Hypophosphatasia (HPP)	For rare metabolic disease
PARTNER	Research collaboration with EyePoint	N/A	Joint Venture with Exscientia	Collaboration with AbCellera
STATUS	Demonstrated feasibility for sustained delivery of Rallybio's C5 inhibitor using EyePoint's proprietary intraocular drug delivery technology	Generated nonclinical data demonstrating favorable tolerability, dose-dependent PK, and sustained PD effects, with best-in-class potential	Presented data from an early lead ENPP1 inhibitor in a model of later-onset HPP at ASBMR demonstrating reductions in PPI and improvements in bone mineralization	Antibody discovery
NEXT MILESTONE	Optimization work is ongoing	Nonclinical data to be presented at ASH Annual Meeting, Dec 7 – 10, 2024	Candidate nomination expected in December 2024	Advance discovery efforts to next research milestone

Translating scientific advances into transformative therapies for patients with devastating rare diseases

PILLARS OF OUR SUCCESS



Lead program aimed at preventing a devastating rare disease



Proven innovators in rare disease R&D



Strong financial position



Evaluating non-dilutive strategies to create value for preclinical assets

RECENT AND UPCOMING MILESTONES

Program	Milestone	Timing
RLYB212	Provide update on Phase 2 discussions with EMA	✓ 1H 2024
RLYB332	Report additional nonclinical data	✓ 1H 2024
RLYB212	Epidemiological analysis results assessing frequency of FNAIT risk	✓ Mid-2024
RLYB116	Complete manufacturing work	✓ 3Q 2024
RLYB212	Present full data from epidemiological analysis assessing frequency of FNAIT risk	✓ 4Q 2024
RLYB116	Present complement biomarker characterization data	4Q 2024
RLYB212	Initiate Phase 2 clinical trial	✓ 4Q 2024
ENPP1 Inhibitor	Candidate nomination	4Q 2024
RLYB212	Publication of Phase 1b proof-of-concept study data results	✓ 2H 2024
RLYB212	Publication of integrated data summary supporting Phase 2 dose	2H 2024

Rallybio

Rallybio

>30,000*

Are at higher risk for FNAIT each year where there is an HPA-1 mismatched fetus and the pregnant woman is:

- HLA-DRB3*01:01 positive
- HPA-1a antibody negative

(based on ~7M live births each year in the US, Canada, UK, major EU Countries, and Australia)

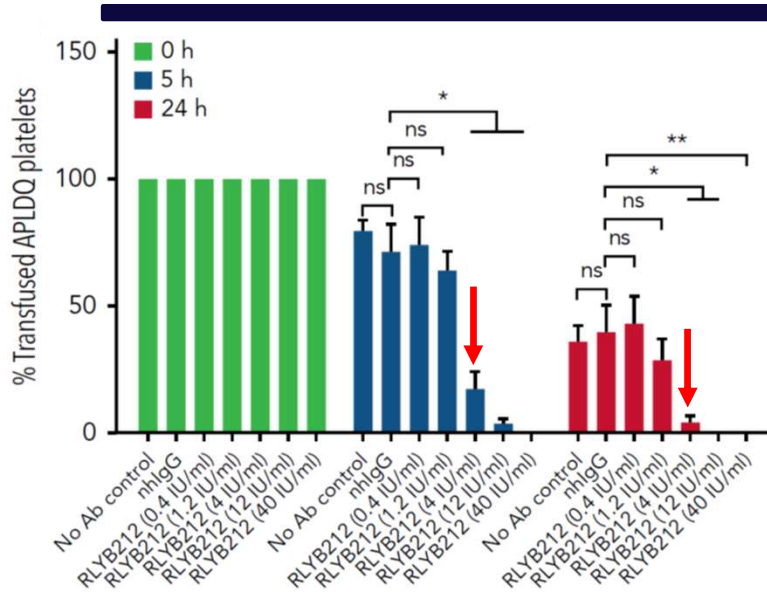
A significant number of pregnancies are at higher risk for FNAIT each year

US and European Ob/Gyns and maternal-fetal specialists have:

- ✓ High recognition of the catastrophic impact of FNAIT
- ✓ High awareness of the need for a preventative therapy
- ✓ Favorable response to RLYB212 target product profile

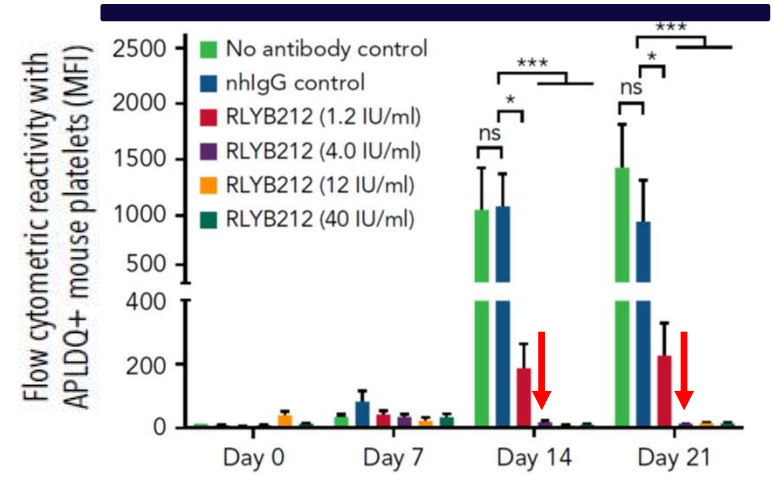
RLYB212 elimination of mismatched platelets correlates with prevention of alloimmunization in a preclinical model of FNAIT

PLATELET ELIMINATION



“APLDQ” mouse model recreates the fetal-maternal mismatch specific to the HPA-1a antigen

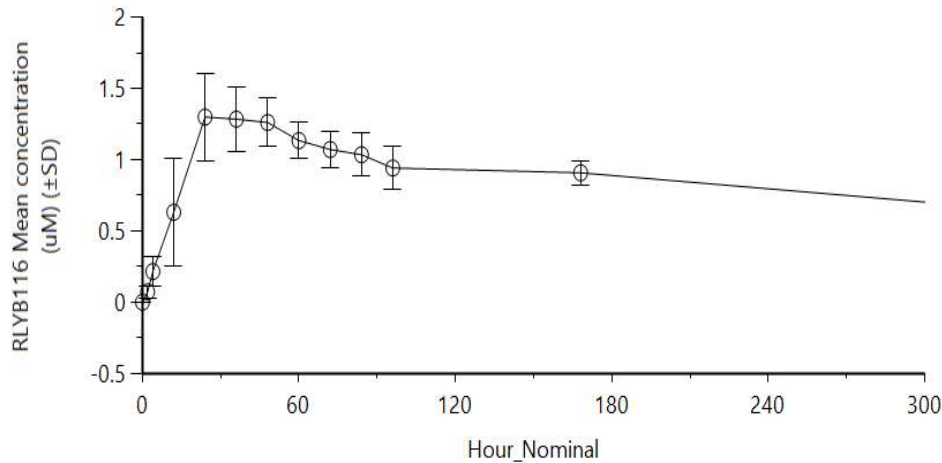
PREVENTION OF ALLOIMMUNIZATION



RLYB116 100 mg Cohort potential for rapid and complete inhibition of C5

RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) PK

Estimated T1/2 is > 300 hours



Subcutaneously administered RLYB116 was generally well-tolerated as a single 100 mg dose with mild adverse events and no serious adverse events reported¹

RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) Free C5 Data²

Participant	Baseline (ng/mL)	At 24 hours (ng/mL)	% reduction
1	91,300	503	99.4%
2	91,300	360	99.6%
3	84,600	562	99.3%
4	94,800	497	99.5%
5	100,000	733	99.3%
6	135,000	747	99.4%
Mean	99,500	567	99.4%

¹ Preliminary data from Phase 1 clinical study; ² Numbering for participants has been de-identified