



TAKING DEVASTATING DISEASES – AND DEVASTATING THEM.

We're going there.

March 2024

Rallybio

Corporate Presentation



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 clinical studies 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 our clinical development of our product candidates, including RLYB212 and RLYB116; the potential clinical effects and benefits of RLYB212 and RLYB116; our ability to initiate, recruit and enroll patients in and conduct our clinical studies at the pace that we project; the timing of providing an update on Phase 2 discussions with regulators; 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; the timing of completing the manufacturing work and an update on the development plan for RLYB116; the timing of disclosing additional preclinical data for RLYB331; our reliance on third parties to manufacture drug substance for use in our clinical trials; 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 expand our pipeline through collaborations, partnerships and other transactions with third parties; 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; 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 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-K for the period ending December 31, 2023, 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: Profoundly Transform the Lives of Patients

- **Diversified portfolio in rare diseases**
 - Announced prioritization of portfolio in February 2024 on Phase 2-ready clinical stage programs, RLYB212 and RLYB116
- **Proven innovators in rare disease R&D**
 - With extensive experience in product development and commercialization
- **Strong financial position and stewardship**
 - \$109.9 million in cash, cash equivalents and marketable securities as of December 31, 2023; revised operating plan provides cash runway into Mid-2026
- **Global business development expertise**
 - International perspective and relationships fostering diverse portfolio of novel programs





Diversified Portfolio in Rare Diseases, Rapid Advancement

Molecule	Therapeutic Area	Program	Approach	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Development Rights
RLYB212	Maternal Fetal Blood Disorders	Prevention of FNAIT	Anti-HPA-1a Monoclonal Antibody						Rallybio
RLYB116	Complement Dysregulation	Rare Diseases*	C5 Inhibitor: Affibody®-ABD Fusion						Rallybio
RLYB114**		Ophthalmology	C5 Inhibitor: Pegylated Affibody®						Rallybio
RLYB331	Hematology	Severe Anemia	Matriptase-2 Inhibitor; Monoclonal Antibody						Rallybio
ENPP1 Program	Metabolic Disorders	HPP	ENPP1 Small Molecule Inhibitor						Rallybio Exscientia
Undisclosed		Undisclosed	Undisclosed						Rallybio AbCellera

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

*Disease areas under consideration: hematology, including disorders such as paroxysmal nocturnal hemoglobinuria (PNH) and Antiphospholipid syndrome and neurology, including disorders such as generalized myasthenia gravis (gMG); ** Rallybio and EyePoint Pharmaceuticals are conducting an evaluation to assess the viability of using EyePoint's delivery technology with Rallybio's complement inhibitor; following the evaluation, the parties will determine whether to advance the collaboration, and EyePoint would assume development rights



RLYB212

Potential Preventative Treatment for
Fetal and Neonatal Alloimmune
Thrombocytopenia (FNAIT)



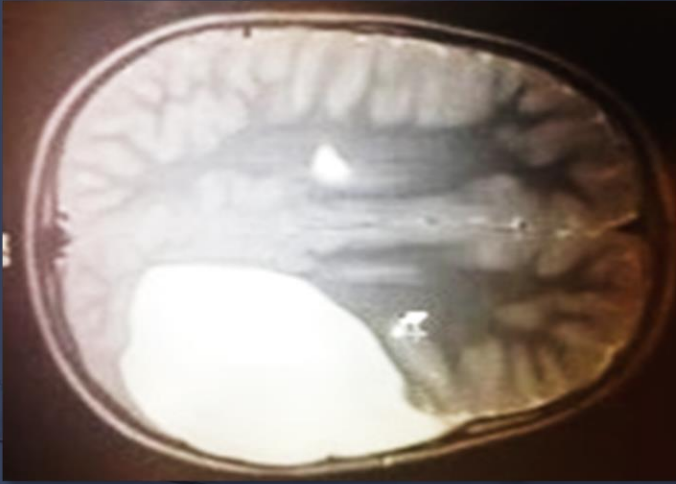
RLYB212: First Potential Novel Product Candidate for Prevention of FNAIT

Descriptive name	Fully human monoclonal anti-HPA-1a IgG
Mechanism of Action	Effect rapid elimination of fetal HPA-1a antigen from maternal circulation, thereby preventing alloimmunization
Route of Administration	Small volume, subcutaneous injection administered once monthly; compatible with patient friendly auto-injector for self-administration
Pharmacokinetic Profile	Limited peak-to-trough variation
Market potential	\$1B+ market opportunity >22,000* pregnancies at higher risk for FNAIT annually
Regulatory Designations	ODD (FDA, EMA) Rare Pediatric Disease Designation (FDA)
Key Intellectual Property	Composition of Matter patents 2035

*Based on 8M live births each year in the US, Canada, UK, major EU Countries, and Australia



FNAIT Impacts >22,000* Pregnancies Each Year with Catastrophic Effects



Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT) results from platelet antigen (HPA-1a) mismatch between expectant mother and fetus

No approved therapy exists for prevention or treatment of FNAIT, which is associated with intracranial hemorrhage (ICH) and:

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



US/European OB/GYNs and maternal/fetal specialists:**

- Are aware of catastrophic impact of FNAIT, need for preventative therapy
- Have a favorable response to RLYB212 target profile

Estimate is based on a ~2% incidence of HPA-1a negative status in the Caucasian population, where the prevalence has been well-characterized. Data from ongoing Natural History Study will inform incidence in non-Caucasians.

Based on 8M live births each year in the US, Canada, UK, major EU Countries, and Australia

*Source: NCHS National Vital Statistics Report Volume 68, Number 13, November 30, 2019, Births: Final Data for 2018; World Bank Population Data (2018); Kjeldsen-Kragh, et al Blood 2007; Hardy-Weinberg estimate; Kjeldsen-Kragh et al Blood 110, 833-839 (2007)

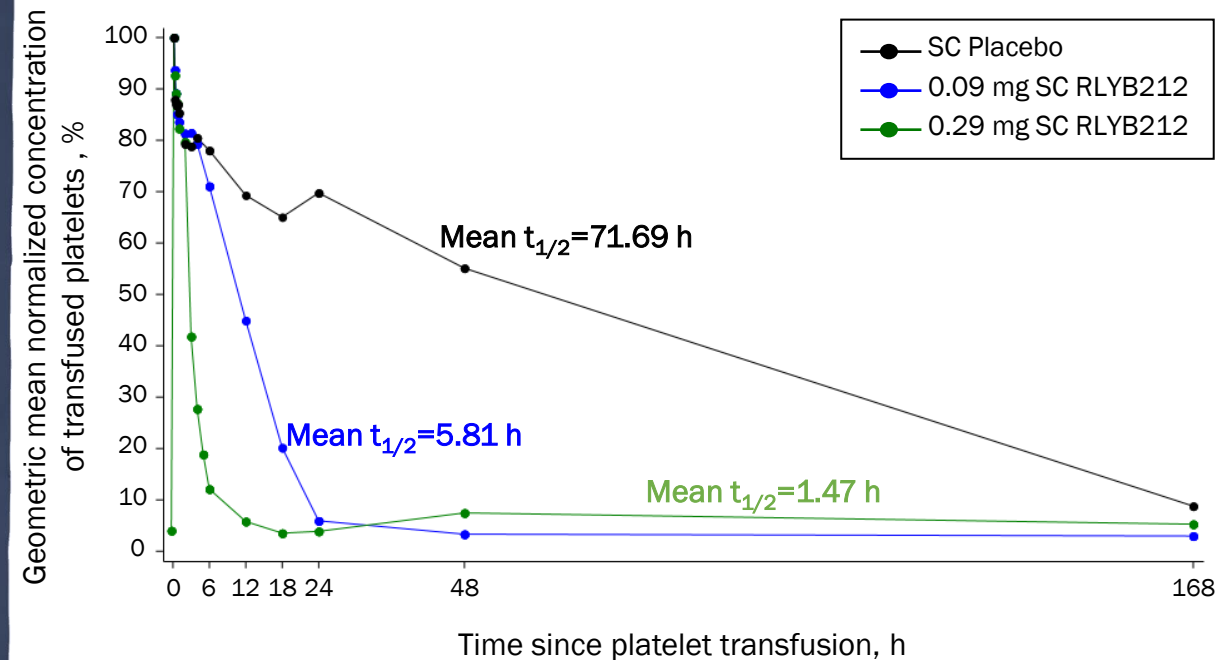
** Based on 2022 Rallybio market research study with 30 US and European HCPs and payers



Phase 1b Results: Rapid and Dose Dependent Elimination of Transfused Platelets

- Eleven healthy HPA-1a negative subjects randomized to RLYB212 0.09mg (n=4), RLYB212 0.29mg (n=5) or placebo (n=2)
- 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
- Transfused platelet dose was designed to mirror a catastrophic bleed that could result in alloimmunization in expectant mothers

PLATELET ELIMINATION 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 was observed to be well-tolerated with no reports of serious or severe adverse events

Geisen et al., Dose-Dependent Elimination of HPA-1a Platelets by Subcutaneous RLYB212, a Monoclonal Antibody to Prevent Fetal and Neonatal Alloimmune Thrombocytopenia. *International Society on Thrombosis and Haemostasis 2023 Congress, June 24-28, 2023. Abstract Presentation #OC 02.1*



Phase 2 Dose Confirmation Study in Pregnant Women

Expected to Start in 2H 2024

STUDY DESIGN

Single-arm, open-label study to assess the pharmacokinetics (PK) and safety of subcutaneously (SC) administered RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization

To be conducted at European sites

STUDY POPULATION/TREATMENT

HPA-1 a negative and HLA-DRB3*0101 positive pregnant women bearing an HPA-1a positive fetus, with no existing alloimmunization

Dosing of RLYB212 initiated by Gestation Week 16 and continued at monthly intervals through pregnancy

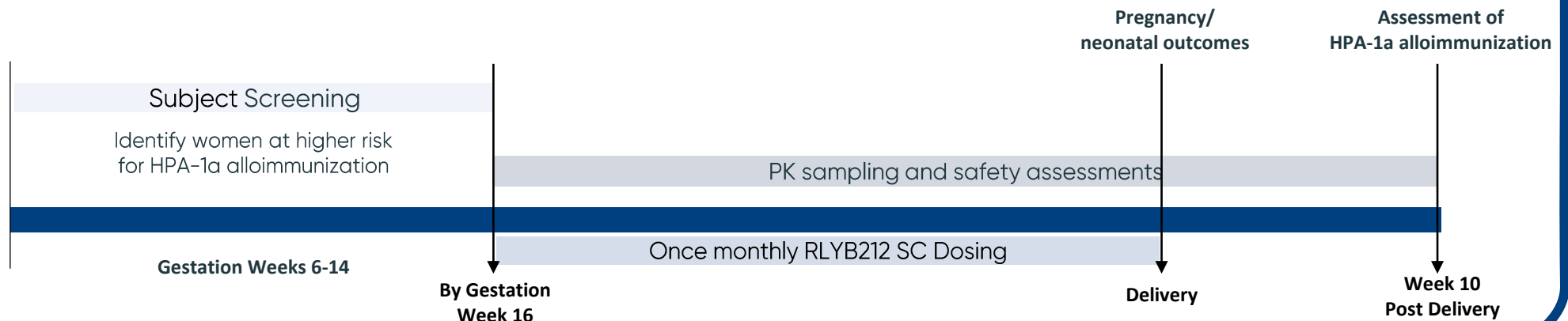
PRIMARY OBJECTIVE

To assess the PK and safety of SC RLYB212 administered antenatally in pregnant women

SECONDARY OBJECTIVES

To assess the safety of RLYB212 in the neonate and neonatal exposure of RLYB212 at time of birth

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



Study Design



FNAIT Natural History Study

To Be Continued in Parallel with Phase 2 Study

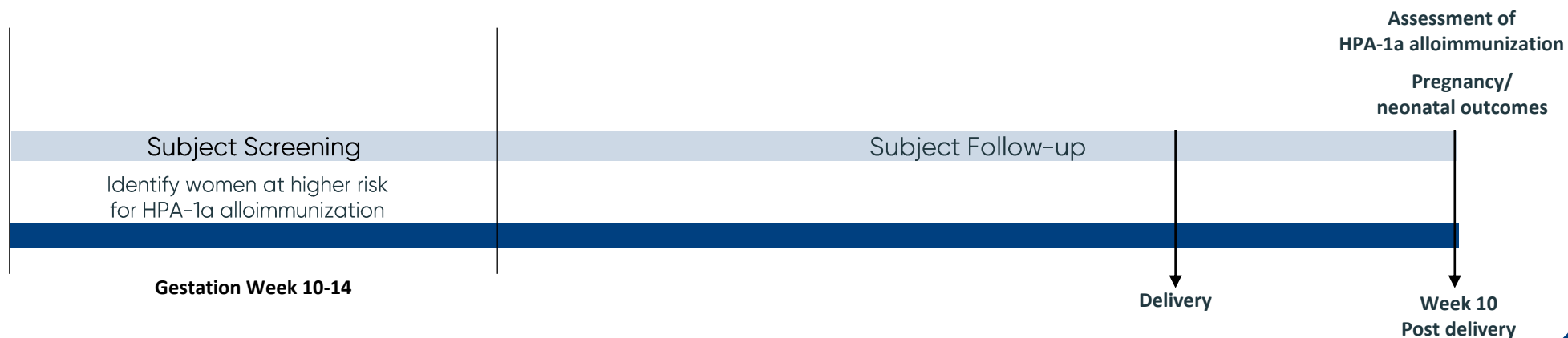
STUDY DESIGN

Prospective, non-interventional, multinational natural history study across ~ 30 sites in US/EU¹

Screen expectant mothers presenting for Gestation Week 10 to 14 prenatal visit for higher FNAIT risk (HPA-1a negative and HLA-DRB3*01:01 positive), with no prior HPA-1a alloimmunization and bearing a HPA-1a positive fetus)

OBJECTIVES

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



Study Design

1. ~20 - 30K to be screened



Screening Tests Are Commercially Available

Can be Validated in FNAIT and Integrated into Routine Prenatal Care

Existing
Routine
Blood
Tests*

FIRST TRIMESTER

- ☒ 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

FNAIT
Screening



SCREENING PROCESS

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

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

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

* Summarized from ACOG Guidelines for Perinatal Care

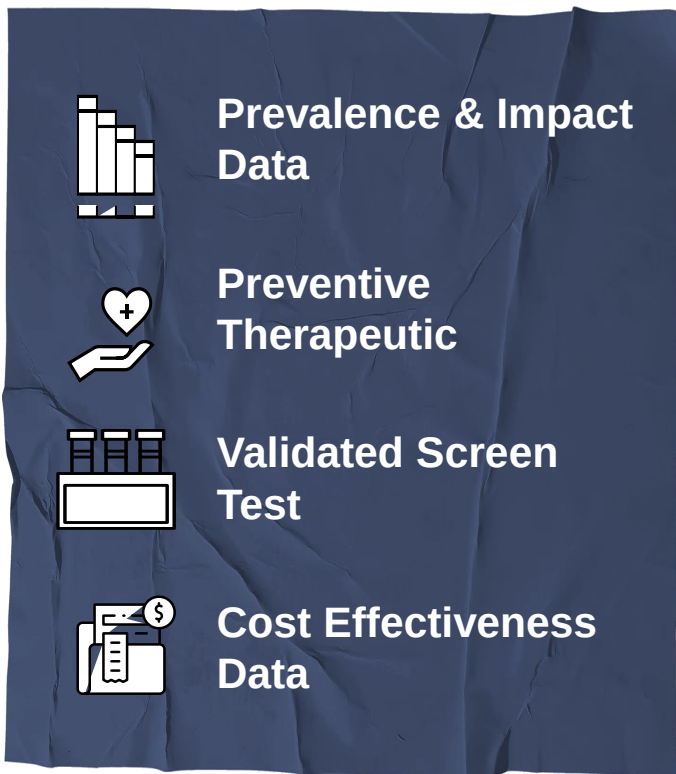
** Estimate is based on a ~2% incidence of HPA-1a negative status in the Caucasian population

*** 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



Rallybio Plans to Lead FNAIT Inclusion in Guidelines, Market Access

Criteria for Payer and Guideline Evaluations



Action Plan

Sci Advisors & Patient Advocacy

- Collaborate with top OB/GYN & MFM experts on development program
- Build relationships with patient advocacy organizations

Natural History & Ph 2 and Ph 3 Data

- Characterize diverse populations at higher FNAIT risk eligible for prophylactic treatment
- Establish effectiveness of screening through global Phase 3 program

Screen Testing Readiness

- Identify IVD partner to validate existing tests in Phase 3, provide low cost commercial HPA-1 screen test

Cost/Benefit Payer Insight

- Engage with payers to confirm data requirements for market access, support cost effectiveness evaluations

Publications & Guidelines Review

- Partner with FNAIT thought leaders to generate & disseminate data to support guideline and market access decisions

Feedback from international medical societies/KOLs suggests guidelines will support routine screening of pregnant mothers



RLYB116

RLYB114

C5 Inhibitors for the Potential Treatment
Diseases due to Complement
Dysregulation



Significant Experience in Complement Dysregulation

■ C5: A proven target

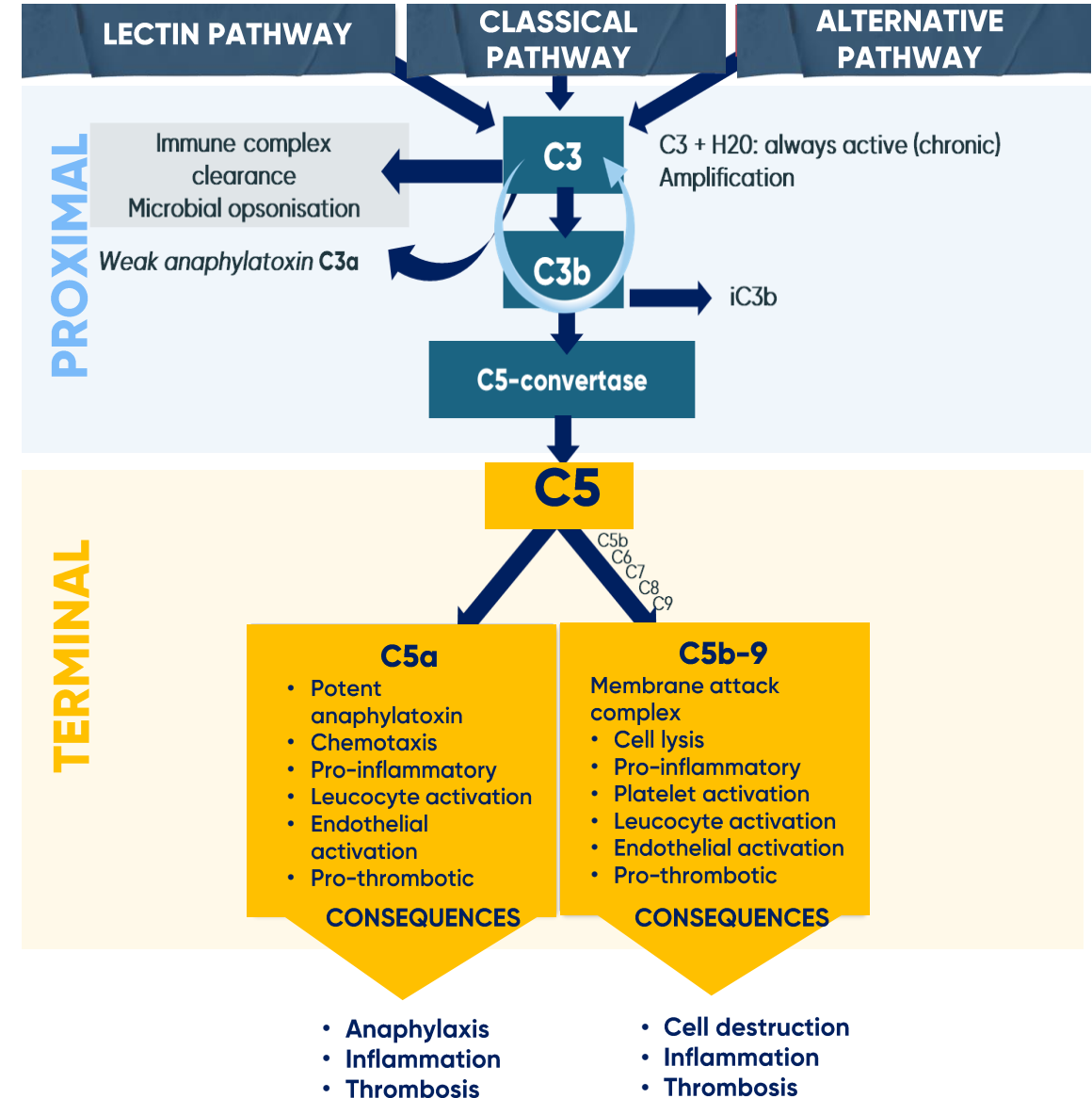
Advance inhibitors of C5 to offer high potency, less frequent dosing, and ease of use

■ Substantial unmet need

Introduce and expand use of complement inhibitors where dysregulation is a major factor

■ Clinical development pathways and commercial focus

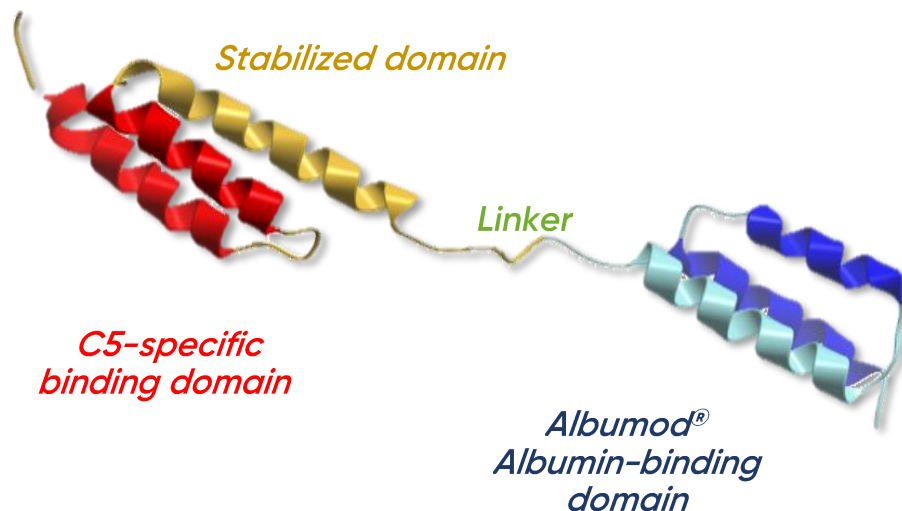
Deep global expertise based on prior design, development, approval of two C5 inhibitors in four rare disease indications





RLYB116: Potential Differentiators

Affibody® molecule



Treatment Goal: Rapid, complete, and sustained terminal complement blockade via C5 inhibition

- Subcutaneous low volume injection
- Suitable for autoinjector self-administration
- Less frequent, more convenient dosing
- Broad tissue distribution
- No drug-target-drug complex (DTDC) formation with switch from an antibody
- Efficiency of manufacturing
- Favorable storage stability
- Potential for pricing flexibility
- Broad indication opportunities

Potential RLYB116 clinical differentiators based on non-clinical research conducted by Rallybio and others



RLYB116 Phase 1 Multiple Ascending Dose Adaptive Study Design

STUDY DESIGN

Adaptive single-blind multiple ascending dose design with 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

STUDY COHORTS

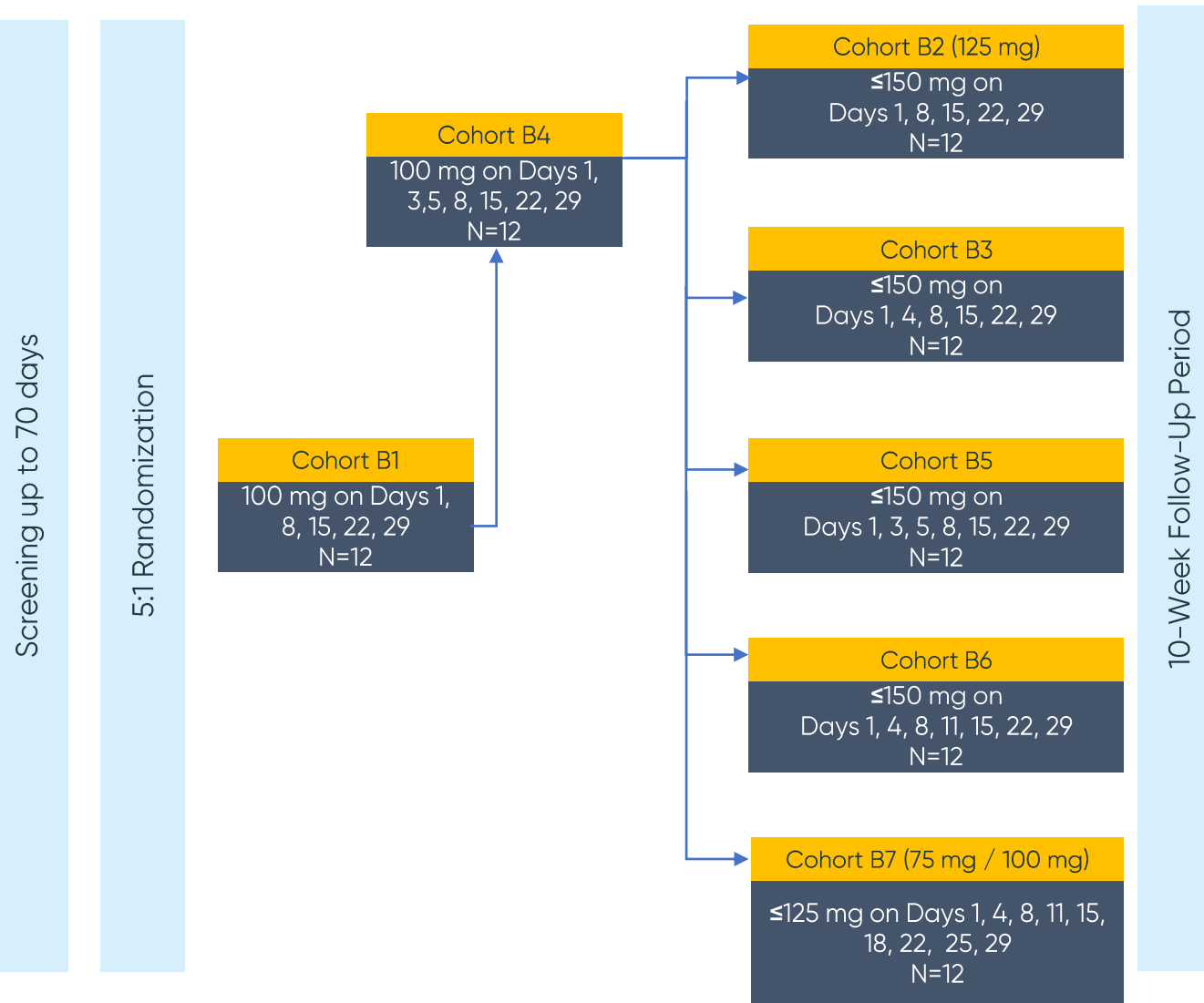
- Cohort 1/B1: weekly dosing of 100mg
- Cohort 2/B4: 3 doses of 100mg the first week then weekly dosing
- Cohort 3/B2: 150mg weekly dosing reduced to 125mg weekly dosing
- Cohort 4/B7: 75 mg twice the first week and then 100 mg twice per week

PRIMARY OBJECTIVE

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

SECONDARY OBJECTIVES

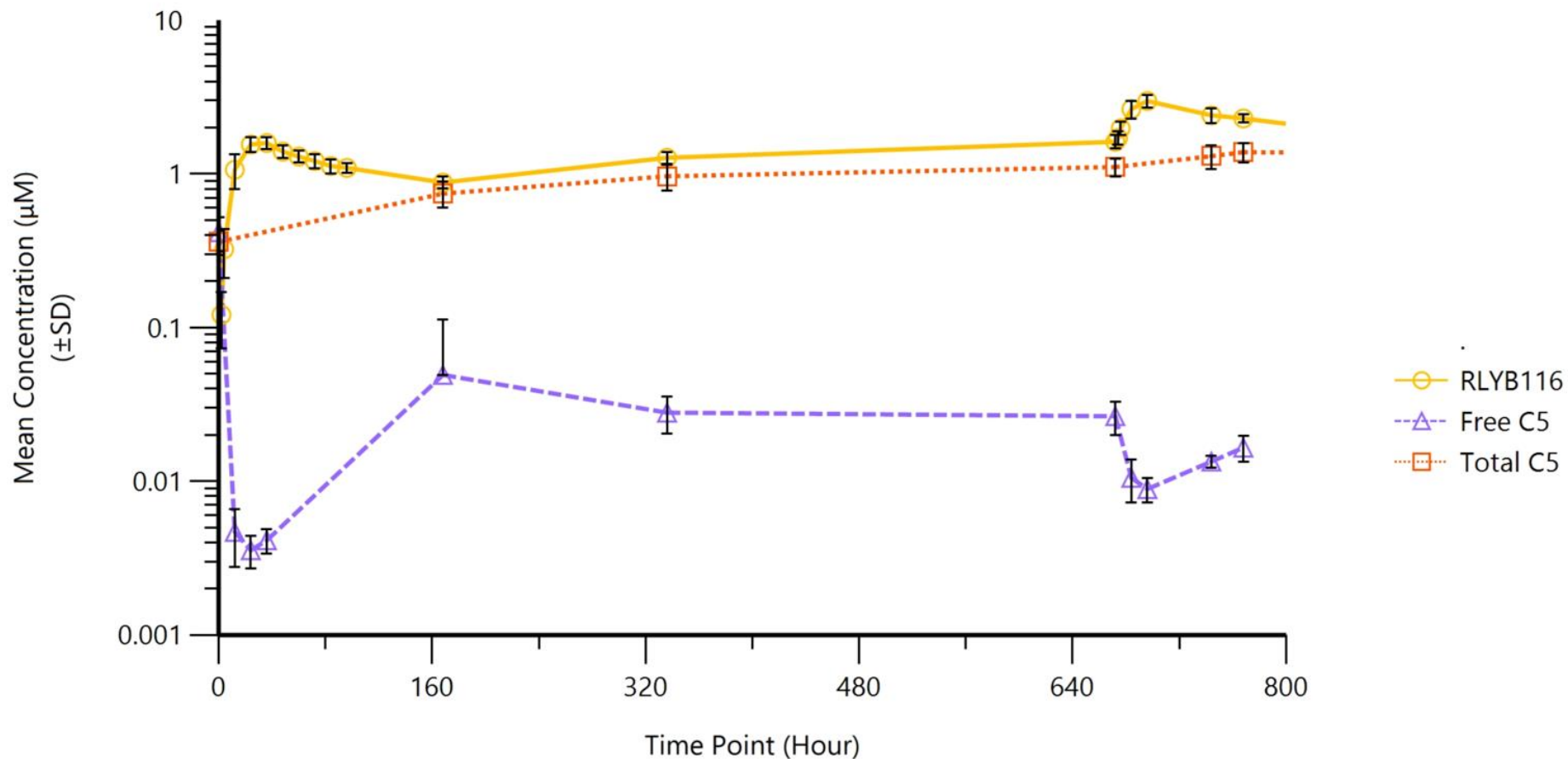
To characterize the pharmacodynamic, immunogenicity, pharmacokinetic properties of RLYB116 following multiple administration





RLYB116 FIH IPC2001 Cohort 1: 100 mg QW PK/PD Data

100 mg weekly sc dose resulted in reductions in free C5 > 99% at 24 hours and sustained reductions > 93% as measured pre-dose at Day 29

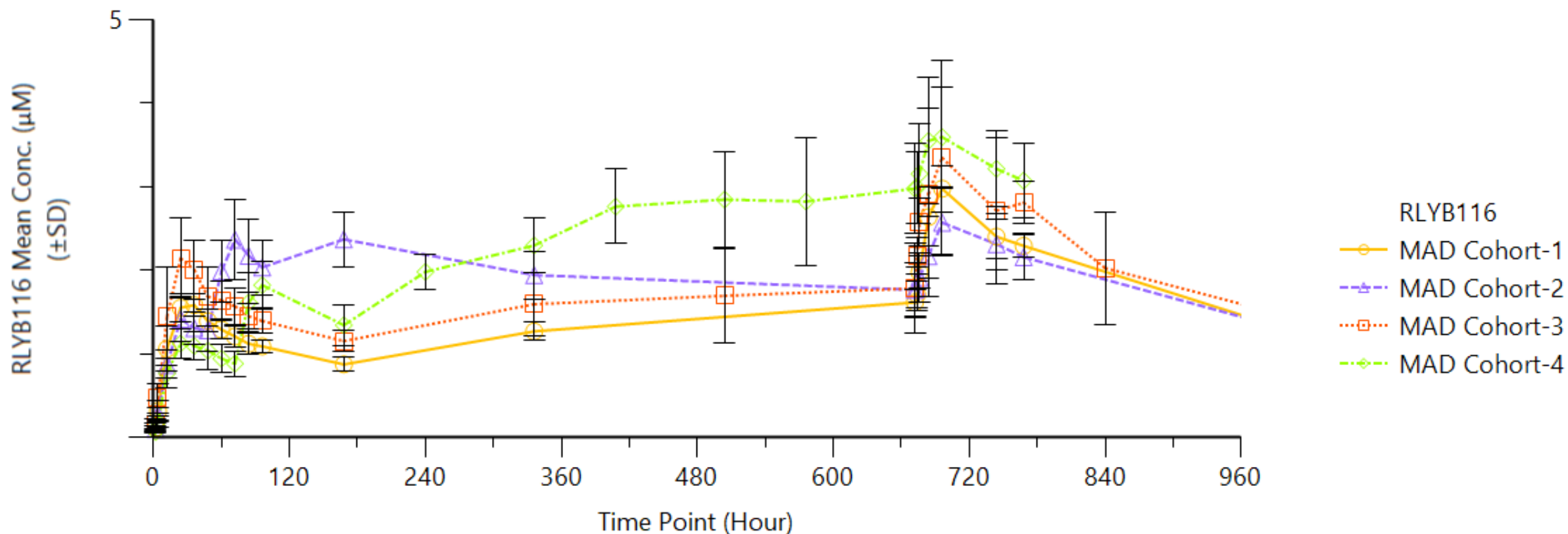


Source: Rallybio IPC2001 data



RLYB116 FIH MAD Pharmacokinetic Data

Sustained exposure greater than 1 μ M for all doses with low inter-subject variability with subcutaneous injection



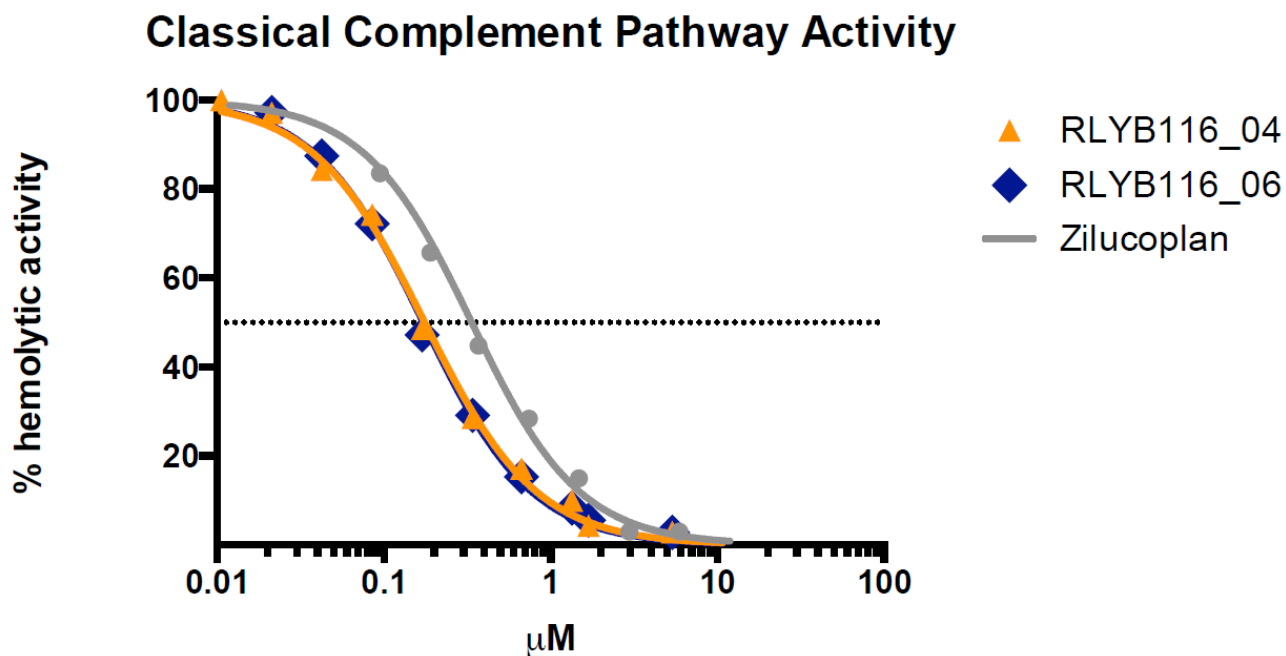
Injection site reaction was the most common adverse event in the MAD (all mild in severity).



RLYB116 CH50 Functional Assay with Lower IC50 than Zilucoplan

Conducted under matching conditions to Zilucoplan published data (1% sera)¹

Similar effect to research-grade Zilucoplan supportive for investigation of RLYB116 in gMG



	Zilucoplan	RLYB116_04	RLYB116_06
IC50	0.3368	0.1761	0.1722

¹Tang 2023



RLYB114: Ophthalmic Indications of Complement Dysregulation

C5-Targeted Affibody[®] Molecule Conjugated to Polyethylene Glycol (PEG)

- Complement dysregulation implicated in pathogenesis of multiple ophthalmic disorders¹
- C5 inhibition is a precededented approach; significant unmet medical need remains

- RLYB114 designed for **ophthalmic use**
- Pegylated to **extend half-life**
- *RLYB114 may have potential for a half-life comparable to Eylea,^{® 2}* based on animal intravitreal PK study
- **February 2023: Announced research collaboration to evaluate Rallybio's C5 inhibitor and EyePoint's proprietary technology for sustained intraocular delivery in geographic atrophy**
- **Next steps: Rallybio and EyePoint expect to provide an update on this collaboration in the first half of 2024.**



RLYB331

ENPP1 Inhibitor

Rallybio/AbCellera

Collaboration

Preclinical Programs



Rallybio Early-Stage Programs Show Significant Promise

RLYB331

- Monoclonal antibody selectively targets matriptase-2 (MTP-2), serine protease that plays role in hepcidin formation
- Completion of ongoing preclinical activities; data expected in the first half of 2024

ENPP1 Inhibitor

- Joint venture with Exscientia, to discover/develop small molecule therapy to treat hypophosphatasia
- Mouse *in vivo* evidence (biomarker) to support modulation of on-target activity
- Lead AI-designed compounds to enter candidate selection in the second half of 2024

RLYB/AbCellera Collaboration

- Multi-year, multi-target collaboration to combine AbCellera's antibody discovery engine with Rallybio's clinical and commercial expertise
- Co-develop up to five rare disease therapeutic targets with first program on rare metabolic diseases
- Advance discovery efforts to next research milestone in the second half of 2024

RLYB331, formerly KY1066, was exclusively licensed from Kymab Limited, a Sanofi company, in May 2022

ENPP1: Ectonucleotide pyrophosphatase/phosphodiesterase 1



Rallybio: Profoundly Transform the Lives of Patients

UPCOMING MILESTONES

- ✓ **1H 2024: RLYB212** Provide an update on Phase 2 scientific discussions with EMA
- **1H 2024: RLYB331**
Additional Preclinical Data
- **2H 2024: RLYB212** Initiate Phase 2 Study
- **2H 2024: RLYB116**
Complete Manufacturing Work and Provide an Update on Development Plan

SUCCESS DRIVERS

- **Diversified portfolio**
- **Proven innovators in R&D**
- **Robust financial position**
- **Global business development expertise**



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Appendix – Backup Slides



Significant Number of Pregnancies at Risk for FNAIT Each Year

>22,000*

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

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

(based on 8M live births each year in the US, Canada, UK, major EU Countries, and Australia)

US and European OB/GYNs and maternal-fetal specialists have:**

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

Estimate is based on a ~2% incidence of HPA-1a negative status in the Caucasian population, where the prevalence has been well-characterized. Data from ongoing Natural History Study will inform incidence in non-Caucasians.

*Source: NCHS National Vital Statistics Report Volume 68, Number 13, November 30, 2019, Births: Final Data for 2018; World Bank Population Data (2018); Kjeldsen-Kragh, et al Blood 2007; Hardy-Weinberg estimate; Kjeldsen-Kragh et al Blood 110, 833-839 (2007)

** Based on 2022 Rallybio market research study with 30 US and European HCPs and payers



RLYB212 Represents a \$1B+ Market Opportunity

Drivers of Commercial Opportunity



Unmet Medical Need

- >22,000 women at higher risk of potentially devastating outcomes, including ICH in ~1/10 FNAIT affected pregnancies
- HCPs and payers understand limitations of current approaches and value prophylactic approach



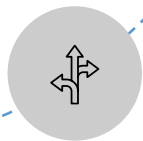
Existing Care is Resource Intensive

- Lifetime medical costs for Cerebral Palsy estimated to be \$921,000*
- Extended and costly NICU stays
- IVIg treatment costs for alloimmunized mothers range from \$100k-\$300k in US (per pregnancy)



Readily Identifiable Population

- Screening tests already commercially available
- Tests can be seamlessly integrated into routine prenatal care
- Payers, HCPs, and pregnant mothers are highly motivated to deliver healthy babies



Broad and Rapid Utilization

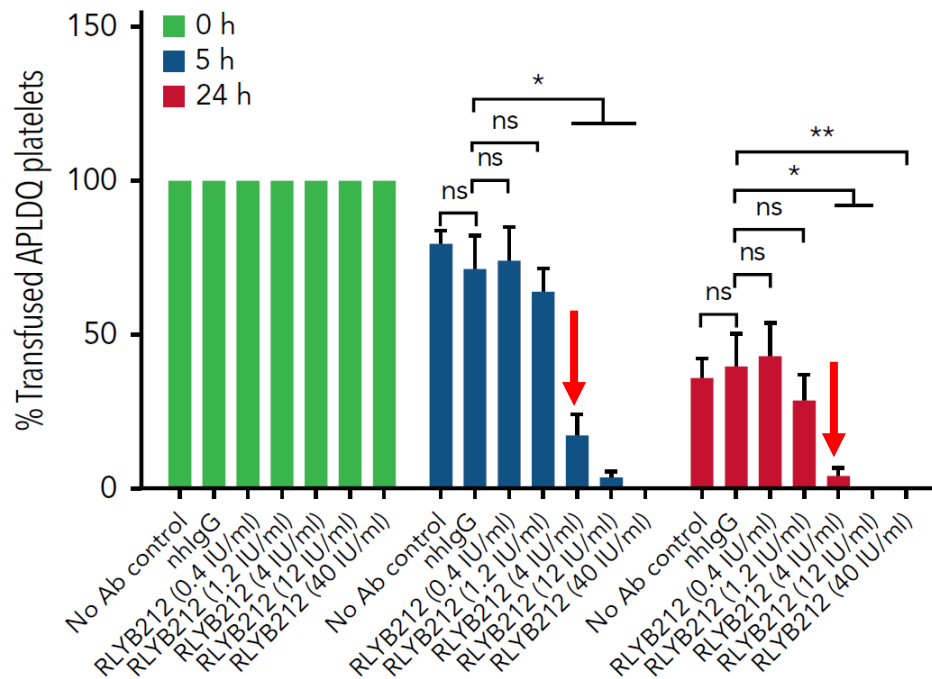
- Reimbursement currently available for existing HPA-1a screen tests which will facilitate screening uptake at launch
- Current analysis indicates modest budget impact
- Guideline adoption will drive rapid and complete adoption of screening and treatment

*Source: CDC MMWR Weekly January 30, 2004 53(03);57-59, Economic Costs Associated with Mental Retardation, Cerebral Palsy, Hearing Loss, and Vision Impairment --- United States, 2003



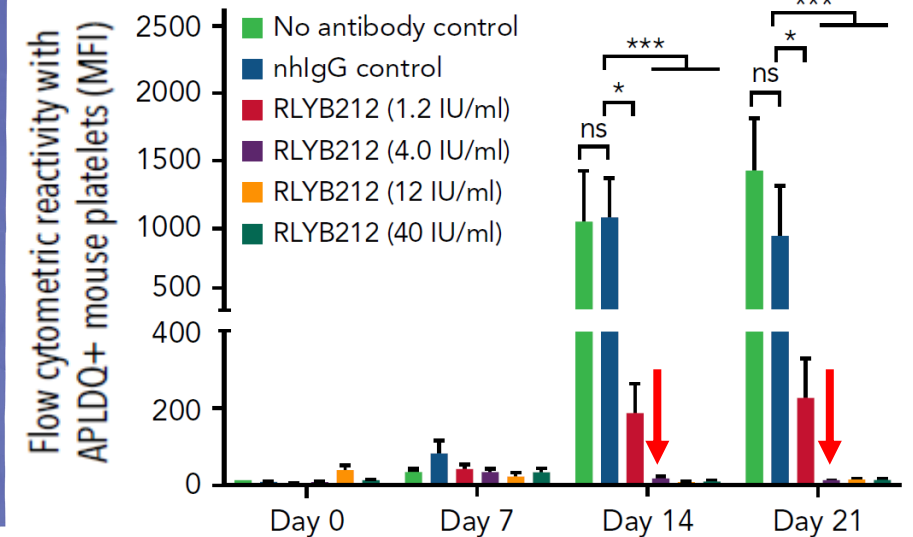
RLYB212 Elimination of Mismatched Platelets Correlates with Prevention of Alloimmunization in a Preclinical Model of FNAIT

PLATELET ELIMINATION



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

PREVENTION OF ALLOIMMUNIZATION

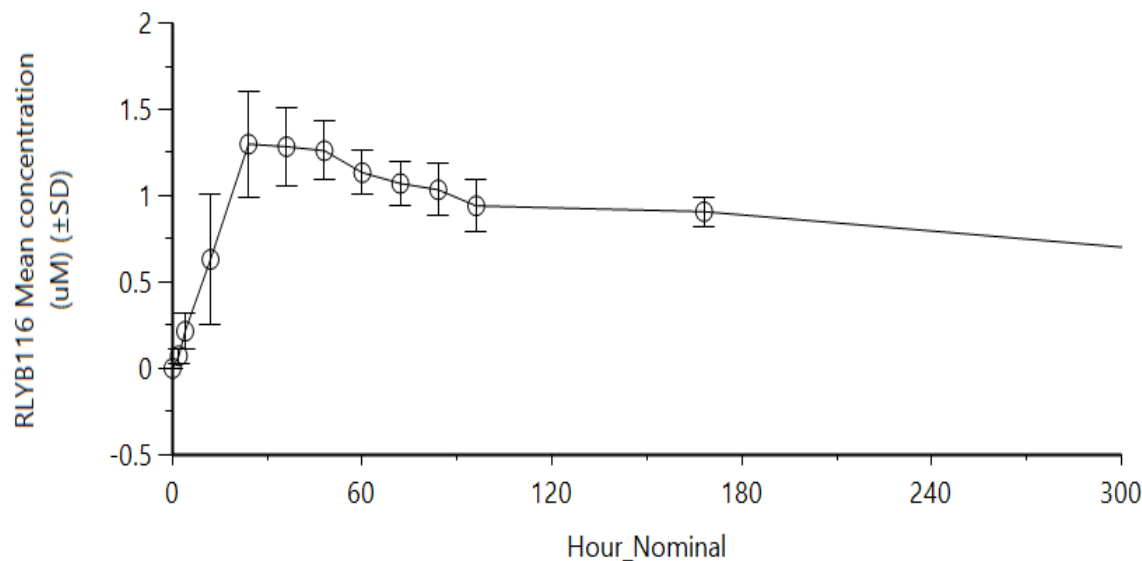




RLYB116 (100 mg Cohort) Potential for Rapid and Complete Inhibition of C5*

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 reported.**

*Preliminary data from ongoing Phase 1 clinical study

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

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%

**numbering for participants has been de-identified