



TAKING DEVASTATING DISEASES – AND DEVASTATING THEM.

We're going there.

November 2023

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 clinical trials for RLYB212 and RLYB116, our RLYB212 toxicology program and the FNAIT natural history study, and related preparatory work, 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 results from the Phase 1 study of RLYB116 and the multiple ascending dose study for RLYB116; the proof-of-concept data from the Phase 1b study of RLYB212 for the prevention of FNAIT; the potential clinical effects and benefits of RLYB212 and RLYB116; our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project; our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved; 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 reliance on third parties to conduct our clinical trials; 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 and validate 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 trials 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 our filings with the Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in our Form 10-Q for the quarter ending September 30, 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's Mission: Profoundly Transform the Lives of Patients

Advancing a diversified portfolio

to address compelling unmet needs, including in maternal-fetal health, complement dysregulation, hematology and metabolic diseases

Proven team of innovators

charting new paths based on industry-leading science and expertise in rare diseases

Strong financial position

\$121.4 million in cash, cash equivalents and marketable securities as of September 30, 2023

Successful business development platform

global relationships result in a robust portfolio of novel programs





Experienced Team in Rare Diseases R&D

Martin Mackay, Ph.D.

Co-Founder and Executive Chairman
Alexion, AstraZeneca, Pfizer

Jonathan Lieber

Chief Financial Officer
AGTC, Histogenics, Danforth Advisors

Róisín Armstrong, Ph.D.

Head of FNAIT Program
Alexion, Pfizer

Ann Houston, M.A., PMP

Head of External Research & Innovation
Alexion, Bristol-Myers Squibb, Pfizer

Douglas Sheridan, Ph.D.

Head of Non-Clinical Development
Alexion

Rachael Alford, Ph.D.

Head of CMC and Integrated Operations
Alexion

Jackie Schumacher

Head of Regulatory and Quality
Lyndra Therapeutics, Pfizer

Steve Uden, M.D.

Co-Founder, Chief Executive Officer and President
Alexion, Wyeth, Novartis, Pfizer

Steve Ryder, M.D.

Chief Medical Officer
Alexion, Astellas, Pfizer

Eric Watsky, M.D.

Head of RLYB116 Program
Alexion, Pfizer, NIMH

Kiran Patki, M.D., M.Sc.

Head of RLYB114 and RLYB331 Programs
Gemini, Aeglea, Alexion

Amanda Hayward, Ph.D.

Global Head of Business Development
Connecticut Innovations, Baxalta Ventures

Laura A. Ekas, Ph.D.

Head of Corporate and Commercial Strategy
Alexion, Insight Strategy, Canaccord

Derek Brown, MBA

Global Commercial Development Lead
Chiasma, Alexion, Boehringer Ingelheim



Rapidly Advancing Our Diversified Portfolio

Therapeutic Area	Program	Molecule	Approach	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Development Rights
Maternal Fetal Blood Disorders	Prevention of FNAIT	RLYB212	Anti-HPA-1a Monoclonal Antibody						Rallybio
Complement Dysregulation	Rare Diseases*	RLYB116	C5 Inhibitor: Affibody®-ABD Fusion						Rallybio
	Ophthalmology	RLYB114**	C5 Inhibitor: Pegylated Affibody®						Rallybio
Hematology	Severe Anemia	RLYB331	Matriptase-2 Inhibitor; Monoclonal Antibody						Rallybio
Metabolic Disorders	HPP	ENPP1 program	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), neurology, including disorders such as generalized myasthenia gravis (gMG), and severe dermatological indications; ** 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

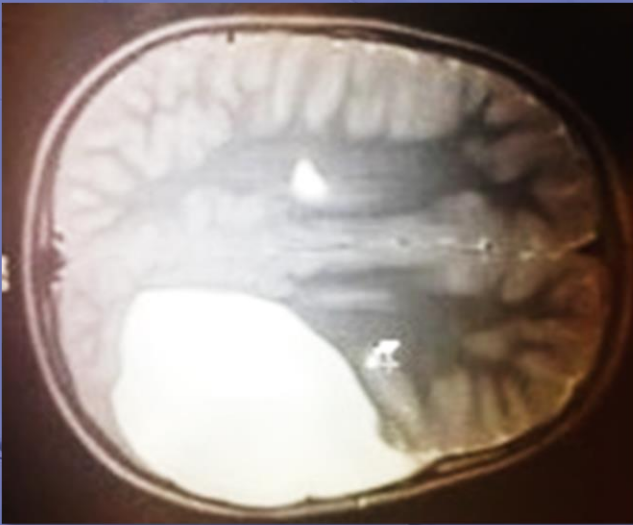


RLYB212

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



Significant Number of Pregnancies at Risk for FNAIT Each Year



Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT)

results from platelet antigen (HPA-1a) mismatch between an expectant mother and her fetus. This can lead to alloimmunization (maternal immune system attacks fetal platelets).

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

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



RLYB212 is a novel candidate designed to prevent HPA-1a alloimmunization and to eliminate FNAIT.



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



With >22,000 Women at Higher Risk for FNAIT Annually, 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



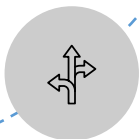
Existing Care is Resource Intensive

- 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



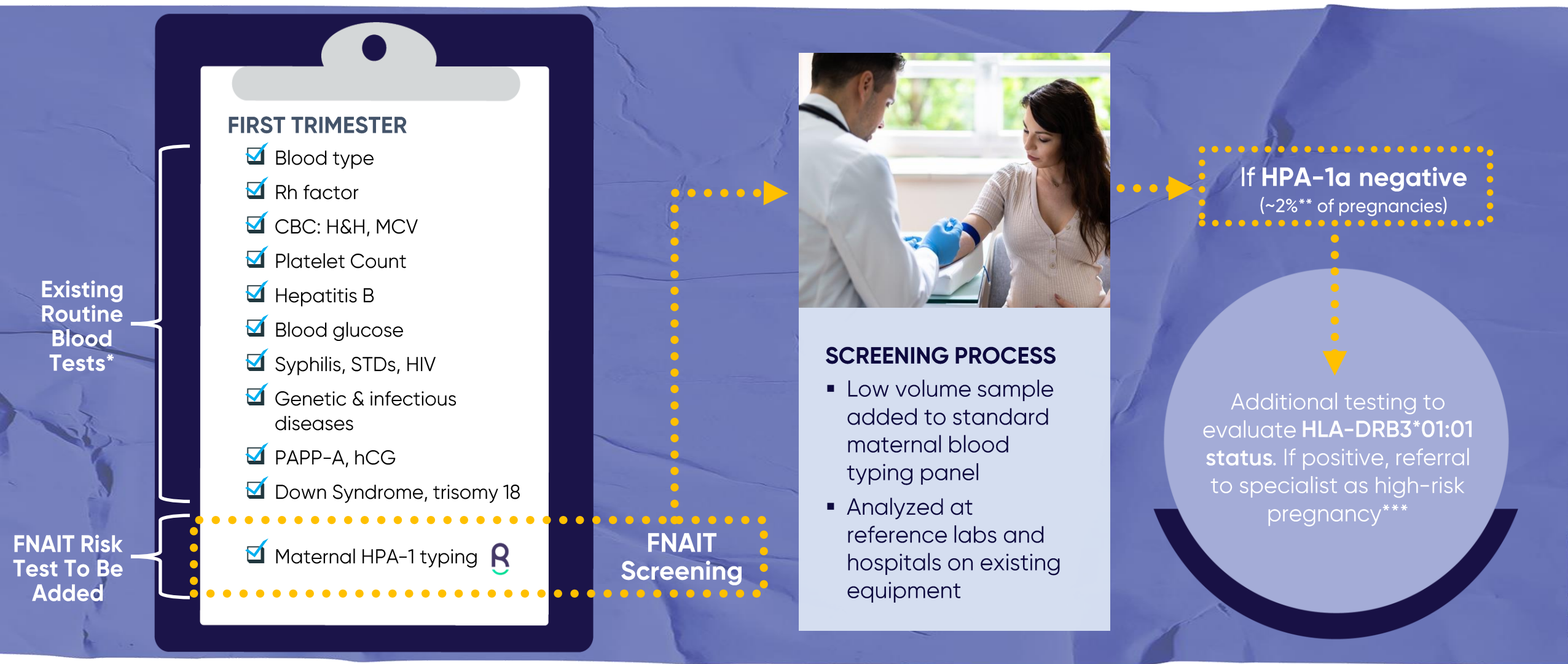
Broad and Rapid Utilization

- 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



Screening Tests Commercially Available; Can be Validated in FNAIT and Integrated into Routine Prenatal Care



* 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



Activities Ongoing to Support Inclusion in Guidelines and Market Access

Criteria for Payer and Guideline Evaluations



Prevalence & Impact Data



Preventive Therapeutic



Validated Screen Test



Cost Effectiveness Data

Action Plan

Sci Advisors & Patient Advocacy

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

Natural History & Ph 2 and Ph 3 Data

- Characterizing ethnically diverse populations at higher risk of FNAIT in Natural History Study who would be eligible for prophylactic treatment
- Planning global registration program to establish the effectiveness of screening and RLYB212

Screen Testing Readiness

- Identifying global IVD partner to validate existing tests in Phase 3 and to provide commercial low cost HPA-1 screen test

Cost/Benefit Payer Insight

- Engaging with payers to confirm data requirements for market access and support cost effectiveness evaluations

Publications & Guidelines Review

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

Based on feedback from international medical societies and KOLs, we believe guidelines will support the routine screening of pregnant mothers



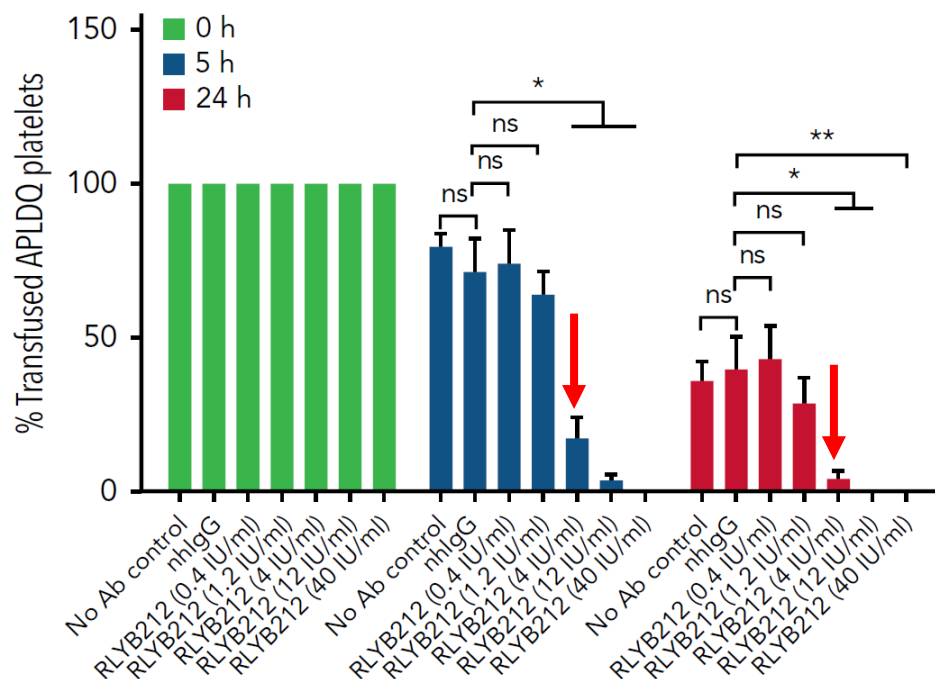
RLYB212: Novel Product Candidate to Prevent Maternal Alloimmunization and FNAIT

Descriptive name	Fully human monoclonal anti-HPA-1a IgG
Mechanism of Action	Effect rapid elimination of fetal HPA-1a antigen from the maternal circulation, thereby preventing alloimmunization
Route of Administration	Small volume, SC injection administered once monthly; compatible with patient friendly auto-injector for self-administration
Pharmacokinetic Results	Limited peak-to-trough variation
Manufacturing	Standard manufacturing for monoclonal antibody
Supply	Robust and stable supply opportunities
Regulatory Designations	ODD (FDA, EMA), Rare Pediatric Disease Designation (FDA)
Key Intellectual Property	Composition of Matter patents



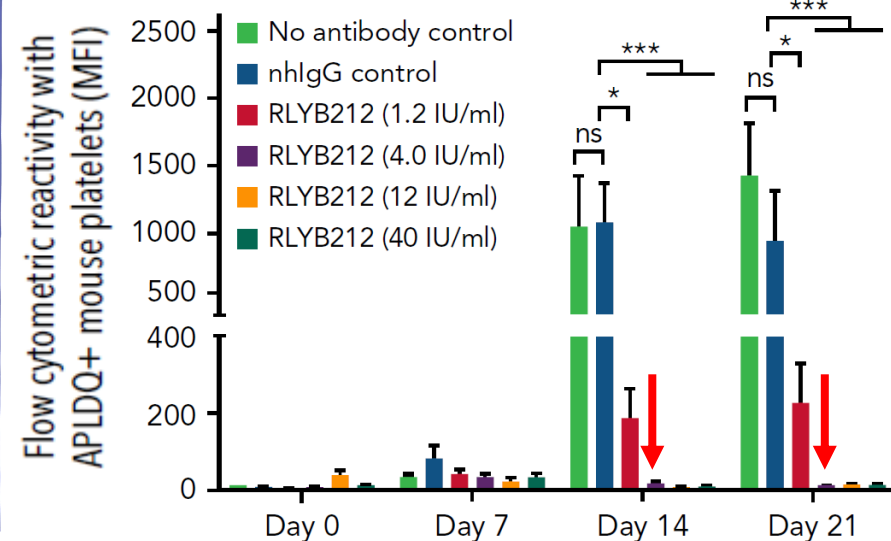
RLYB212 Elimination of Mismatched Platelets Correlates with Prevention of Alloimmunization in a Preclinical Model of FNAIT

PLATELET ELIMINATION



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

PREVENTION OF ALLOIMMUNIZATION

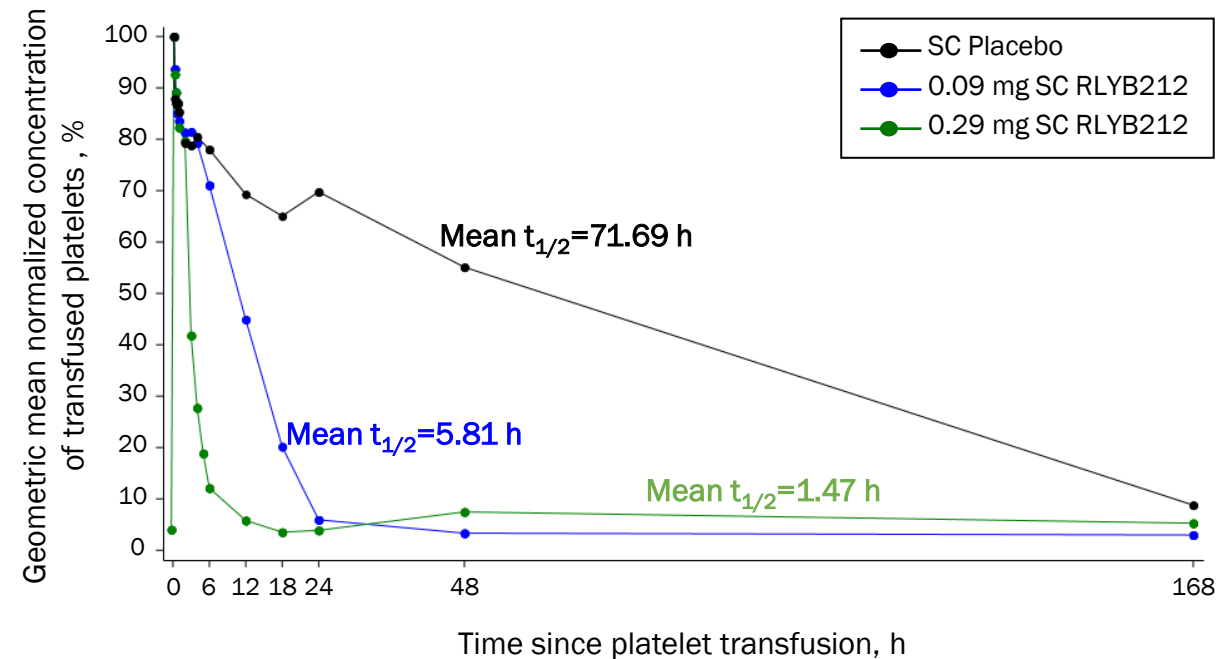




Rapid and Dose Dependent Elimination of Transfused Platelets by RLYB212

- Eleven healthy HPA-1a negative subjects randomized to RLYB212 0.09mg (n=4), RLYB212 0.29mg (n=5) or placebo (n=2)
- RLYB212 produced a 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*



RLYB212 Phase 2 Study in Pregnant Women at Higher Risk for Maternal HPA-1a Alloimmunization

Design Principles

Comprehensive PK to characterize systemic exposure through pregnancy and at parturition

Sentinel dosing with sequenced cohorts

Safety assessed for mother, fetus and newborn, including pregnancy and neonatal outcomes

Monitor post partum for occurrence of maternal HPA-1a alloimmunization





FNAIT Natural History Study

To Be Continued in Parallel with Phase 2 Study

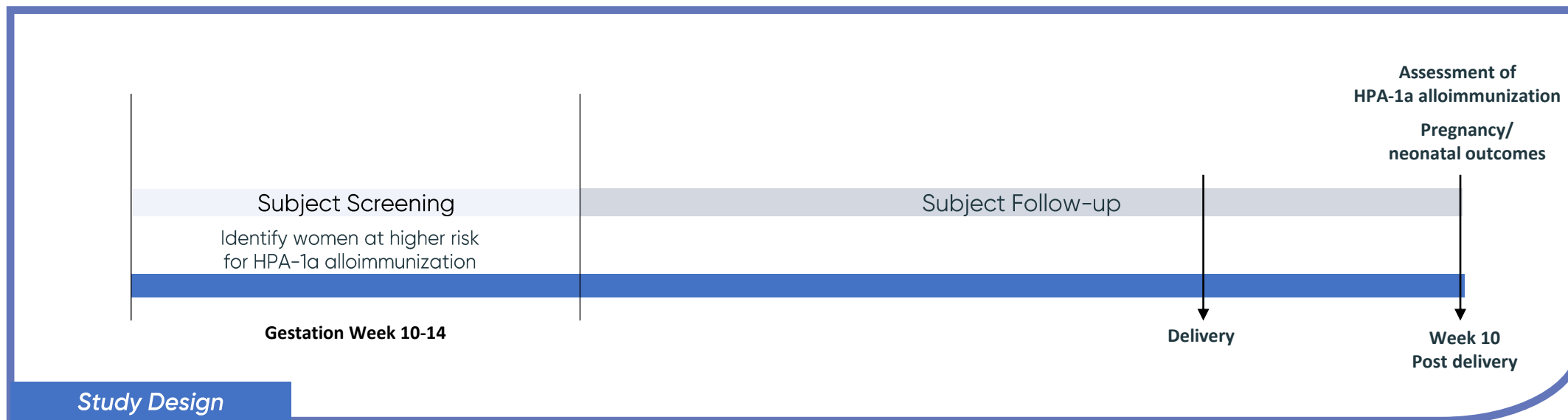
STUDY DESIGN

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)

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



1. ~20 - 30K to be screened



RLYB212: Summary

- No approved therapy exists for the prevention or treatment of FNAIT
- Screening tests already exist; can be validated for FNAIT and integrated into routine prenatal care
- Proof of concept established in March 2023
- Phase 2 dose confirmation study expected to commence in 2H 2024
- Natural history study continues to progress in parallel with Phase 2 study
- Rallybio remains committed to advancing the first potential prophylactic to prevent HPA-1a alloimmunization and eliminate FNAIT



COMPLEMENT INHIBITORS

C5 Blockers for the Potential Treatment of
Diseases due to Complement
Dysregulation



We Have Significant Expertise in Complement Dysregulation

- **C5 is a proven target**

Rallybio is advancing inhibitors of C5 that are designed to offer high potency, less-frequent dosing, and greater convenience/ease of use.

- **Substantial unmet need**

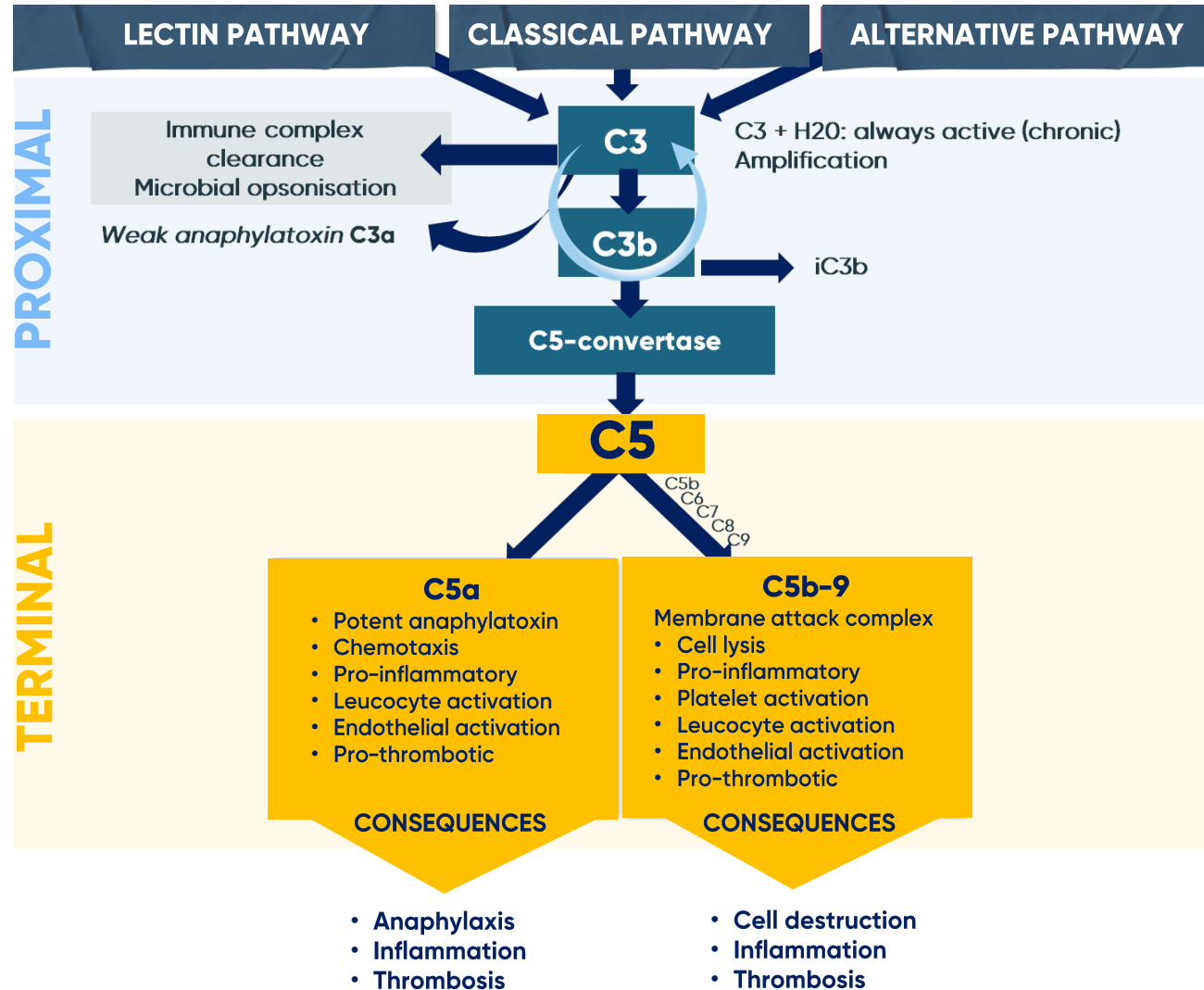
We are seeking to introduce or expand use of complement inhibitors in diseases where complement dysregulation is central or a major factor, including in hematology, dermatology, and ophthalmology.

- **Clinical development pathways and commercial focus**

Prior to working at Rallybio, members of our team designed, developed, and/or secured approval for two C5 inhibitors in four rare disease indications globally.



Complement Dysregulation Implicated in Growing Number of Diseases



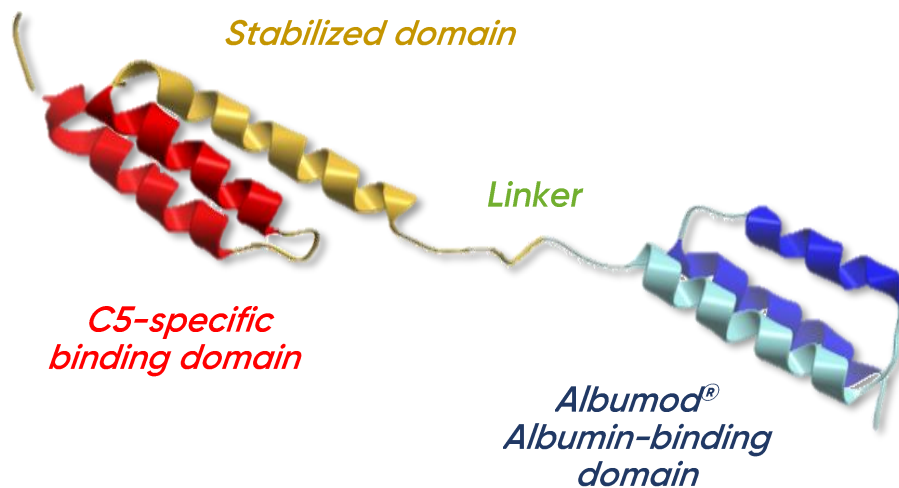
Implicated in more than 50 diseases across many therapeutic areas including:

- Hematology
- Neurology
- Ophthalmology
- Nephrology
- Dermatology
- Rheumatology



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 are based on non-clinical research conducted by Rallybio and others



RLYB116 Phase 1 Single Ascending Dose Trial

STUDY DESIGN

Single-blind, placebo-controlled, dose escalation study investigating the safety, pharmacokinetics and pharmacodynamics of single dose RLYB116 in healthy participants

STUDY COHORTS

- Five sequential ascending dose cohorts, each enrolling 8 subjects (6 treated with RLYB116 and 2 with placebo)
- Escalation to next-higher dose after review of clinical safety and PK data
- Post-treatment / safety follow-up will continue for 10 weeks

PRIMARY OBJECTIVE

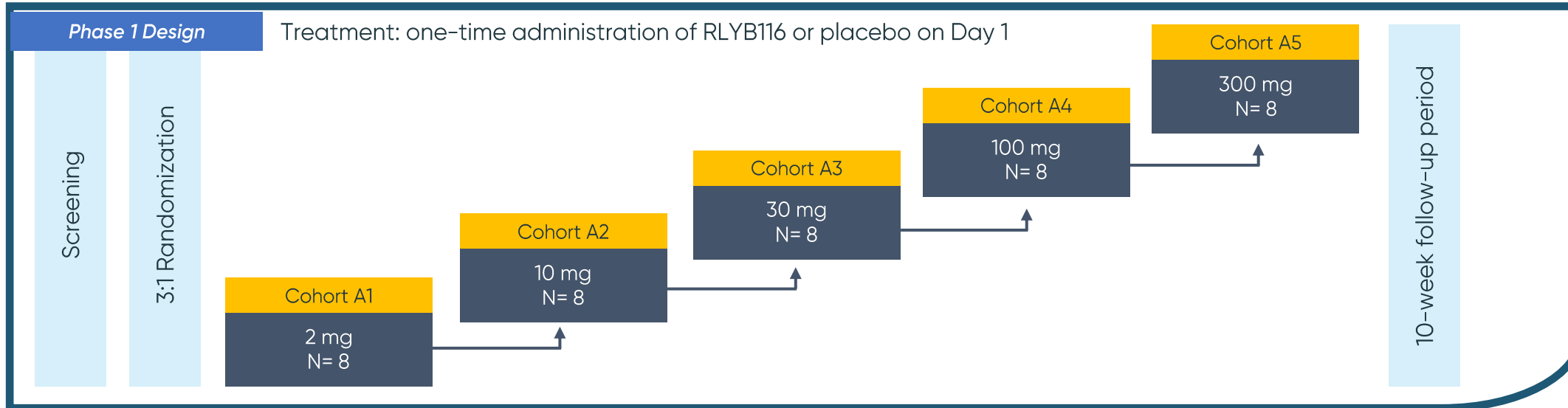
To evaluate the safety and tolerability of RLYB116 in healthy participants following single administration

SECONDARY OBJECTIVES

To evaluate the PK profile of RLYB116 following subcutaneous administration

To evaluate the immunogenicity of single doses of RLYB116

To characterize the PD proprieties of RLYB116 following single administration

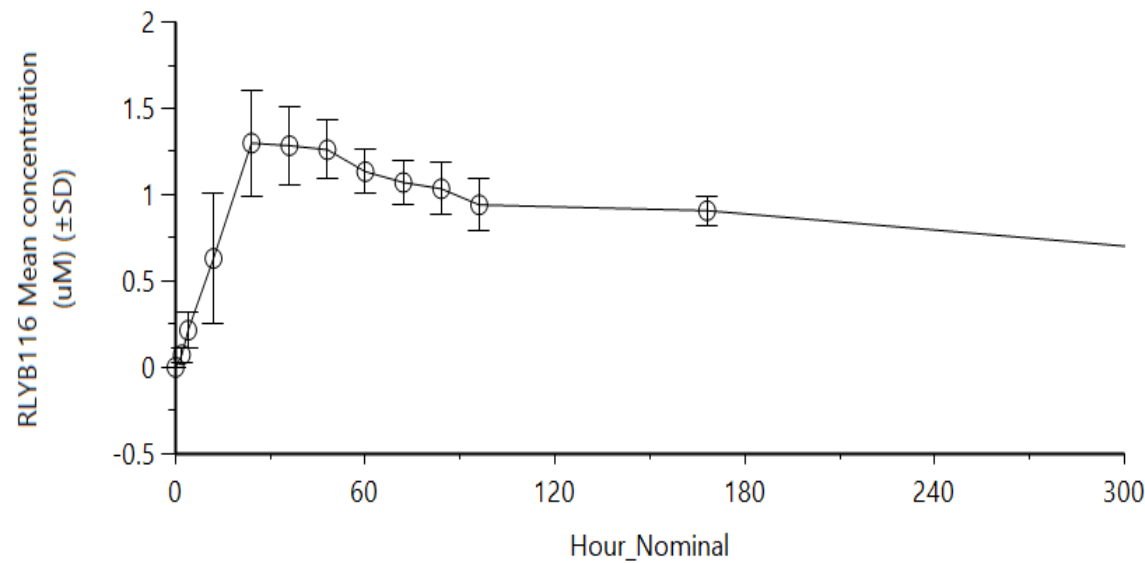




RLYB116 (100 mg Cohort) Potential for Rapid and Complete Inhibition of C5*

RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) PK

Estimated T1/2 is > 300 hours



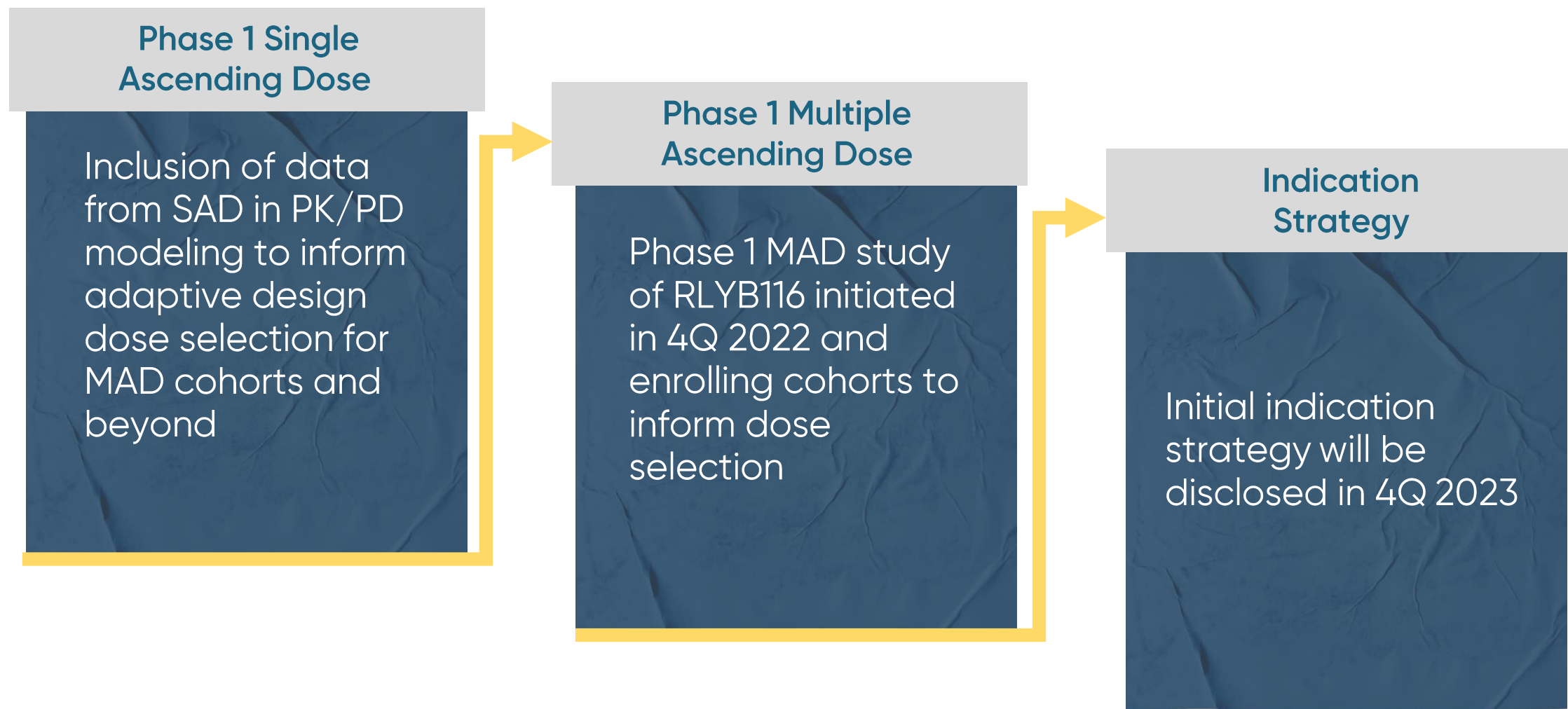
*Subcutaneously administered RLYB116 was generally well-tolerated as a single 100 mg dose with mild adverse events and no serious adverse events reported.**

*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

What's Planned Next for RLYB116?





Ophthalmic Indications of Complement Dysregulation

Complement dysregulation is implicated in the pathogenesis of multiple ophthalmic disorders¹

C5 inhibition is a precedented approach; significant unmet medical needs remain



RLYB114: C5-targeted Affibody[®] molecule conjugated to polyethylene glycol (PEG)

- Designed for **ophthalmic use**
- Pegylated to **extend half-life**
- *RLYB114 may have potential for a half-life comparable to Eylea,^{® 2} based on an animal intravitreal PK study*
- **February 2023: Announced research collaboration to evaluate Rallybio's C5 inhibitor and EyePoint's Durasert[®] technology for sustained intraocular delivery in geographic atrophy**

1. Park et al 2019 Frontier in Immunology; -2. Park et al 2016 Inv Ophthalmol Vis Sciences, Christoforidis et al 2012 Current Eye Research. For illustration purpose only – not a head-to-head comparison.



Preclinical Programs

RLYB331

ENPP1 Inhibitor

Rallybio / AbCellera Collaboration



RLYB331: Potential First-in-Class Compound for Severe Anemias

- RLYB331 is a monoclonal antibody that selectively targets matrilysin-2 (MTP-2), a serine protease that plays a critical role in hepcidin formation
- IND-enabling activities are underway to support transition of asset into clinical development
- Potential to develop RLYB331 in multiple indications



ENPP1: Potential Novel Treatment for Hypophosphatasia

- Joint venture with Exscientia, to discover and develop a small molecule therapy to treat HPP
- Through controlled inhibition of ENPP1, the major source of extracellular inorganic pyrophosphate, we aim to reduce PPi and improve mineralization, restoring hydroxyapatite formation and improving bone mineralization
- Mouse *in vivo* evidence (biomarker) to support modulation of on-target activity
- *In vivo* efficacy data in the HPP mouse model expected in 2H 2023
- IND-enabling activities to commence following preclinical efficacy data read-out



Strategic Alliance: Rallybio / AbCellera

- Announced in December 2022
- 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
- First program to focus on rare metabolic diseases



Rallybio, A Leading Rare Disease Company

CLINICAL PROGRAMS

- ✓ **4Q 2023: RLYB212**
Complete Toxicology Program (maternal-fetal toxicology)
- ✓ **4Q 2023: RLYB212** Multiple Dose Cohort (safety/PK)
- **4Q 2023: RLYB116** Phase 1 MAD study (safety/PK/PD)

EARLIER-STAGE PROGRAMS

- **RLYB114** in ophthalmology
- **RLYB331** for severe anemias
- **ENPP1 inhibitor** for HPP
- **ABCL** in metabolic diseases

DRIVERS OF SUCCESS

- **Diversified product candidate portfolio**
- **Proven team of innovators**
- **Strong financial position**
- **Global business development platform**



Rapidly Advancing Our Portfolio to Transform the Lives of Patients

Rallybio

Rallybio