UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 7, 2022

RALLYBIO CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40693**	**85-1083789**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

234 Church Street, Suite 1020 **New Haven, Connecticut** **(Address of Principal Executive Offices)**	**06510** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 203 859-3820

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RLYB	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company
☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
☐

Item 7.01. Regulation FD.

On March 7, 2022, Rallybio Corporation (Rallybio) updated its corporate presentation to disclose, among other things, that the first healthy volunteers have been dosed in Rallybio's Phase 1 study of RLYB116, and that single dose safety, pharmacokinetic, and pharmacodynamic data are expected in the second half of 2022. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K. The corporate presentation will also be available on Rallybio's website in the Investors section at https://investors.rallybio.com/events-and-presentations/events. Rallybio may in the future post updates to its corporate presentation or other information important to its investors on the Investor page of its website.

The information contained in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RALLYBIO CORPORATION

Date: March 7, 2022

By: /s/ Jeffrey M. Fryer
Jeffrey M. Fryer, CPA
Chief Financial Officer and Treasurer


Rallybio
MARCH 2022
TAKING A DEVASTATING DISEASE – AND DEVASTATING IT.
We're going there.
Rallybio
Corporate Presentation

Forward Looking Statements

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," "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 the timing of initiation and completion of our clinical trials for RLYB211, RLYB212, and RLYB116, and the natural history study for our FNAIT prevention program, and related preparatory work, and the period during which the results of the trials will become available; the success and cost of the clinical development of our product candidates, including RLYB212, RLYB116 and RLYB114; the timing of our planned nomination of a compound for our ENPP1 program under our joint venture with Exscientia; 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 PNH and gMG; 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, RLYB116, RLYB114 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 expand our pipeline through collaborations, partnerships and other transactions with third parties; our ability to identify and advance through clinical development any additional product candidates; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue; our ability to retain and recruit key personnel; our ability to obtain and maintain adequate intellectual property rights; 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 expected uses of the net proceeds to us from our initial public offering; 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 ability to attract collaborators with development, regulatory and commercialization expertise; our financial performance; and developments and projections relating to our competitors or our industry. The forward-looking statements in this presentation are only predictions and are based largely on our 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 those described in our filings with the SEC, including under the heading "Risk Factors" in our Form 10-Q for the quarter ending on September 30, 2021, filed with the SEC on November 10, 2021, 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.

Our Mission

To identify and accelerate the development of transformative therapies for patients with severe and rare disorders

We've gathered a proven team of innovators with the fearlessness to create new paths forward others haven't tried

And we want to develop therapies that shatter expectations of what's possible

Because it's time to tackle the undone, the too difficult, the inaccessible – and change the odds for patients with rare diseases.

Building for Growth

GROUNDWORK FOR SUCCESS

- **Diversified portfolio** of five programs across three areas: maternal-fetal, complement dysregulation and metabolic
- **Strong focus on expanding our pipeline** through global business development platform
- **Strong** financial position; Completed $93M IPO in August 2021. Over $186 million in cash and equivalents as of 9/30/21

MULTIPLE NEAR-TERM CATALYSTS

RLYB212

✓ Phase 1 study start 4Q 2021

Phase 1b study start 2Q 2022

Phase 1b PoC data 3Q 2022

RLYB116

✓ Phase 1 study start 1Q 2022

Phase 1 single dose safety, PK and PD data 2H 2022

RE Venture I Program

Initiation of IND-enabling studies for ENPP1 2H 2022

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***	Monoclonal HPA-1a Antibody						Rallybio
		RLYB211	Polyclonal HPA-1a Antibody						Rallybio
Complement Dysregulation	PNH, gMG	**RLYB116**	C5 Inhibitor; Affibody-ABD Fusion						Rallybio
	Ophthalmic Disease	**RLYB114**	C5 Inhibitor; Pegylated Affibody						Rallybio
Metabolic Disorders	HPP	**RE Ventures I**	ENPP1 Small Molecule Inhibitor						Rallybio Exscientia

FNAIT: Fetal and neonatal alloimmune thrombocytopenia; **HPA-1a:** Human platelet antigen 1a; **PNH:** Paroxysmal nocturnal hemoglobinuria; **gMG:** Generalized myasthenia gravis; **ABD:** Albumin binding domain; **HPP:** Hypophosphatasia; **ENPP1:** Ectonucleotide pyrophosphatase/ phosphodiesterase 1

*RLYB212 is the lead candidate in development for the prevention of FNAIT and has the same mechanism of action as RLYB211. RLYB212 has additional favorable attributes that include convenient SC dosing which can enable optimized exposure over the course of treatment to prevent maternal alloimmunization and a sustainable commercial supply.

Pursuing Transformative Science Around the Globe to Expand Our Portfolio with New Assets and Partners

PRODUCT CANDIDATE REQUIREMENTS

- ✓ Clear mechanism of action
- ✓ Validated modality

TARGET DISEASE REQUIREMENTS

- ✓ Well-understood pathophysiology
- ✓ Significant unmet patient need
- ✓ Potential for transformative benefit

BD ACTIVITIES

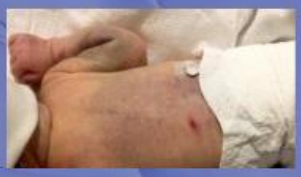
- ✓ Global business development platform
- ✓ Employing artificial intelligence tools to identify new opportunities
- ✓ Leveraging global relationships within industry and academia
- ✓ Partnering to identify new targets

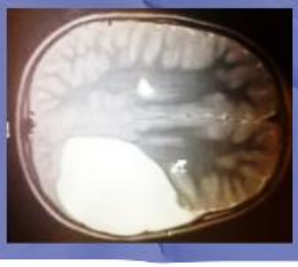
Strong Focus on Portfolio Expansion

Programs for the Prevention of Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT)

RLYB212
RLYB211

Potential to Eradicate a Devastating Disease in Fetuses and Newborns





Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT) is a rare condition in which the mother's immune system attacks the platelets of her fetus.

Destruction of fetal platelets can lead to potentially catastrophic fetal and neonatal morbidity and mortality. Intracranial hemorrhage (ICH) associated with FNAIT may cause:

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

No approved therapy exists for the prevention or treatment of FNAIT

Prevention of maternal alloimmunization should eliminate the risk of FNAIT in the fetus

Each Year, Approximately 22,700 Pregnancies Estimated at High Risk for FNAIT

~8M LIVE BIRTHS ANNUALLY

US, Canada, UK, other major EU Countries, and Australia

~22,700

ARE AT HIGH RISK FOR FNAIT

due to expectant mother who is
- HPA-1a negative
- HLA-DRB3*01:01 positive
- HPA-1a antibody negative

AND Fetus is HPA-1a positive

- We are committed to ensuring that all expectant mothers of any race or ethnicity who are at high risk of FNAIT are identified and eligible for treatment
- FNAIT natural history study will better inform the size of the total FNAIT at risk population
- Potential for commercialization in additional markets

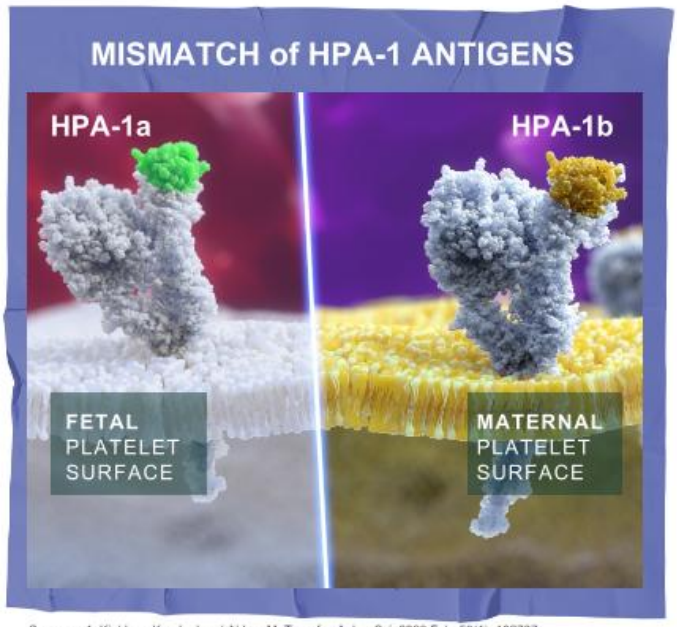
US and EU OB/GYNs and maternal-fetal specialists have:

- High awareness of the catastrophic impact of FNAIT
- High willingness to screen expectant and mothers
- High willingness to provide preventative therapy to at-risk expectant mothers

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

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 a l Blood 110, 833-839 (2007)

FNAIT is Caused by a Platelet Antigen Mismatch Between Mother and Fetus



FNAIT occurs when the mother's immune system attacks the platelets of her fetus

Caused by a mismatch in the type of Human Platelet Antigen 1 (HPA-1) between expectant mother and fetus

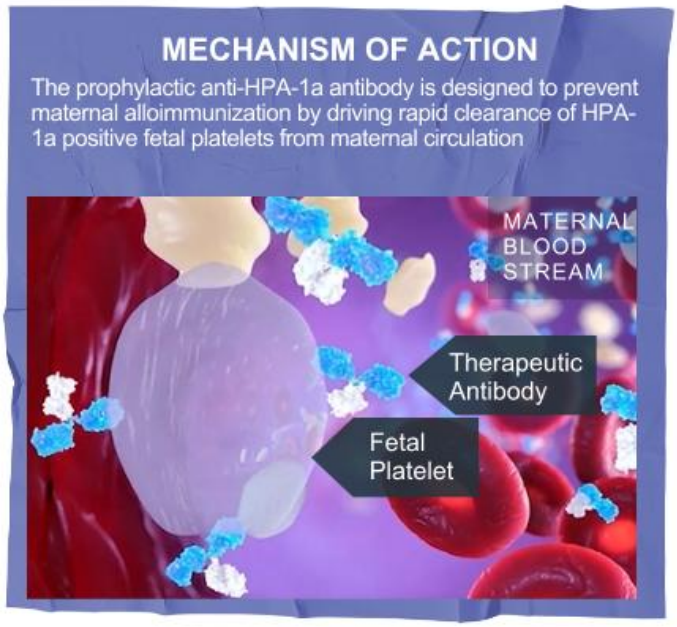
When fetal platelets enter the mother's circulation, the mother recognizes the fetal HPA-1a as foreign and generates an antibody response known as alloimmunization

Maternal antibodies then cross the placenta where they attack and destroy the fetal platelets

Mothers with a specific gene variant, HLA-DRB3*01:01, are at a much higher risk of alloimmunization[1]

Sources: 1. Kjeldsen-Kragh, J and Ahlen, M. Transfus Apher Sci. 2020 Feb; 59(1): 102707

Potential First-in-Class Preventive Therapy for FNAIT



RLYB211

- Polyclonal anti-HPA-1a antibody
- Achieved clinical proof-of-concept in ongoing Phase 1/2 study, reinforcing preventative approach to treating FNAIT

RLYB212

- Monoclonal anti-HPA-1a antibody
- Moved to lead candidate **for prevention of FNAIT in 3Q 2021**
- Dosing has initiated in Phase 1 safety and PK study
- Proof-of-concept data from Phase 1b study expected 3Q 2022

Rapid Elimination of Transfused Platelets Following Administration of RLYB211, an Anti-HPA-1a Antibody

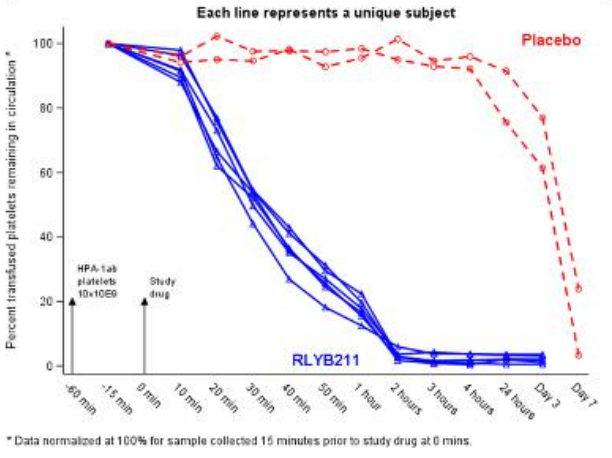
COHORT 1 RESULTS

- 8 participants received either single dose RLYB211 1000 IU (n=6) or placebo (n=2) to assess elimination of HPA-1a positive platelets, based on $t_{1/2}$ of $10x10^9$ transfused platelets
- RLYB211 markedly accelerated the elimination of transfused HPA-1a positive platelets compared with placebo
  - Half-life of mismatched platelets 0.32 hrs. for RLYB211 vs. 65.29 hrs. for placebo ($p<0.001$)

COHORT 1B RESULTS

- 4 participants received platelet transfusion 7 days following RLYB211 1000 IU (n=3) or placebo (n=1)
- RLYB211 markedly accelerated the elimination of HPA-1a positive platelets 7 days post-administration
- Data supports the sustained treatment capacity of anti HPA-1a antibody

PLATELET CLEARANCE: COHORT 1



Across both cohorts, RLYB211 showed acceptable safety and tolerability with no serious adverse events

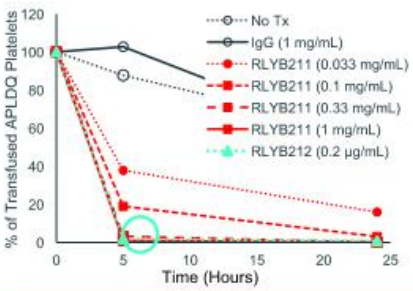
Clinical Proof-of-Concept Achieved with RLYB211; Favorable Attributes of RLYB212 Could Provide Best Option for Expectant Mothers

	RLYB211	RLYB212
Mechanism of Action	✓ Anti-HPA-1a antibody	✓ Anti-HPA-1a antibody
Route of Administration	IV bolus injection	✓ Subcutaneous injection
Pharmacokinetic Profile	Wider peak-to-trough variation	✓ Limited peak-to-trough variation
Manufacturing	Purified from plasma donors	✓ Standard manufacturing for monoclonal antibody
Supply	Diminishing supply with success in preventing alloimmunization	✓ Robust and stable supply opportunities
Regulatory Designations	✓ ODD (FDA, EMA), Rare Pediatric Disease Designation (FDA)	✓ ODD (FDA, EMA), Rare Pediatric Disease Designation (FDA)
Key Intellectual Property	Method of Use patents	✓ Composition of Matter patents

Platelet Clearance and Prevention of Alloimmunization Demonstrated with RLYB212 in Preclinical Model of FNAIT

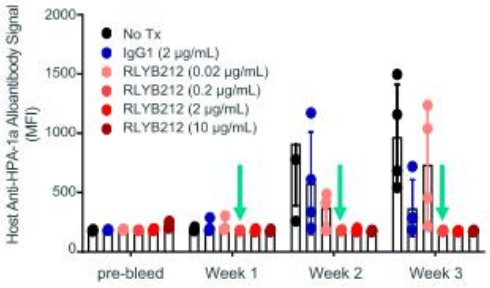
The "APLDQ" mouse was engineered to recapitulate the HPA-1a antigen in mice, thus enabling a murine FNAIT model with maternal-fetal mismatch in only the HPA-1a antigen

PLATELET CLEARANCE



- RLYB212 rapidly and completely eliminates HPA-1a positive platelets at concentrations more than 1000-fold lower than RLYB211

PREVENTION OF IMMUNIZATION



- RLYB212 prevents host antibody production

Source: Data on file, MFI = Mean Fluorescence Intensity

RLYB212 Phase 1 Safety and PK Study Underway

STUDY DESIGN

Single-blind, placebo-controlled study investigating the safety and pharmacokinetics of RLYB212 in HPA-1a negative healthy volunteers

STUDY COHORTS

- Cohort 1: N = 8 subjects to receive single dose of RLYB212 or placebo
- Cohort 2: N = 8 subjects to receive a loading dose followed by weekly doses of RLYB212 or placebo for 11 weeks
- Post-treatment safety follow-up through 12 weeks for all subjects

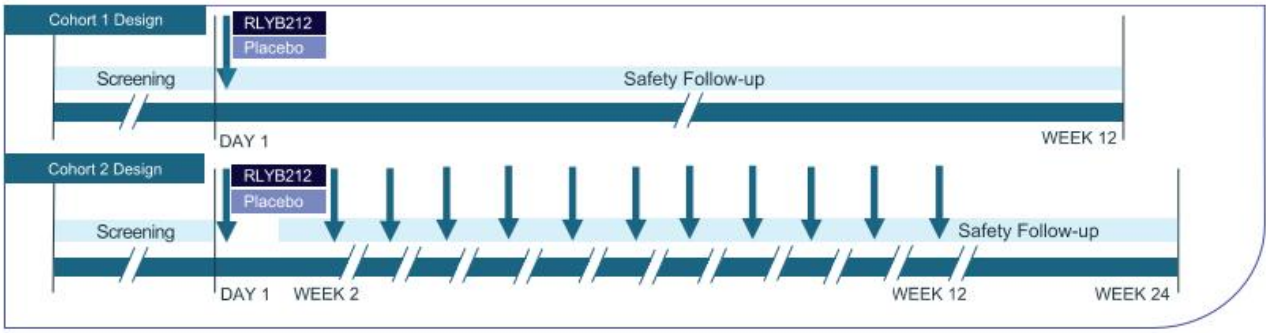
PRIMARY OBJECTIVE

To evaluate the safety of single and repeat subcutaneous doses of RLYB212

SECONDARY OBJECTIVES

To evaluate the immunogenicity of single and repeat doses of RLYB212

To establish the PK profile of RLYB212 following subcutaneous administration



RLYB212 Phase 1b Proof-of-Concept Study to Start 2Q 2022

STUDY DESIGN

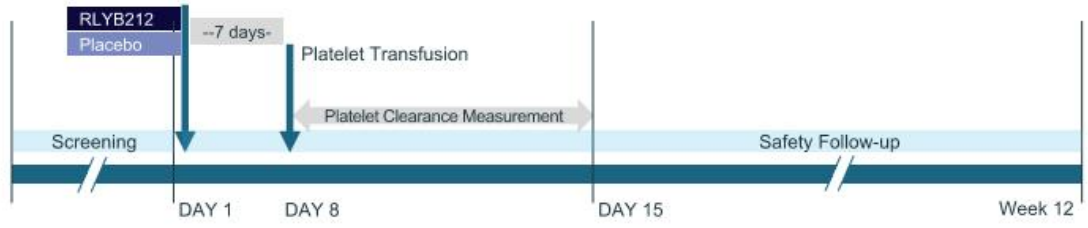
Single-blind, placebo-controlled, proof-of-concept study investigating the capacity of RLYB212 to rapidly eliminate HPA-1a positive platelets transfused to HPA-1a negative healthy male volunteers (N=8 subjects)

PRIMARY OBJECTIVE

To establish the ability of RLYB212 to markedly accelerate the elimination of HPA-1a positive platelets transfused to HPA-1a negative healthy male volunteers

SECONDARY OBJECTIVES

To evaluate the safety of a single dose of RLYB212 and to monitor for potential alloimmune response to HPA-1a positive platelets



Study Design

FNAIT Natural History Alloimmunization Study Underway

STUDY SUMMARY

- Prospective, non-interventional, multinational natural history study conducted at sites in US/EU
- Screen expectant mothers presenting at Gestation Week 10 to 14 prenatal visit for higher FNAIT risk
- Primary endpoint: Presence of anti-HPA-1a alloantibodies at 10 weeks post-pregnancy
- Study initiated in 3Q 2021

STUDY OBJECTIVES

- Obtain better prevalence estimates of the FNAIT at-risk population in racial and ethnic groups that may have been under-represented in previously published studies
- Provide historical alloimmunization rate to control a future single arm Phase 2/3 registrational trial
- Establish operational precedence for the planned registration trial, including application of screening lab tests to identify mothers at risk for FNAIT risk

Screening For Risk of FNAIT Fits Into Routine First Trimester Prenatal Care Practice

Key to Eradicating FNAIT: Identification of High-Risk Pregnancies

	1st TRIMESTER	2nd TRIMESTER	3rd TRIMESTER
ROUTINE TESTS*	**WEEK 8 – 10** • Blood type • Rh factor • CBC: H&H, MCV • Platelet Count • Hepatitis B • Blood glucose • Urine C&S • Syphilis STDs, HIV • Genetic & infectious diseases **WEEK 10 – 14** • PAPP-A, hCG • Down Syndrome trisomy 18 • Ultrasound – Fetal nuchal translucency • **Maternal HPA-1 typing** • **Maternal HLA-DRB3*01:01 status *(sequential)*****	**WEEK 24 – 28** Gestational Diabetes	**WEEK 27 – 36** Tdap **WEEK 28 – 29** • Repeat Rh (if neg) • CBC, H&H **WEEK 32 – 34** Repeat STDs **WEEK 36** Group B Strep
OPTIONAL TESTS*	**WEEK 11 – 14** • Chorionic villus sampling (CVS) • Down Syndrome trisomy 13 or 18 • Inherited disorders	**WEEK 15 – 20** • Ultrasound: anatomical survey • Quad Screen: Blood test for alpha-fetoprotein, estriol, hCG, inhibin • Screens for Down Syndrome, trisomy 18, open neural tube defects	

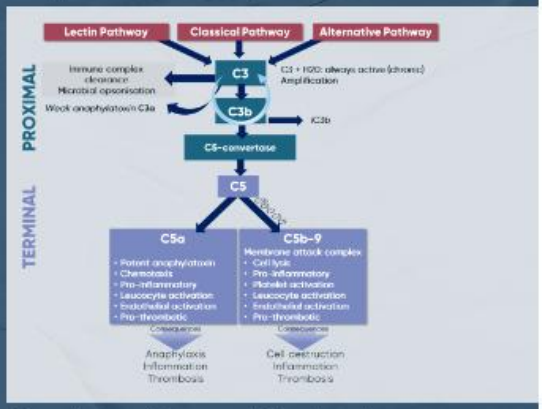
* Summarized from ACOG Guidelines for Perinatal Care; ** For pregnancies identified at high FNAIT risk, physicians may conduct additional follow-up testing, e.g., maternal anti-HPA-1a antibody status, fetal HPA-1a genotype, at their discretion

C5 INHIBITORS

For the Treatment of Diseases due to Complement Dysregulation

Applying Our Expertise to Transform Diseases of Complement Dysregulation

The complement system plays a central role in innate immunity as well as shaping adaptive immune response



Complement dysregulation has been implicated in the pathogenesis of a growing number of diseases

WHAT WE KNOW

- **Our team** has designed, developed, and/or secured approval for **two C5 inhibitors in four rare disease indications** globally
- C5 represents a **proven target** for intervention
- Efficacy requires a **rapid, complete, and sustained inhibition** of C5
- **Relationships with experts and KOLs** at key institutions around the world

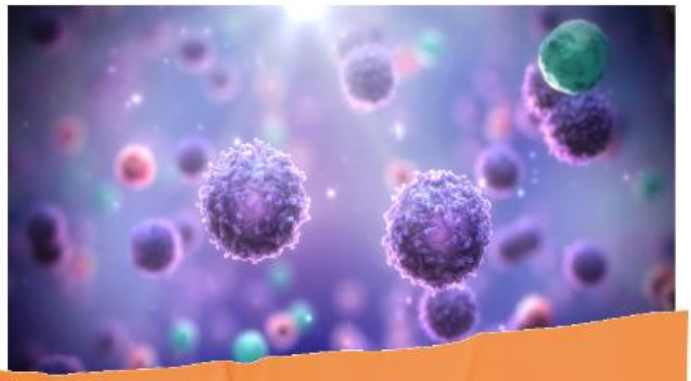
POTENTIAL DIFFERENTIATORS

- **Subcutaneous (sc)** administration
- **Less frequent** dosing
- **Broad tissue distribution**
- Favorable storage **stability**
- **Efficiency** of manufacturing
- **Broad indication** opportunities
- **No drug-target-drug complex (DTDC) formation** with switch from an antibody

Our Approach to Treating Diseases of Complement Dysregulation

RLYB116

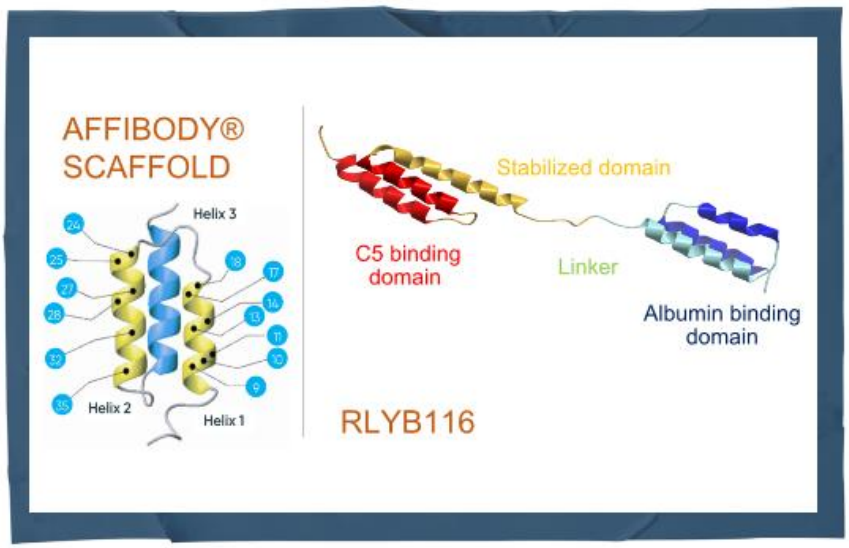
- Affibody® molecule linked to an Albumod® albumin binding domain
- Suitable for subcutaneous administration
- Phase 1 study initiated in February 2022
- Single dose safety, PK, and PD data expected 2H 2022



PHARMACODYNAMIC PROPERTIES

An *ex vivo* hemolytic inhibition assay indicates that RLYB116 inhibits C5-mediated red blood cell destruction at a dose that could be clinically useful

RLYB116 is Designed to Possess Attributes for Clinical and Commercial Success



ATTRIBUTES FOR CLINICAL AND COMMERCIAL SUCCESS

- Terminal complement blockade
- Rapid, complete, and sustained inhibition of C5
- Designed to be optimized for C5 binding, stability, and long half-life in serum
- Small size enabling sc administration
- Safety profile consistent with currently approved C5 inhibitors
- Broad tissue distribution with albumin binding
- Pricing flexibility

RLYB116 Phase 1 Study Design: Evaluating Safety, PK and PD of Single Ascending Dose

STUDY DESIGN

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

STUDY COHORTS

- Up to 6 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

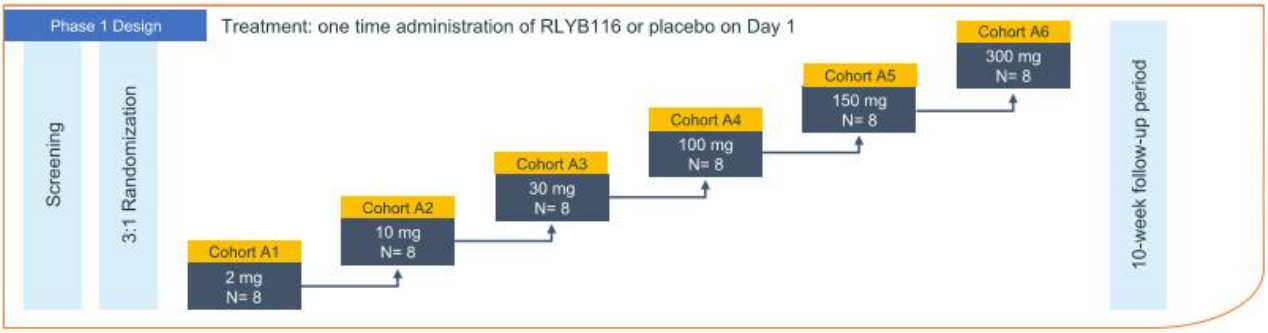
To evaluate the safety and tolerability of RLYB116 in healthy participants following single administration

SECONDARY OBJECTIVES

To establish 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



Lead Indication Strategy Guided by Biology

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

A potentially life-threatening, rare hematologic disorder characterized by complement-mediated destruction of red blood cells (RBCs) that lead to anemia, hemoglobinuria, and thrombosis. [1]

The prevalence of PNH has been estimated to be approximately 16 people per million. [2]

- Well-understood pathophysiology driven by complement system
- Opportunity for early clinical validation using objective endpoints
- Addresses significant outstanding unmet patient needs

GENERALIZED MYASTHENIA GRAVIS (gMG)

A potentially life-threatening, rare, autoimmune neuromuscular disorder characterized by weakness impacting the eyes, face, neck, jaw, throat, limbs and/or respiratory system. [3]

The prevalence of Myasthenia Gravis has been estimated to be at least 100 people per million. [4]

- Complement overactivity is known to contribute to disease pathophysiology
- Opportunity to address significant unmet need in a relatively large patient population with earlier-stage gMG

1. Brodsky, RA. Blood. 2014; 124 (18): 2804-2811; 2. Sahin, F. Am J Blood Res 2015; 5 (1): 1-9; 3. Howard, JF. Ann N Y Acad Sci. 2017; 1412 (1): 113-128; 4. Punga, AR. Lancet Neurol 2022; 21: 176-188

RLYB114 for Ophthalmic Indications of Complement Dysregulation

C5-targeted Affibody® molecule conjugated to polyethylene glycol (PEG)

- Complement dysregulation implicated in the pathogenesis of multiple ophthalmic disorders[1]
- C5 inhibition is a precedented approach, but significant unmet medical needs remain

Key Attributes

- Suitable for **ophthalmic use**
- Pegylated to extend half-life and reduce immunogenicity
- RLYB114 may have a half-life comparable to Lucentis®[2] and Eylea,®[3] based on an animal intravitreal PK study

1. Park et al 2019 Frontier in Immunology; 2. Bakri et al 2007 Ophthalmology; 3. Park et al 2016 Inv Ophthalmol Vis Sciences, Christoforidis et al 2012 Current Eye Research

RE VENTURES I

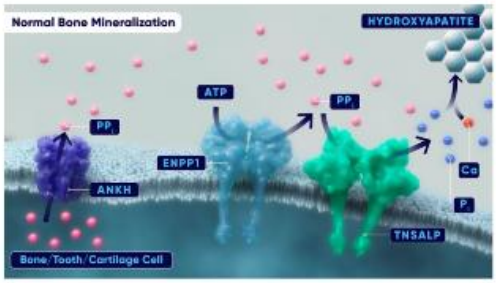
Joint Venture with Industry-leading AI/ML Pharmatech Exscientia

ENPP1 Inhibitor Program for Hypophosphatasia (HPP)

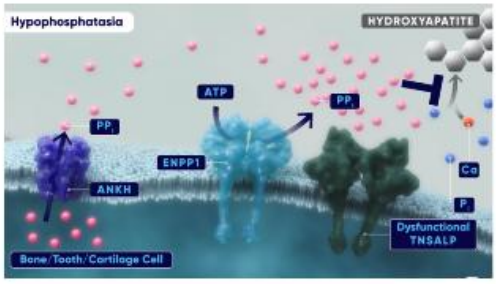
Hypophosphatasia is a Rare, Potentially Life-Threatening Genetic Disease

HPP DISEASE OVERVIEW

- Characterized by mutations in the ALPL gene that causes multiple skeletal pathologies
- ALPL mutation diminishes TNSALP enzyme activity leading to accumulation of inorganic pyrophosphate (PPi), an inhibitor of bone mineralization
- The most severe forms of HPP tend to occur before birth and in early infancy and can lead to life-threatening complications
- The incidence of HPP is reported to be 1 in 100,000 (US and Canada) to 1 in 300,000 (EU) for severe disease and 1 in 6,370 (EU) for less severe forms



Under normal conditions, the level of PPi and inorganic phosphate (Pi) is kept in balance by activity of TNSALP, ENPP1 and ANKH



In patients with hypophosphatasia, the reduction of PPi hydrolysis by TNSALP results in a relative increase in PPi, leading to an inhibition of mineralization, and inhibited hydroxyapatite formation

TNSALP: Tissue Non-Specific Alkaline Phosphatase

ENPP1 Inhibitor Approach to Address Unmet Need for Patients with HPP

UNMET NEED IN HPP

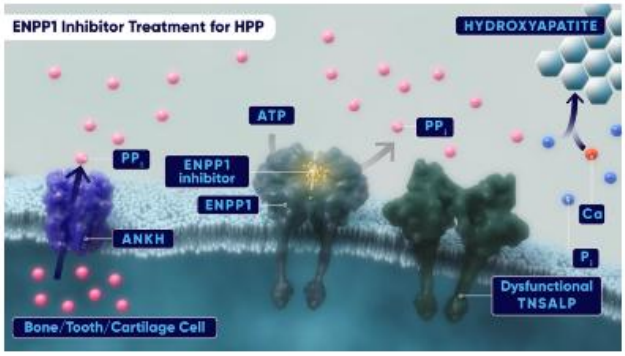
§ Significant population of underserved patients exist due to variability in disease severity and access to approved therapy

PROGRAM FOCUS & RATIONALE

- Small molecule inhibitors of ENPP1
- ENPP1 is the major source of extracellular inorganic pyrophosphate, which regulates bone mineralization

CANDIDATE PROFILING

- Multiple lead development candidates identified and profiling activities in progress
- IND-enabling activities anticipated in 2H22



Through controlled inhibition of ENPP1, we aim to reduce PPi and improve mineralization, restoring hydroxyapatite formation

ERT: Enzyme replacement therapy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