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): December 20, 2023

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	**06510**
(Address of Principal Executive Offices)	(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 Disclosure.

On December 20, 2023, Rallybio Corporation issued a press release announcing Phase 1 multiple ascending dose data for RLYB116, Rallybio's injected inhibitor of complement component 5 in development for the treatment of patients with complement-mediated diseases. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In connection with the press release, Rallybio posted an investor presentation to its website at www.rallybio.com. A copy of the presentation related to the announcement is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) 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 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	Press release issued by the Company on December 20, 2023.
99.2	Investor Presentation dated December 20, 2023.
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: December 20, 2023

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Exhibit 99.1

Rallybio Announces Preliminary Phase 1 Multiple Ascending Dose Data for RLYB116, an Innovative Subcutaneously Injected Inhibitor of Complement Component 5

-- 100 mg Results Demonstrated a Mean Reduction of Greater than 93% in Free C5 with Low Volume Once-a-Week Subcutaneous Dosing --

-- Data Supports the Study of RLYB116 as a Differentiated Therapeutic for the Treatment of Generalized Myasthenia Gravis --

-- Company Announces Extension of Runway to 3Q 2025 As Part of Portfolio Prioritization --

-- Conference Call and Webcast Today at 8:30 AM Eastern Time --

NEW HAVEN, Conn., December 20, 2023 – Rallybio Corporation (Nasdaq: RLYB) today announced preliminary Phase 1 multiple ascending dose (MAD) data for RLYB116, an innovative, long-acting, low volume subcutaneously injected inhibitor of complement component 5 (C5), in development for patients with complement-mediated diseases.

The Phase 1 MAD study for RLYB116 evaluated the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of subcutaneous RLYB116 in healthy participants with multiple dose administration. The MAD study utilized an adaptive design and included four cohorts of 12 participants receiving doses of up to 200 mg per week of RLYB116 or placebo, with a four-week treatment duration and a 10-week follow-up period.

The preliminary results showed:

- A 100 mg low volume (1 mL) once-a-week dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at Day 29 with measurement prior to the last dose. The reduction in free C5 at 24 hours after the first dose of 100 mg was greater than 99%. These data and additional work we have conducted with RLYB116 reinforce our confidence that RLYB116 has the potential to be an effective treatment for patients with certain complement-mediated diseases, including generalized myasthenia gravis (gMG).
- RLYB116 also demonstrated low inter-subject variability and consistent increases in exposure relative to dose. The mean estimated elimination half-life for RLYB116 was >300 hours.
- In comparison to 100 mg weekly administration, higher concentrations of RLYB116 were observed in a cohort with 100 mg administered twice per week and were associated with a greater than 97% mean reduction in free C5.
- RLYB116 administered as a 100 mg once-a-week dose was observed to be generally well tolerated. The most common adverse event (AE) in the cohort was injection site reaction (ISR), which occurred in 60% of the participants in the cohort. All AEs during subcutaneous administration with the 100 mg weekly dose were mild in severity.

- The ISR rate for all participants in the 4 cohorts was 59% and all were mild in severity. There were no serious AEs reported for participants receiving study treatment.
- A participant with a history of hepatitis A receiving the 150 mg dose experienced liver enzyme test elevation that resulted in discontinuation and a reduction in the dose for the 3rd cohort from 150 mg to 125 mg.
- The measurement of anti-drug antibody (ADA) formation in the study did not demonstrate an effect on PK or PD parameters and did not appear to be associated with an effect on AE incidence or severity.

“The preliminary results from this Phase 1 multiple ascending dose study of RLYB116 support continued development in patients with gMG,” said Eric Watsky, M.D., RLYB116 Program Lead for Rallybio. “We are encouraged by the free C5 reductions demonstrated by RLYB116 as well as the exposures achieved with subcutaneous administration. Through enhancements in the manufacturing process, we believe we have the opportunity to increase the dose of RLYB116 and improve the tolerability thereby opening up the opportunity to treat a wider range of complement mediated diseases. Our market research is consistent with our belief that an effective, once-a-week, well-tolerated therapy that can be rapidly self-administered with an autoinjector would be an attractive alternative for patients.”

RLYB116 Near-Term Development Plans and Cash Runway

The preliminary data from the Phase 1 MAD study confirm improvements made to date in the manufacturing process will enable the Company to advance RLYB116 into studies in patients. Rather than immediately proceed to a Phase 2 study in gMG, the Company intends to prioritize near-term investments in RLYB116 in the manufacturing process. The Company expects that the additional manufacturing work will improve tolerability at higher doses with a low injection volume and infrequent subcutaneous administration. The Company believes such enhancements will enable higher exposure to RLYB116 and potentially increase C5 reduction, which can result in treating a broader range of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria and antiphospholipid syndrome. In addition, this will allow the Company to direct available cash resources to advance RLYB212, its product candidate for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT).

The Company is also updating its cash runway guidance and now expects its current cash, cash equivalents and marketable securities to extend the runway into the third quarter of 2025.

“We are pleased to see substantial reductions in free C5 with once weekly subcutaneous dosing of RLYB116,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio. “The Phase 1 MAD data show us that RLYB116 can be a potential therapeutic to treat gMG and other complement mediated diseases. In the spirit of managing our cash runway to realize the most value from our portfolio, we have decided to focus our RLYB116 investments on the manufacturing process with a goal of expanding the scope of therapeutic indications and addressing unmet medical need. In parallel, we continue to advance our lead program, RLYB212, and have extended our runway into the third quarter of 2025.”

Conference Call Information

Rallybio will host a conference call and webcast today, December 20, 2023 at 8:30 a.m. Eastern Time to discuss the RLYB116 Phase 1 multiple ascending dose (MAD) study. The live webcast and replay may be accessed by visiting Rallybio's website at http://investors.rallybio.com. In addition, key slides from the RLYB116 Phase 1 MAD study will be discussed on the conference call and are posted to the "Events and Presentations" section of the Rallybio website. A replay of the webcast will be available on the Rallybio website for 30 days following the event.

About RLYB116 Phase 1 Study

RLYB116 is an innovative, long-acting, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-mediated diseases. Phase 1 in healthy participants included the study of RLYB116 as a single ascending dose and multiple ascending dose. The multiple ascending dose (MAD) study of RLYB116 included an adaptive single-blind design initiated in the first quarter of 2023 with a 4-week treatment duration to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneous RLYB116 in healthy participants with multiple dose administration.

The MAD study of RLYB116 included 4 cohorts: Cohort 1 (weekly dosing of 100 mg), Cohort 2 (3 doses of 100 mg the first week followed by weekly dosing), Cohort 3 (150 mg weekly dosing reduced to 125 mg weekly dosing) and Cohort 4 (75 mg twice the first week followed by 100 mg twice per week).

Post-treatment / study follow-up continued for 10 weeks.

About Rallybio

Rallybio (NASDAQ: RLYB) is a clinical-stage biotechnology company with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Rallybio has built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. The Company has two clinical stage programs: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT) and RLYB116, an inhibitor of complement component 5 (C5), with the potential to treat several diseases of complement dysregulation, as well as additional programs in preclinical development.

Rallybio is headquartered in New Haven, Connecticut with an additional facility at the University of Connecticut's Technology Incubation Program in Farmington, Connecticut. For more information, please visit www.rallybio.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements that are based on our management's beliefs and assumptions and on currently available information. All statements, other than statements of historical facts contained in this press release are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements concerning results from the Phase 1 MAD study of RLYB116; potential clinical effects and benefits of RLYB116, including for the treatment of gMG; the timing and initiation of future clinical studies for RLBY116; the success cost and timing of our clinical development of our product candidates, including RLYB212 and RLYB116; and statements concerning the Company's anticipated use of cash and cash runway. The forward-looking statements in this press release are only predictions and are based largely on management's current expectations and projections about future events and financial trends that management believes may affect Rallybio's business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our ability to successfully initiate and conduct our planned clinical 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, our ability to enter into strategic partnerships or other arrangements, competition from other biotechnology and pharmaceutical companies, and those risks and uncertainties described in Rallybio's filings with the U.S. Securities and Exchange Commission (SEC), including Rallybio's Quarterly Report on Form 10-Q for the period ended September 30, 2023, and subsequent filings with the SEC. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise.

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Forward-Looking Statements

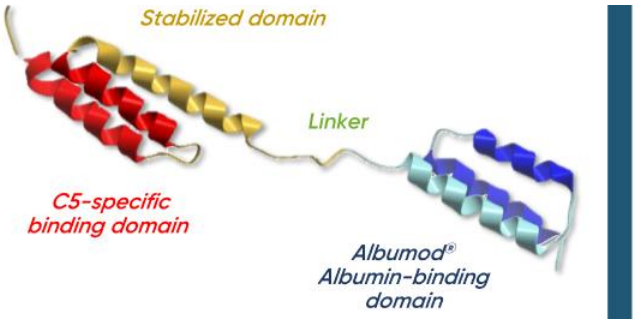
This presentation contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this presentation are forward-looking statements. some cases, you can 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 results from the Phase 1 multiple ascending dose study for RLYB116; the potential clinical effects and benefits of RLYB11 including for the treatment of gMG; the timing of initiation and completion of future clinical studies for RLYB116, including a Phase 2 study evaluatin RLYB116 for the treatment of gMG, and the period during which the results of such studies will become available; the success, cost and timing of ou clinical development of our product candidates; including RLYB212 and RLYB116; our ability to obtain and maintain regulatory approval of our prod candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved; our ability to compete v companies currently marketing or engaged in the development of treatments for diseases that RLYB116 is designed to target, including gMG; our ability to successfully and timely implement modifications to the manufacturing process for RLYB116, and whether such modifications would result i desired effects; our expectations regarding government and third-party payor coverage and reimbursement; our estimates of our expenses, ongo losses, capital requirements and our needs for or ability to obtain additional financing; 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 projection about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-look statements speak only as of the date of this presentation and are subject to a number of known and unknown risks, uncertainties and assumption including but not limited to, our ability to successfully initiate and conduct our planned clinical trials and complete such clinical trials and obtain res on our expected timelines, or at all, whether our cash resources will be sufficient to fund our operating expenses and capital expenditure requirem and whether we will be successful raising additional capital, competition from other biotechnology and pharmaceutical companies, and those risk and uncertainties described in our filings with the Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in ou 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 which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. The events and circumstan 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. N risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as require by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained herein, whether as a result of any information, future events, changed circumstances or otherwise.

RLYB116: Potential Differentiators

Affibody® molecule

- Subcutaneous low volume injection
- Suitability for rapid autoinjector self-



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

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 o

RLYB116

Single Ascending Dose Data

RLYB116 Phase 1 Single Ascending Dose

STUDY DESIGN

Single-blind, placebo-controlled, dose escalation study design 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

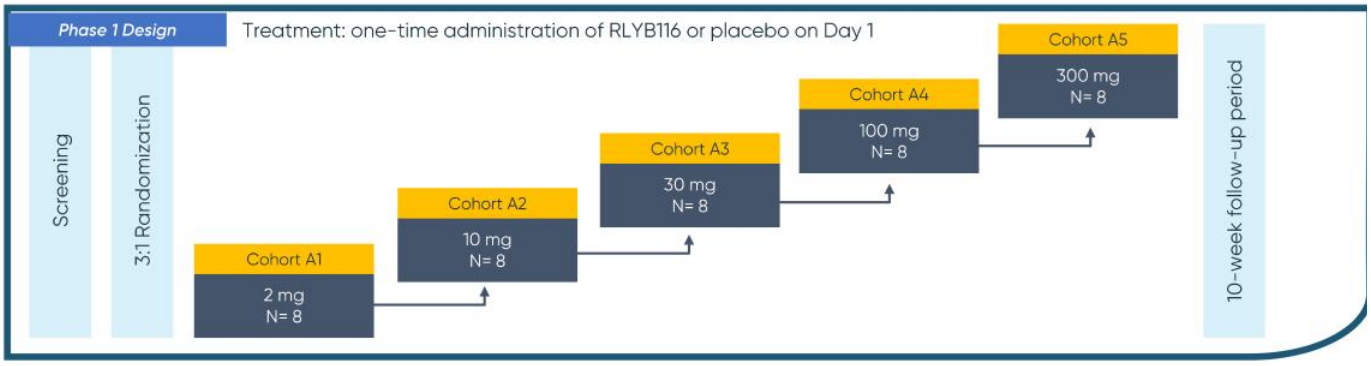
To evaluate the safety and tolerability of RLYB116 in healthy participants following single dose administration

SECONDARY OBJECTIVES

To evaluate the PK profile of RLYB116 following subcutaneous administration

To evaluate the immunogenicity of single doses of RLYB116

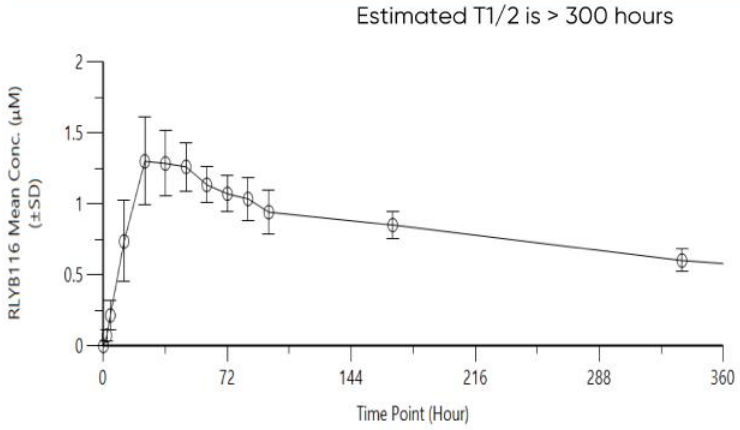
To characterize the PD proprieties of RLYB116 following single administration



Source: RLYB116 IPC2001

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

RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) PK



RLYB116 IPC2001 FIH SAD Cohort 4 (100 Free C5 Data**			
Participant	Baseline (ng/mL)	At 24 hours (ng/mL)	% reduc
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

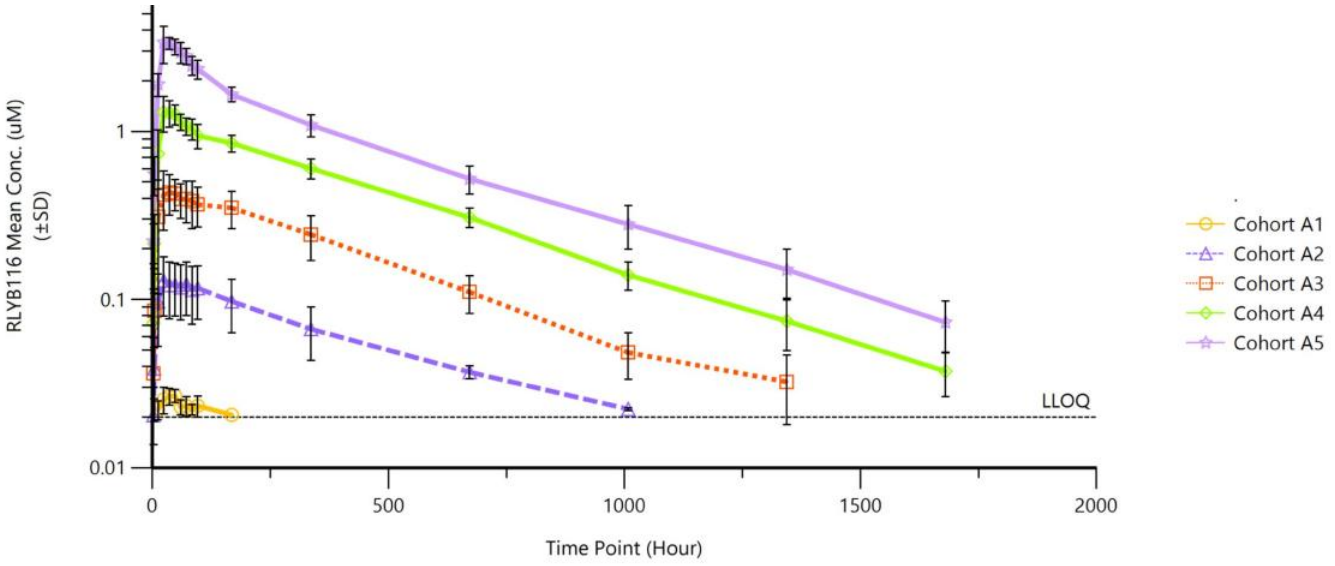
**numbering for participants has been de-ide

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

*Source: Rallybio IPC2001 data

RLYB116 FIH SAD Pharmacokinetic Data

Consistent increases in exposure with increasing dose levels, low inter-subject variabilit and a mean elimination half-life greater than 300 hours with subcutaneous injection



Source: ICW 2023

Draft Treatment-Emergent Adverse Events (Single-Dose) ≥ 5.0

AE preferred term	RLYB116					Placebo N=10 n (%)	All N=40 n (%)
	2 mg N=6 n (%)	10 mg N=6 n (%)	30 mg N=6 n (%)	100 mg N=6 n (%)	300 mg N=6 n (%)		
Gastrointestinal disorders							
Abdominal pain/discomfort				2 (33.3)	2 (33.3)		4 (10.0)
Diarrhea	1 (16.7)			1 (16.7)	3 (50.0)	1 (10.0)	6 (15.0)
Nausea/Vomiting					2 (33.3)		2 (5.0)
General disorders and administration							
Fatigue/Lethargy		1 (16.7)	1 (16.7)				2 (5.0)
Infections and infestations							
COVID-19	1 (16.7)		1 (16.7)	1 (16.7)			3 (7.5)
Upper respiratory tract infection		1 (16.7)		1 (16.7)		1 (10.0)	3 (7.5)
Musculoskeletal and connective tissue disorders							
Back pain		2 (33.3)					2 (5.0)
Myalgia					1 (16.7)	1 (10.0)	2 (5.0)
Nervous system disorder							
Dizziness/dizziness postural					2 (33.3)	1 (10.0)	3 (7.5)
Headache/migraine	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)	2 (33.3)	2 (20.0)	9 (22.5)
Presyncope		1 (16.7)		1 (16.7)			2 (5.0)

[1]RLYB116 DSUR 2023

Adverse events were mild to moderate in severity and there was a dose-related increase in the frequency of gastrointestinal adverse events. No drug-related serious adverse events.

RLYB116

Multiple Ascending Dose Data
IPC2001: Adaptive Study Design

RLYB116 Phase 1 Multiple Ascending Dose Adaptive Study Desi

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

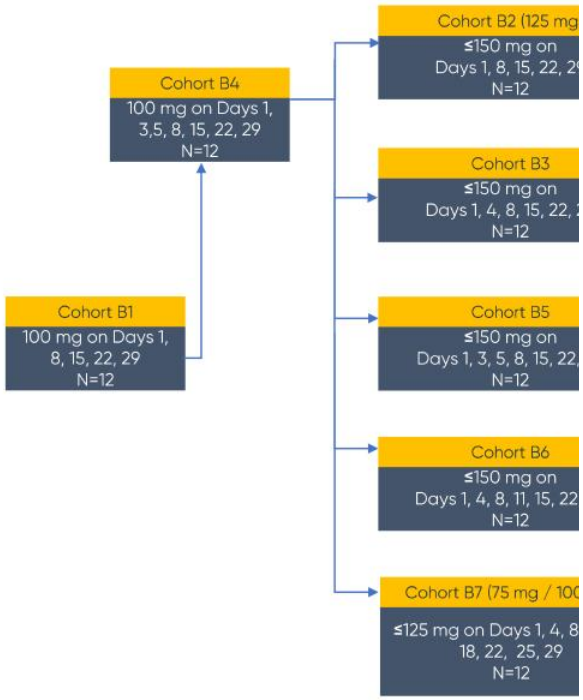
To evaluate the safety and tolerability of RLYB116 in healthy participants following multiple administration

SECONDARY OBJECTIVES

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

Screening up to 70 days

5:1 Randomization



Source: RLYB116 IPC2001

Multiple Ascending Dose Adaptive Design (What We Did)

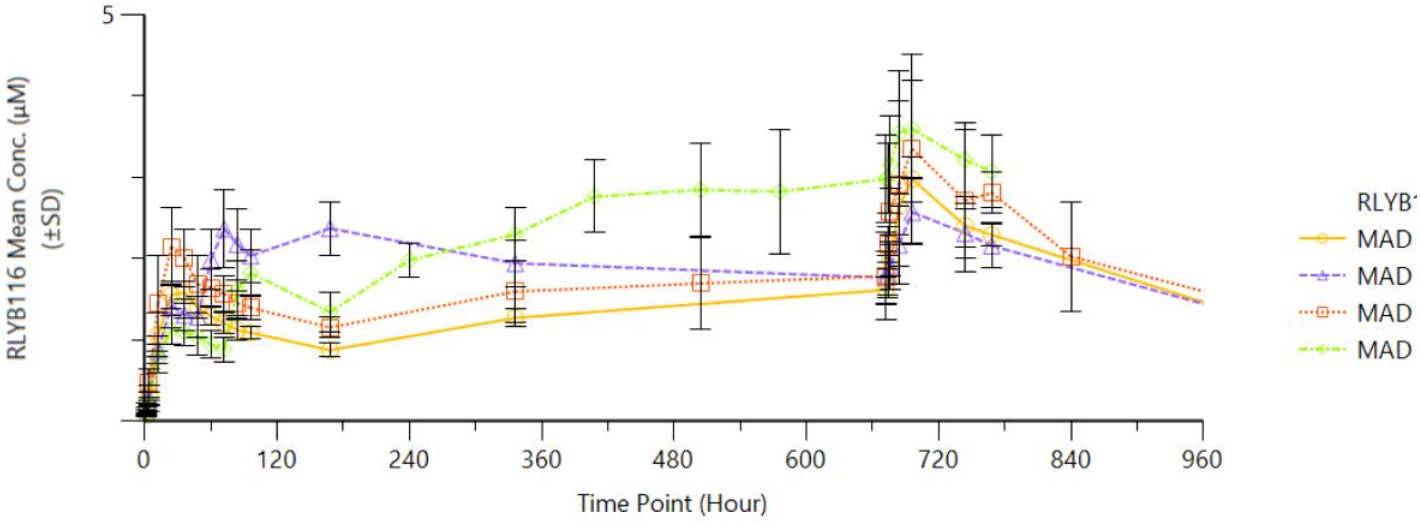
Treatment Duration – 4 Weeks

- Cohort 1/B1: 100 mg weekly

- Cohort 2/B4: 100 mg 3 times for the first week and then weekly
- Cohort 3/B2: 150 mg weekly adjusted to 125 mg weekly
- Cohort 4/B7: 75 mg 2 times for the first week and then 100 mg twice per we

RLYB116 FIH MAD Pharmacokinetic Data

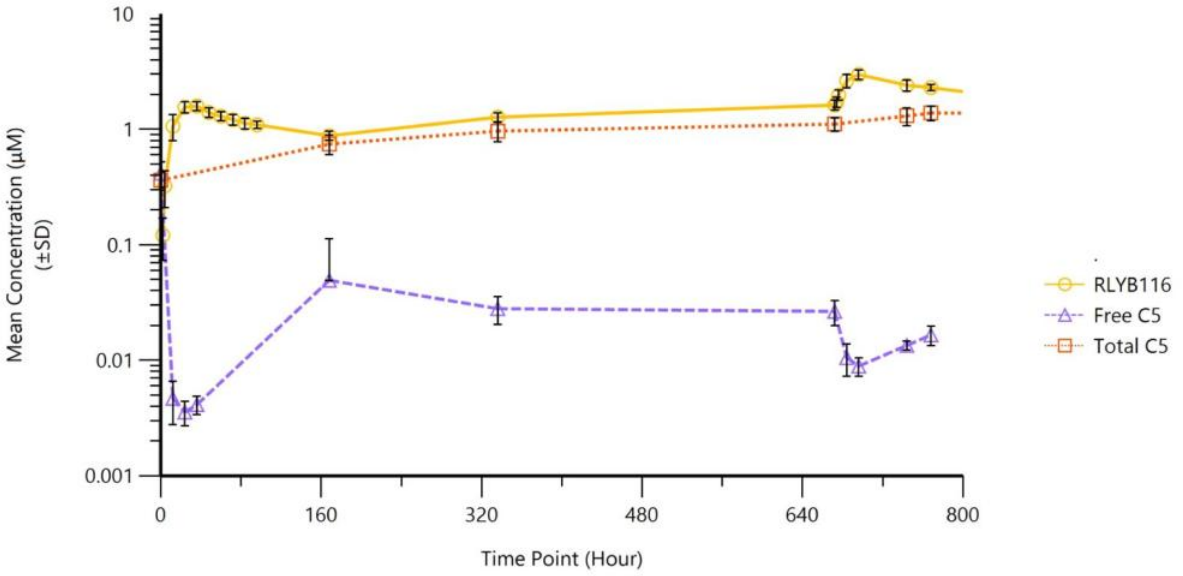
Sustained exposure greater than 1µM for all doses with low inter-subject variability with subcutaneous injection



Source: Rallybio IPC2001 data

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

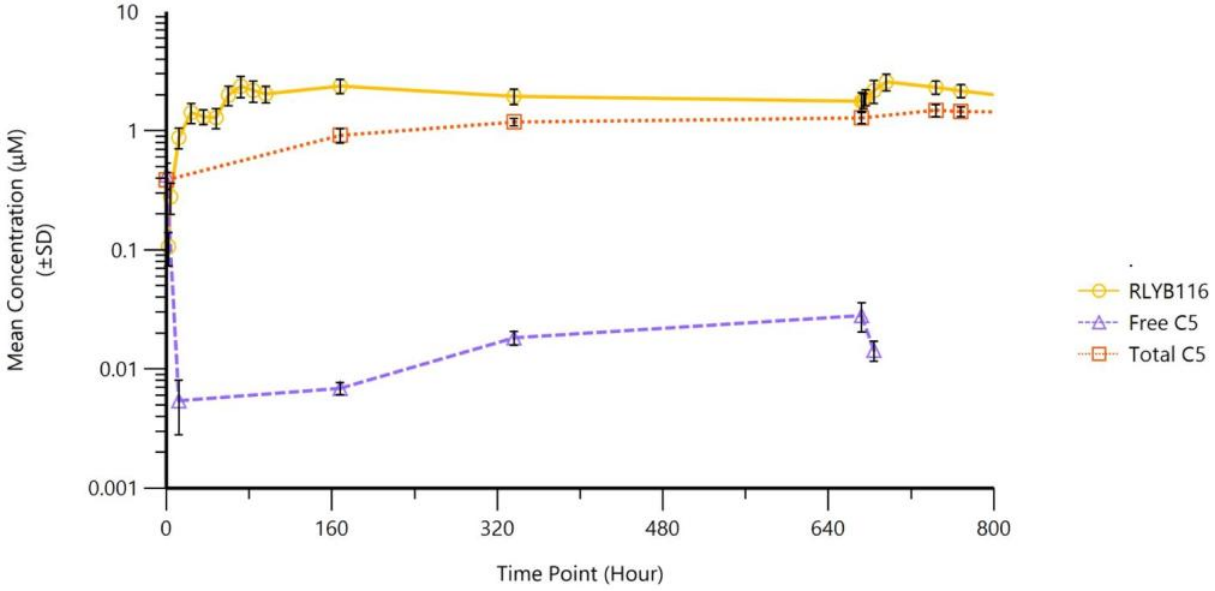
100 mg weekly sc dose resulted in reductions in free C5 > 99% at 24 hours and sustained reductions > 93% as measured pre-dose at Day 29



Source: Rallybio IPC2001 data

RLYB116 FIH IPC2001 Cohort 2: 100 mg induction PK/PD Data

100 mg induction dosing with weekly dose resulted in <10% higher concentrations of RLY at steady-state and similar reductions in free C5 compared with 100 mg QW

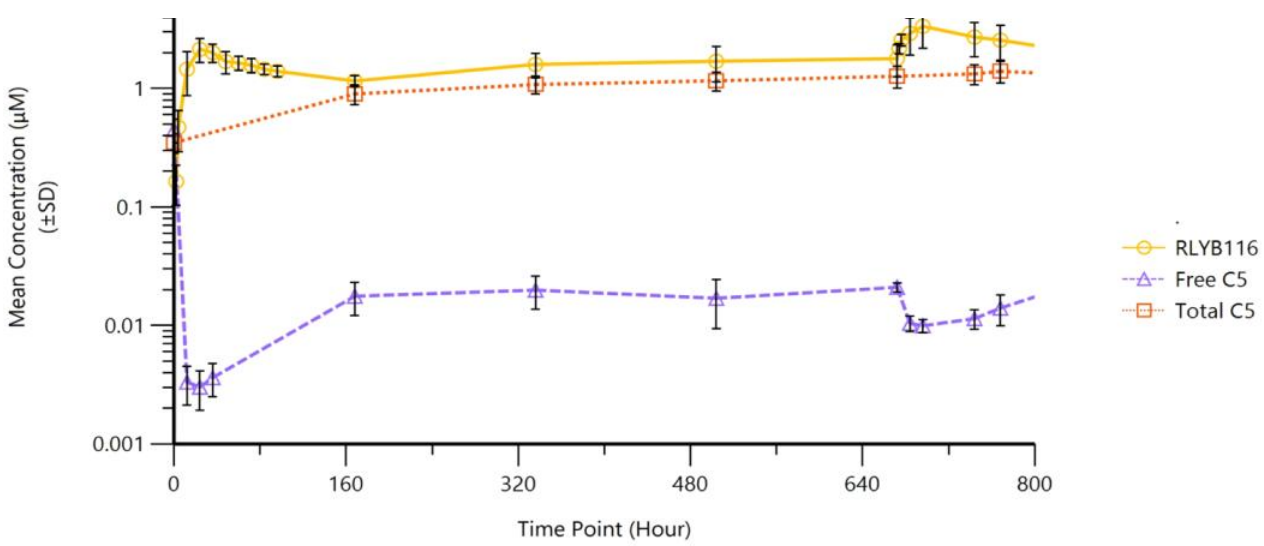


Source: Rallybio IPC2001 data

RLYB116 FIH IPC2001 Cohort 3: 150/125 mg QW PK/PD data

Adjustments made to dose level from 150 to 125 mg based on emergent adverse event

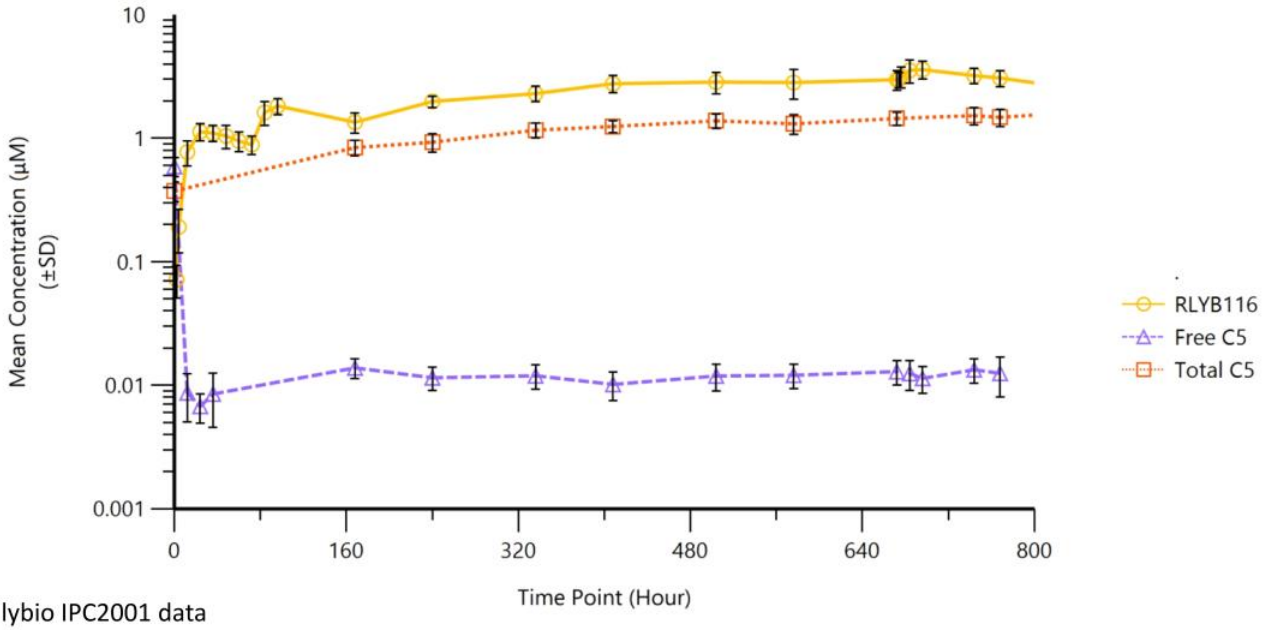
125 mg weekly dose resulted in similar sustained steady-state reductions in free C5 concentrations when compared with 100 mg weekly



Source: Rallybio IPC2001 data

RLYB116 FIH IPC2001 Cohort 4: 75 mg/100 mg BIW PK/PD

Concentrations of RLYB116 nearly 2X and sustained free C5 halved compared with prior cohorts but did not result in sustained effects on free C5 below the 0.5 µg/mL threshold identified for PNH



Source: Rallybio IPC2001 data

Draft Treatment-Emergent Adverse Events (Multiple-Dose) ≥ 5.

AE System Organ Class and Preferred Terms	RLYB116				Placebo N=9 n (%)	All N=49 n (%)
	100 mg QW N=10 n (%)	100 mg induction N=10 n (%)	150/125 mg QW N=10 n (%)	75/100 mg BIW N=10 n (%)		
Gastrointestinal disorders						
Abdominal pain/discomfort	2 (20.0)	2 (20.0)	2 (20.0)			6 (12.2)
Diarrhea	1 (10.0)			2 (20.0)		3 (6.1)
Nausea/Vomiting	1 (10.0)	2 (20.0)	4 (40.0)	2 (20.0)		9 (18.4)
General disorders and administration						
Fatigue/Lethargy	1 (10.0)	1 (10.0)	1 (10.0)	2 (20.0)		5 (10.2)
Injection site reaction (ISR)	6 (60.0)	5 (50.0)	8 (80.0)	10 (100.0)		29 (59.2)
Pyrexia			3 (30.0)	1 (10.0)		4 (8.2)
Infections and infestations						
Upper respiratory tract infection	2 (20.0)			1 (10.0)	1 (11.1)	4 (8.2)
Nervous system disorder						
Dizziness/dizziness postural	2 (20.0)		2 (20.0)	1 (10.0)	1 (11.1)	6 (12.2)
Headache/migraine	2 (20.0)	4 (40.0)	2 (20.0)	3 (30.0)	2 (22.2)	13 (26.5)
Respiratory, thoracic, and mediastinal disorders						
Oropharyngeal pain			1 (10.0)	1 (10.0)	1 (11.1)	3 (6.1)

Injection si
reaction (ISR)
the most com
adverse even
mild in sever
Gastrointest
adverse eve
increased w
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[1]RLYB116 DSUR 2023

RLYB116 IPC2001 Anti-Drug Antibody (ADA) Update

No impact apparent for ADA on PK, PD, and safety data

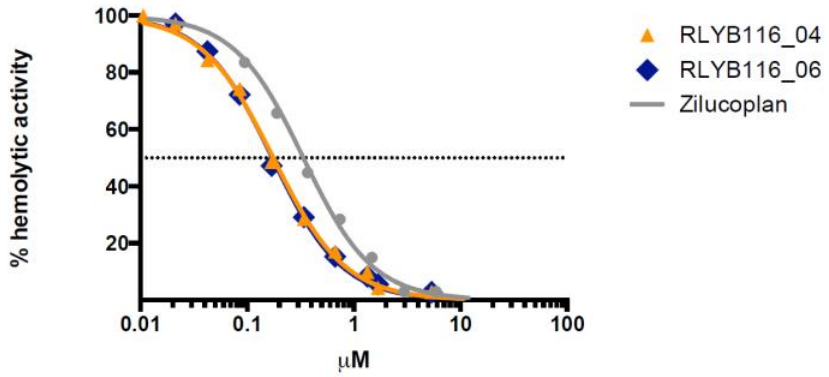
- MAD Day 99 data: rate of treatment-emergent ADA formation (which includes ≥4x titre increase post-baseline for participants with pre-existing ADA)
  - RLYB116 40.8%
  - Placebo 12.5%
- No apparent impact on PK or PD parameters
- Adverse events for ADA outliers comparable to overall study population
- ADA data appears to be consistent with other reported experience with affibodies

Source: Rallybio Phase 1 IPC2001 data

RLYB116 CH50 functional assay with lower IC50 than zilucopla

Conducted under matching conditions to zilucoplan published data (1% sera)[1]
Similar effect to research-grade zilucoplan supportive for investigation of RLYB116 in gM

Classical Complement Pathway Activity



	Zilucoplan	RLYB116_04	RLYB116_06
IC50	0.3368	0.1761	0.1722

[1]Tang 2023

RLYB116: CMC Activities Underway

- Drug substance manufacturing processes are being developed with our CDMO consistent with a continuous improvement, phase-appropriate approach
- We have employed additional analytical tools to identify process-related impurities below the sensitivity of the existing test methods
- We are optimizing the manufacturing process to minimize the presence of these process-related impurities
- A newly available and innovative custom step which can be easily incorporated will be included in future manufacturing campaign to further reduce process-related impurities
- While we will be able to quantify the reduction in these process-related impurities, we will not know if the reduction improves the clinical tolerability profile until tested clinically

RLYB116: Summary and Plan Forward

- Reduction in free C5 with 100 mg weekly dose in MAD study has the potential to be effective for patients with gMG
- Market research supports that a once weekly, small volume, and rapid self-administered therapeutic has the potential to address unmet need for more patient-friendly treatment options in gMG
- Potential to further improve the tolerability profile and enable greater free C5 reductions through adjustments to the manufacturing process
- Further planning for future clinical studies under consideration