TAKING DEVASTATING DISEASES – AND DEVASTATING THEM.

December 2023

We're going there.

Rallybio

RLYB116 Conference Call

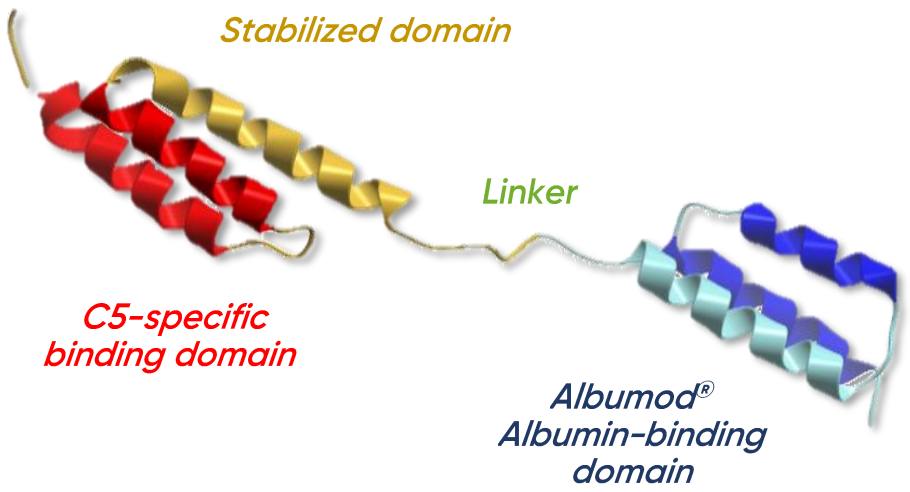
Forward-Looking Statements

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 results from the Phase 1 multiple ascending dose study for RLYB116; the potential clinical effects and benefits of RLYB116, including for the treatment of gMG; the timing of initiation and completion of future clinical studies for RLYB116, including a Phase 2 study evaluating 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 our clinical development of our product candidates; including RLYB212 and RLYB116; 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 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 in the desired effects; our expectations regarding government and third-party payor coverage and reimbursement; our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing; our ability to 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.

RLYB116: Potential Differentiators

Affibody® molecule



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

- Subcutaneous low volume injection
- Suitability for rapid 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

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

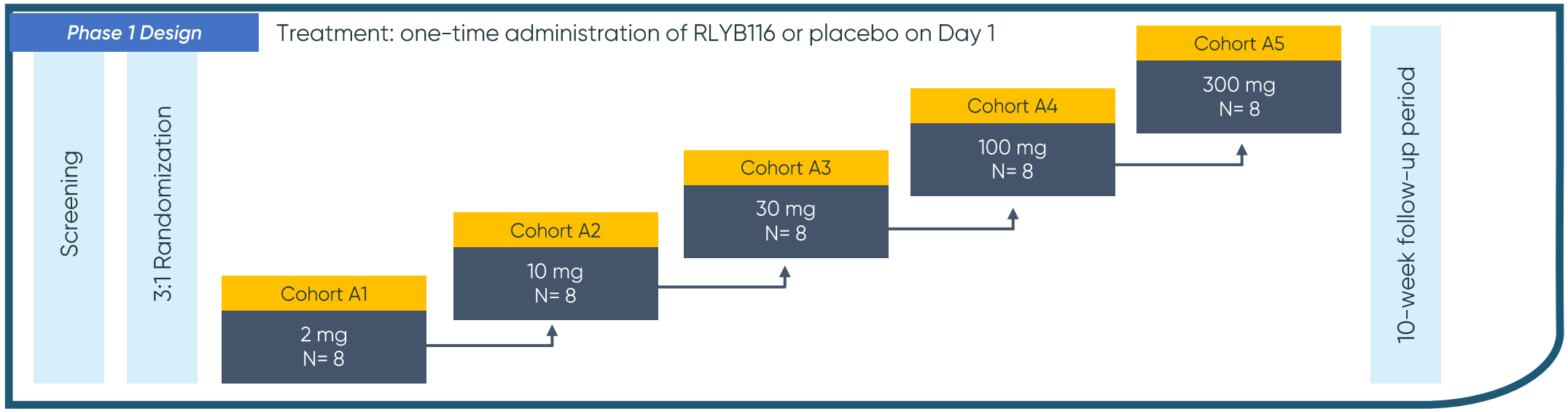
To evaluate the safety and tolerability of RLYB116 in healthy participants following single dose administration

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

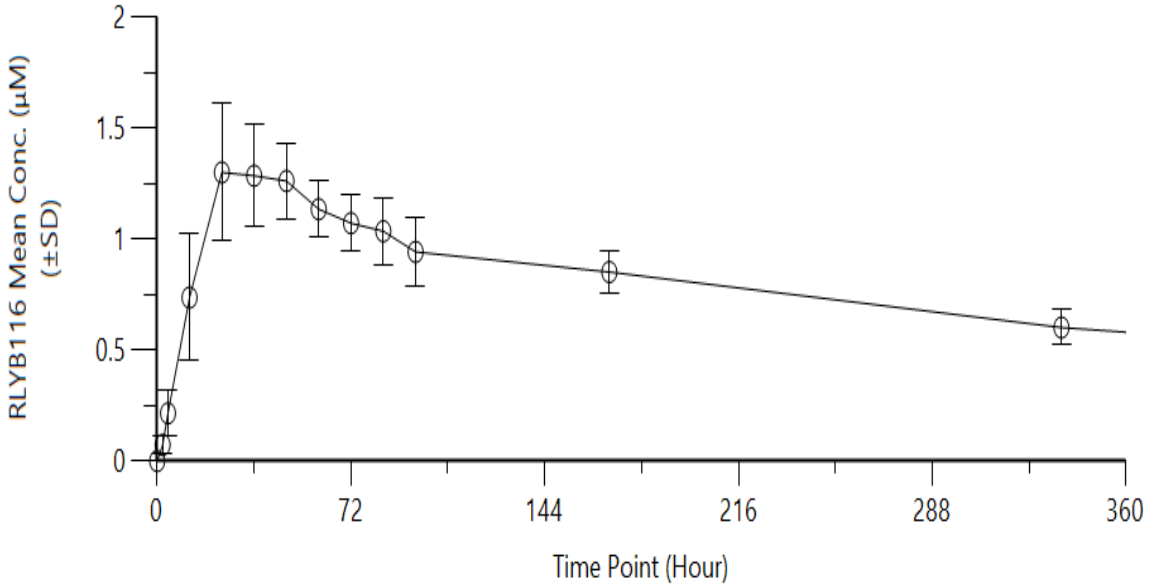


Source: RLYB116 IPC2001

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

RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) PK

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.**

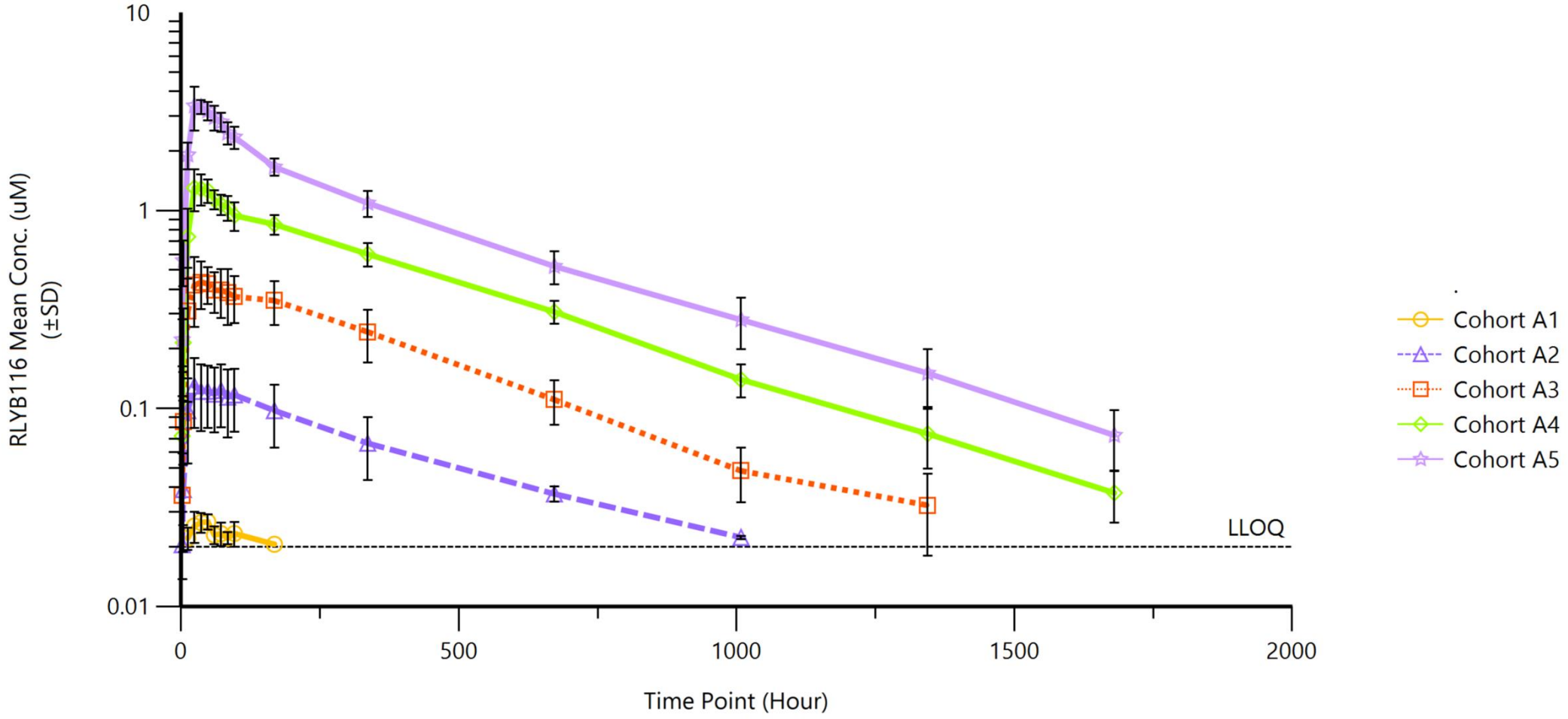
RLYB116 IPC2001 FIH SAD Cohort 4 (100 mg) Free C5 Data**			
Participant	Baseline (ng/mL)	At 24 hours (ng/mL)	% reduction
1	91,300	503	99.4%
2	91,300	360	99.6%
3	84,600	562	99.3%
4	94,800	497	99.5%
5	100,000	733	99.3%
6	135,000	747	99.4%
Mean	99,500	567	99.4%

**numbering for participants has been de-identified

*Source: Rallybio IPC2001 data

RLYB116 FIH SAD Pharmacokinetic Data

Consistent increases in exposure with increasing dose levels, low inter-subject variability, 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%[1]

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)

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.

[1]RLYB116 DSUR 2023

RLYB116

Multiple Ascending Dose Data
IPC2001: Adaptive Study Design

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

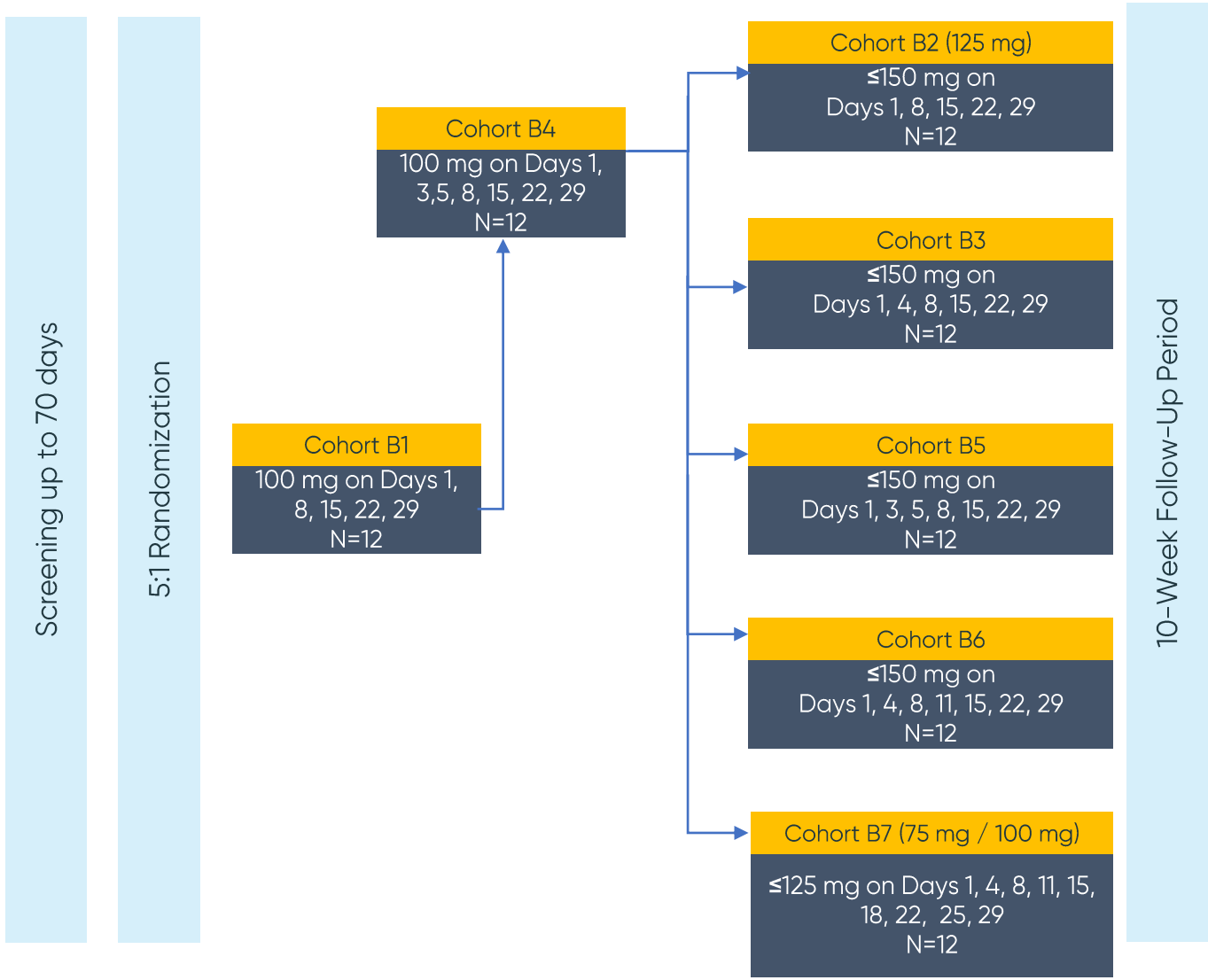
- Cohort 1/B1: weekly dosing of 100mg
- Cohort 2/B4: 3 doses of 100mg the first week then weekly dosing
- Cohort 3/B2: 150mg weekly dosing reduced to 125mg weekly dosing
- Cohort 4/B7: 75 mg twice the first week and then 100 mg twice per week

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



Source: RLYB116 IPC2001

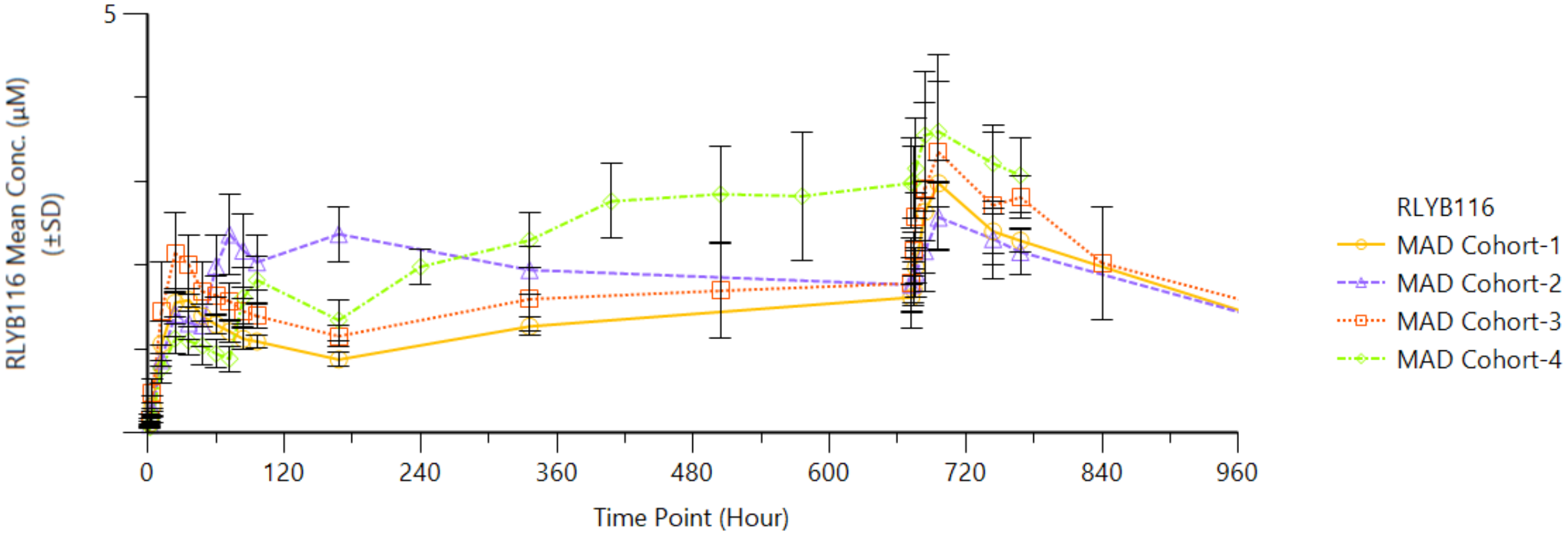
Multiple Ascending Dose Adaptive Design (What We Did)

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 week

RLYB116 FIH MAD Pharmacokinetic Data

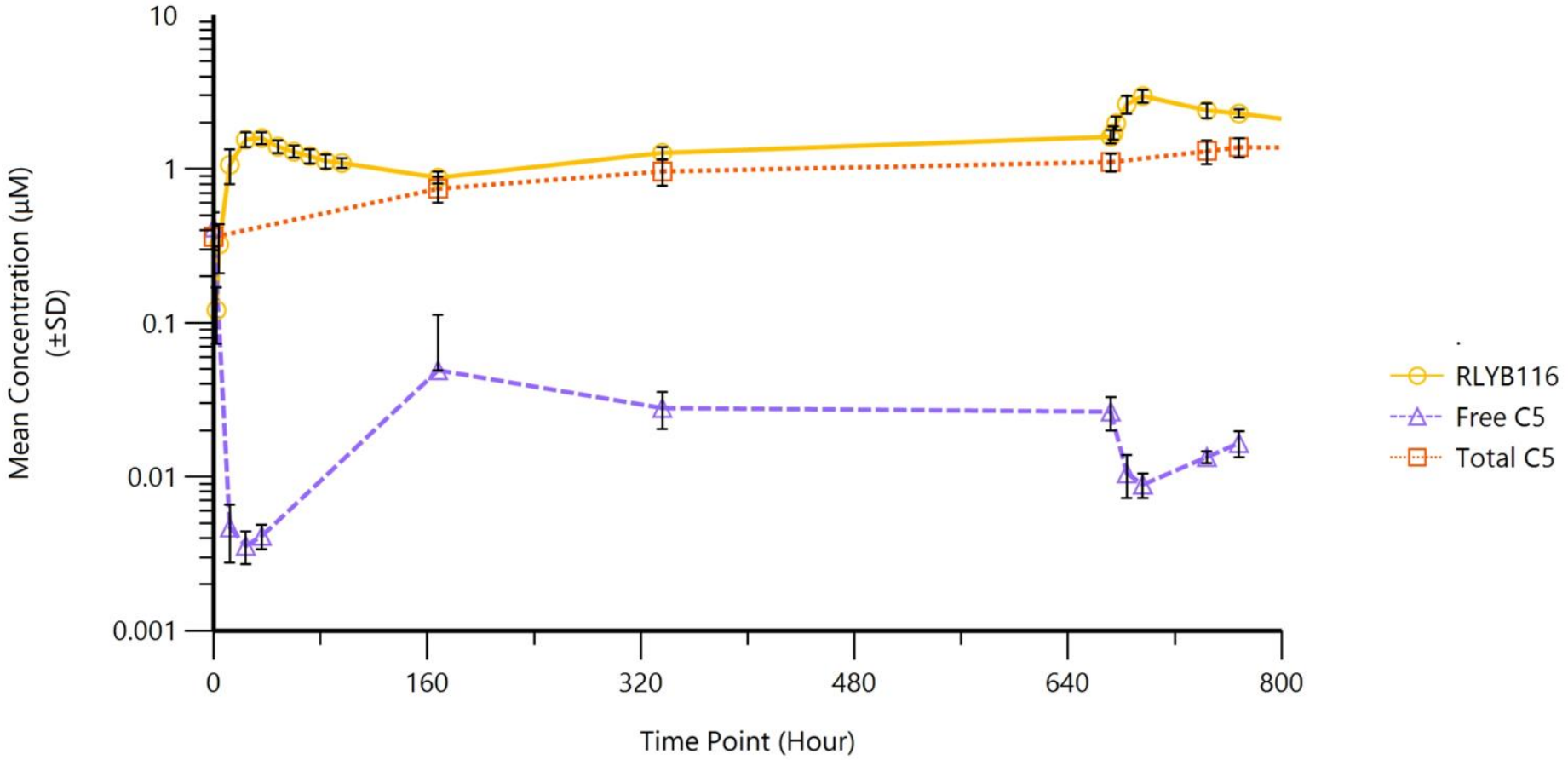
Sustained exposure greater than 1µM for all doses with low inter-subject variability with subcutaneous injection



Source: Rallybio IPC2001 data

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

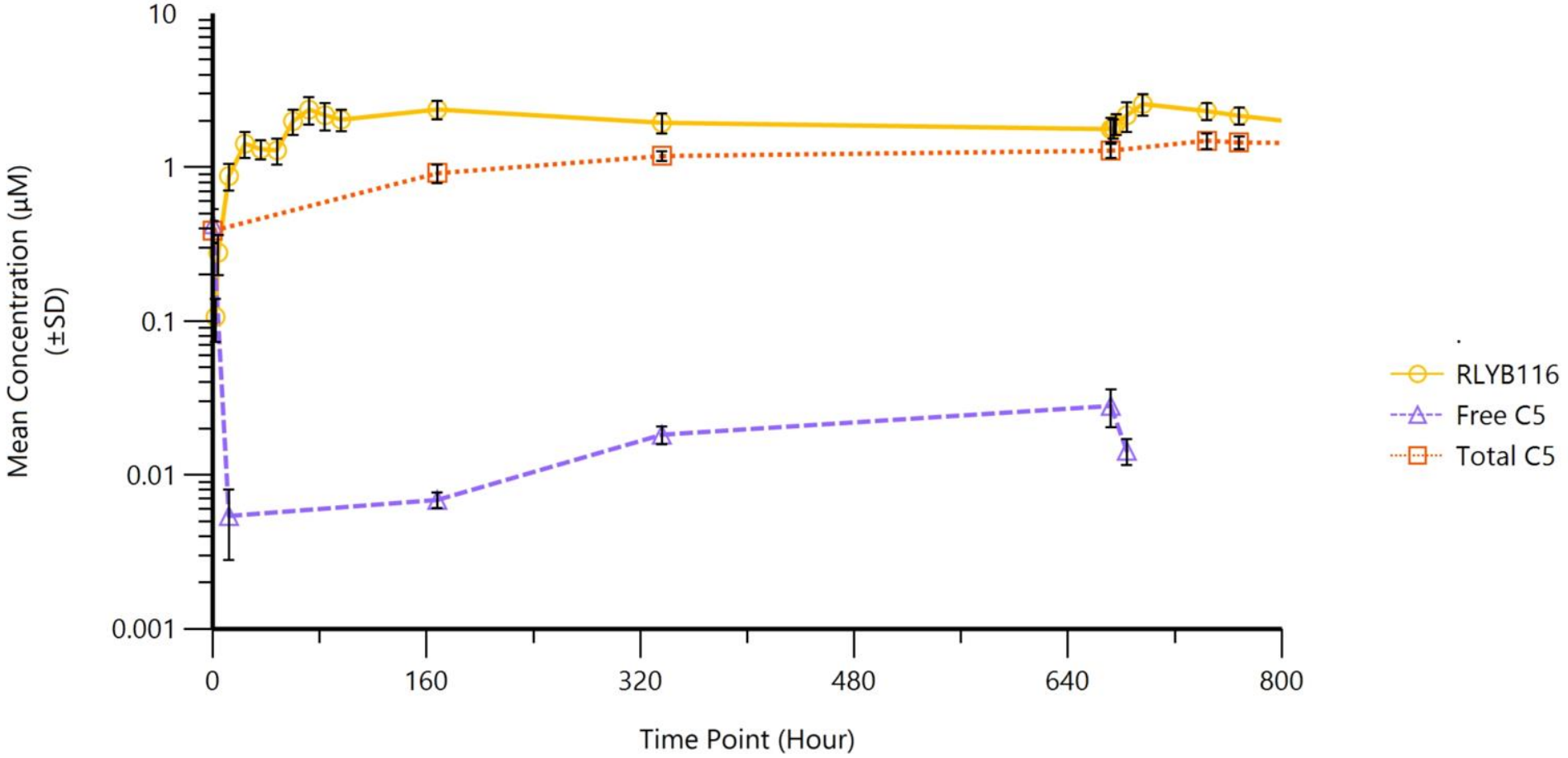
100 mg weekly sc dose resulted in reductions in free C5 > 99% at 24 hours and sustained reductions > 93% as measured pre-dose at Day 29



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 RLYB116 at steady-state and similar reductions in free C5 compared with 100 mg QW

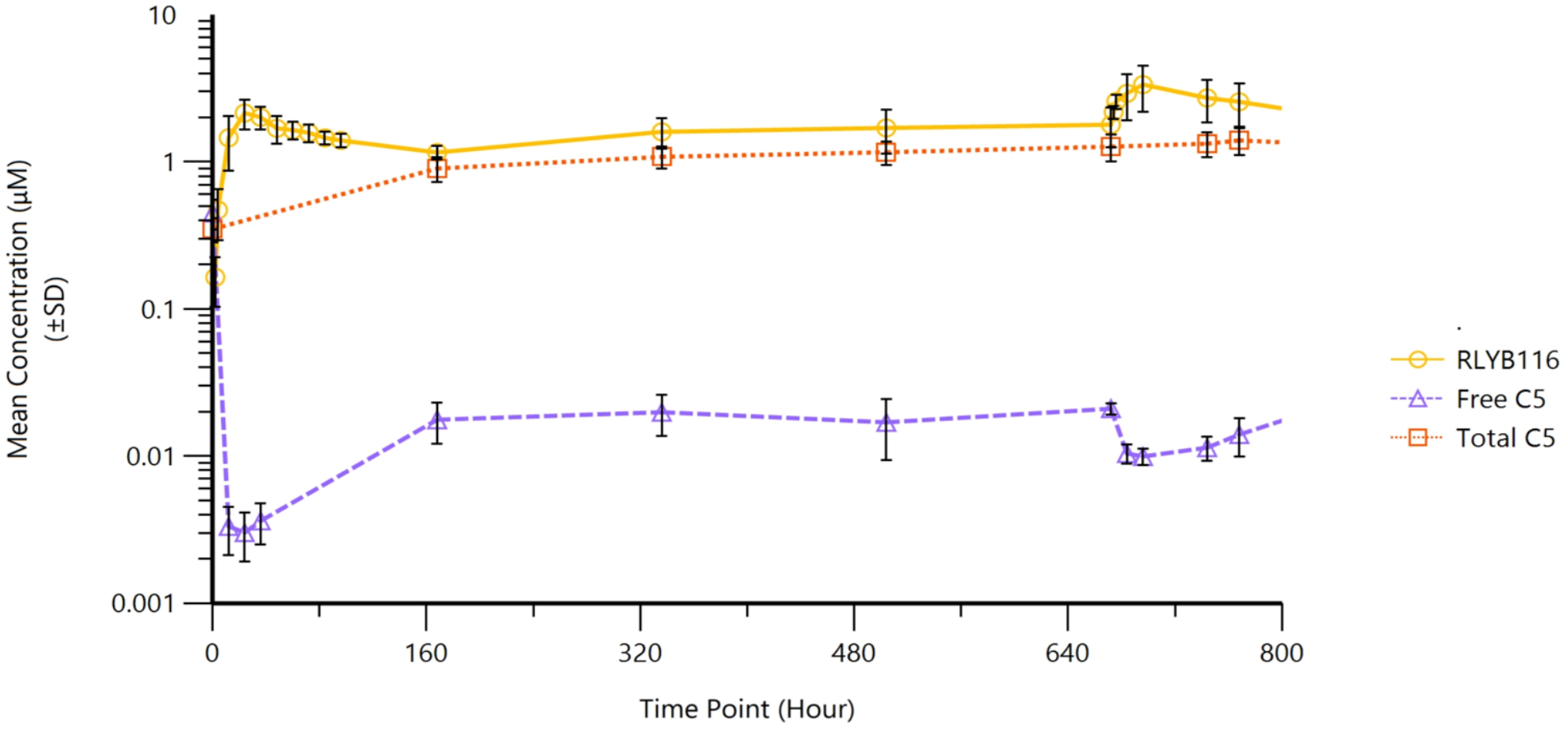


Source: Rallybio IPC2001 data

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 data

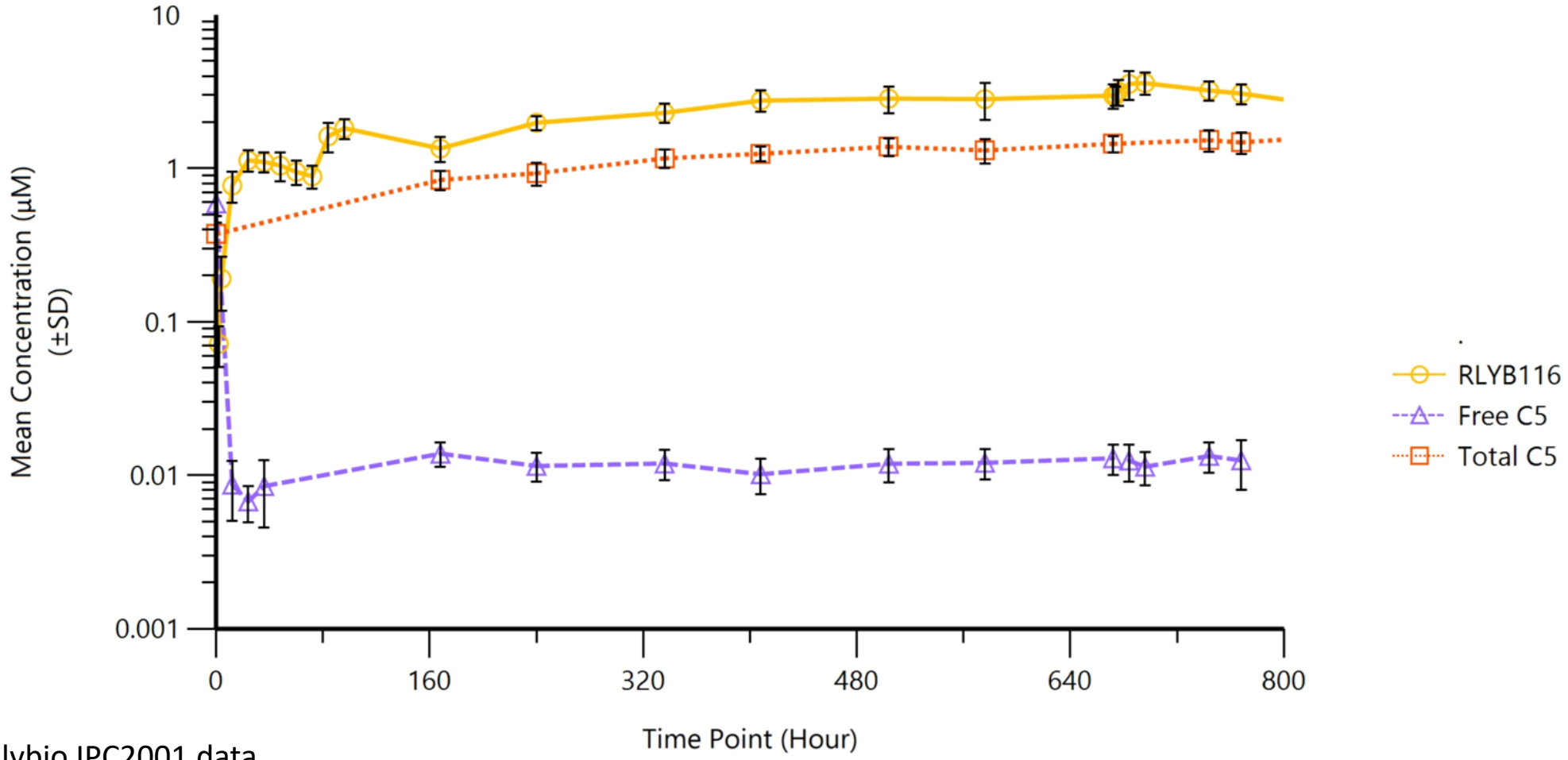
125 mg weekly dose resulted in similar sustained steady-state reductions in free C5 concentrations when compared with 100 mg weekly



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) ≥ 5.0%[1]

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 site reaction (ISR) was the most common adverse event (all mild in severity), Gastrointestinal adverse events increased with increasing dose. 1 case of severe LFT elevation in Cohort 3 resulted in treatment discontinuation.

[1]RLYB116 DSUR 2023

RLYB116 IPC2001 Anti-Drug Antibody (ADA) Update

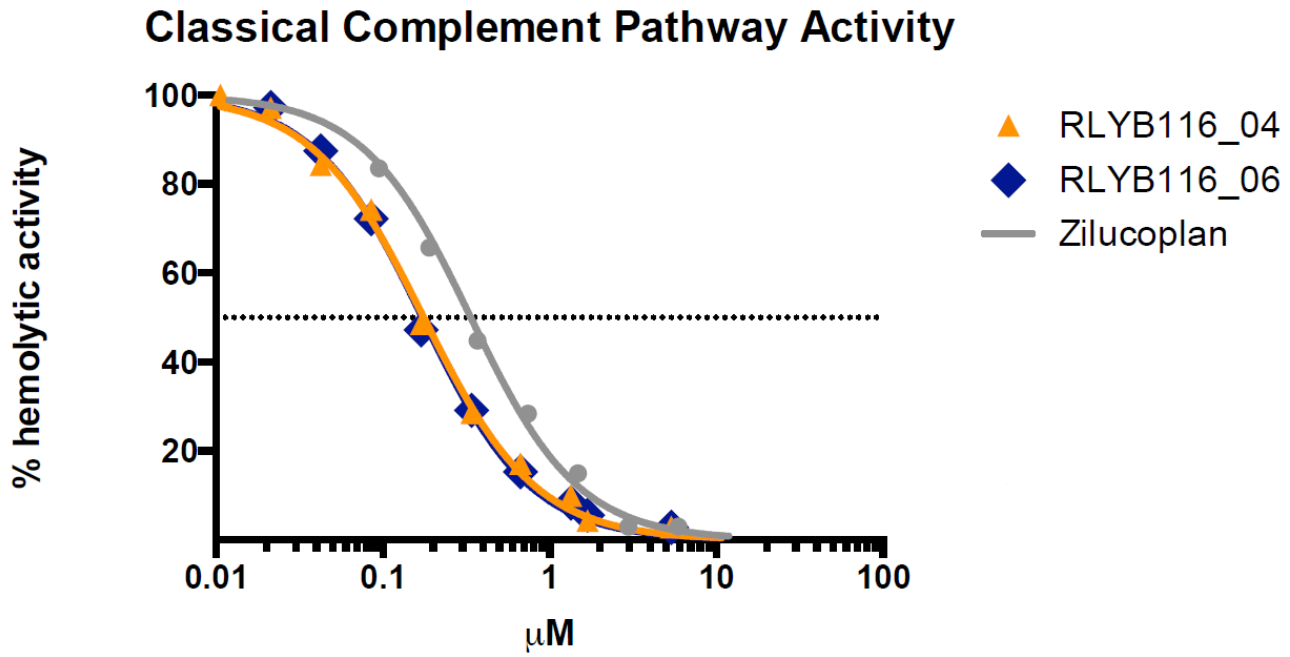
No impact apparent for ADA on PK, PD, and safety data

- 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 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

[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