Enanta Pharmaceuticals
Great Chemistry Cures

Phase 2a Human Challenge Study of EDP-323: Topline Results

Conference Call and Webcast

September 26, 2024

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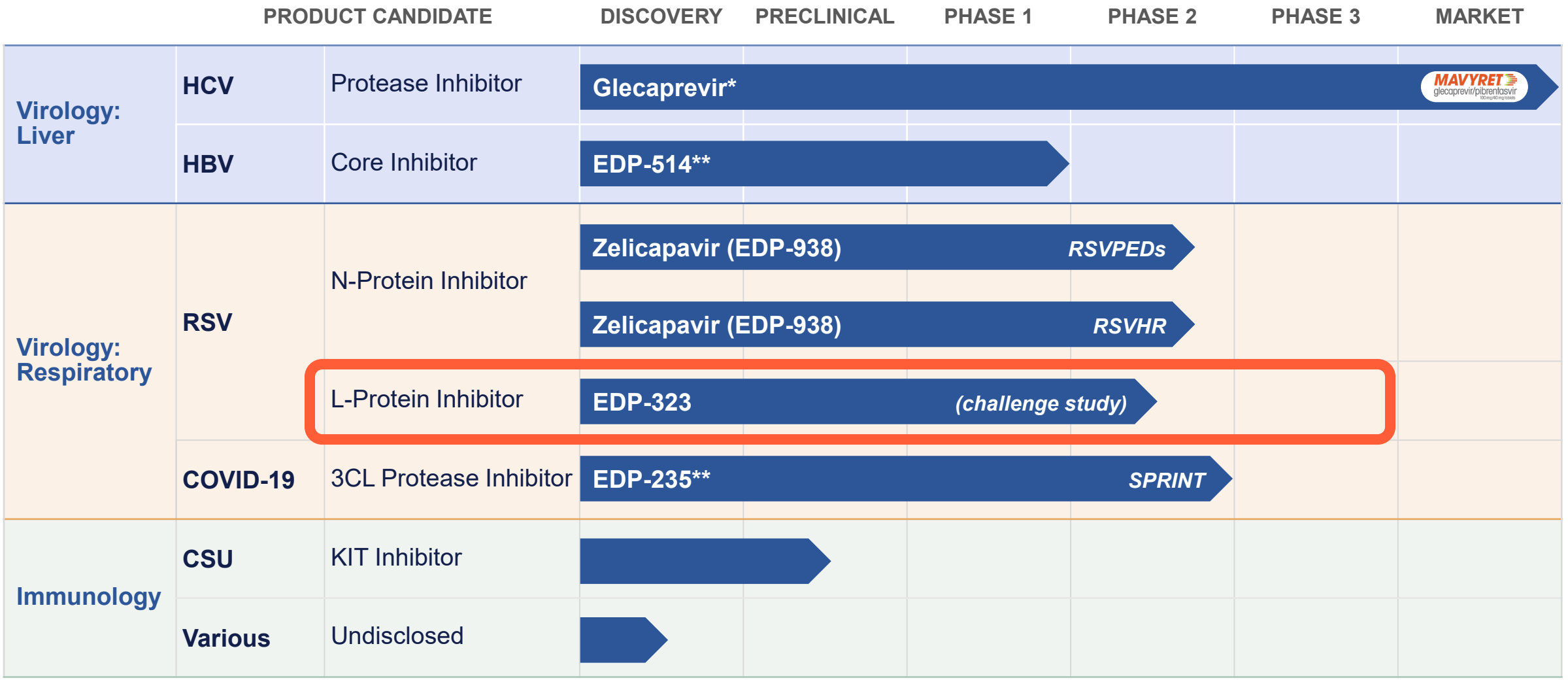
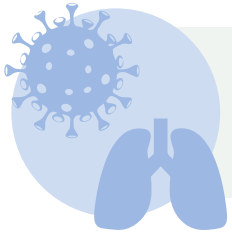
Enanta Pipeline



*Fixed-dose antiviral combination contains glecaprevir and AbbVie's NS5A inhibitor, pibrentasvir. Marketed by AbbVie as MAVYRET® (U.S.) and MAVIRET® (ex-U.S.).
**Continued development dependent on a future collaboration.

Respiratory Syncytial Virus (RSV)



Causes severe lung infections, including bronchiolitis (infection of small airways in the lungs) and pneumonia. Leading cause of hospitalization in infants[1]. No safe and effective treatments.

Populations at higher risk for severe illness:

- Pediatrics (infants and children)
- High-risk adults (>65 yrs, COPD, asthma, CHF)
- Immunocompromised (e.g. HIV, transplant)

RSV at a Glance

Children < 5 years[2]	Adults > 65 years[3]
33M global cases	
3M global hospitalizations	177K U.S. hospitalizations
101K global deaths	14K U.S. deaths

Significant unmet need for antiviral treatment despite availability of prophylaxis:

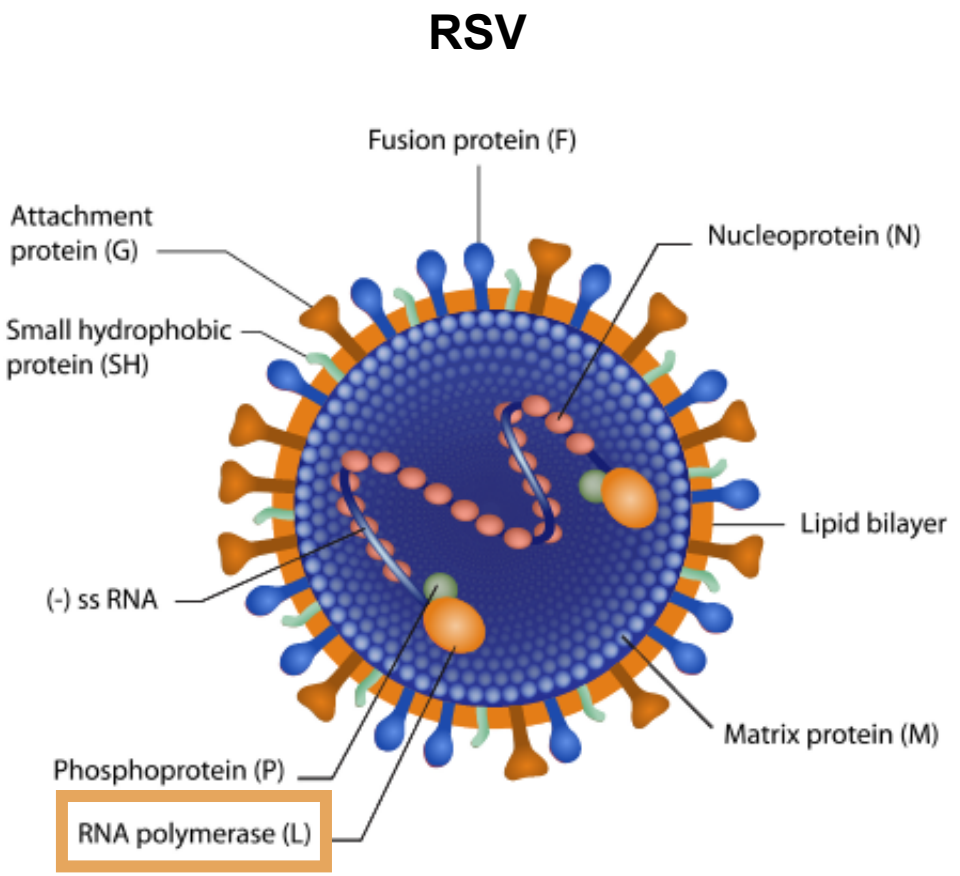
- Adoption of adult vaccines is sub-optimal and not recommended for all FDA-approved patient groups*
  - Peak adoption of vaccines for elderly range from ~35% (shingles[4]) to ~55% (flu[5])
- Pediatric prophylaxis approaches provide passive immunity; will shift first infection to next season
  - Antibody approach has a low barrier to resistance
- Even with adoption, breakthrough infections will still occur

*FDA-approved for adults age ≥60 & 50-59 years who are at increased risk for LRTD caused by RSV[6,7]
ACIP-recommended for adults age ≥75 years and age 60-74 years at increased risk of severe RSV[8]

Sources: 1. https://www.cdc.gov/rsv/infants-young-children/index.html ; 2. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00478-0/fulltext 3. https://pubmed.ncbi.nlm.nih.gov/15858184/ ; 4. https://www.cdc.gov/nchs/products/databriefs/db370.htm: 33.4% in 2016 & 34.5% in 2018 for Age 60+
5. https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-coverage-adults-65-over.htm: 54% 2021-2022; 58% 2020-2021; 56% 2019-2020 for age 65+
6. Pfizer approved label 7. GSK approved label 8. ACIP recommendation

EDP-323: RSV L-Protein Inhibitor

- Direct-acting antiviral targeting the L-protein
- Granted Fast Track designation by the FDA
- Potential to be used alone or in combination
  - Additive to synergistic activity with zelicapavir
  - No cross resistance expected with other mechanisms
- Sub-nanomolar potency against RSV-A and B
- Protects mice in a dose-dependent manner from RSV infection
- Phase 1 supported 200 or 600mg once-daily as safe and efficacious dose
  - Trough plasma concentrations were 11- to 44-fold over protein adjusted EC_{90}



Phase 2a Human Challenge Study of EDP-323: Topline Results

A Phase 2a, Randomized, Double-blind, Placebo-controlled Study To Evaluate The Safety, Pharmacokinetics And Antiviral Activity Of Multiple Doses Of Orally Administered EDP-323 Against Respiratory Syncytial Virus Infection In The Virus Challenge Model In Healthy Adults

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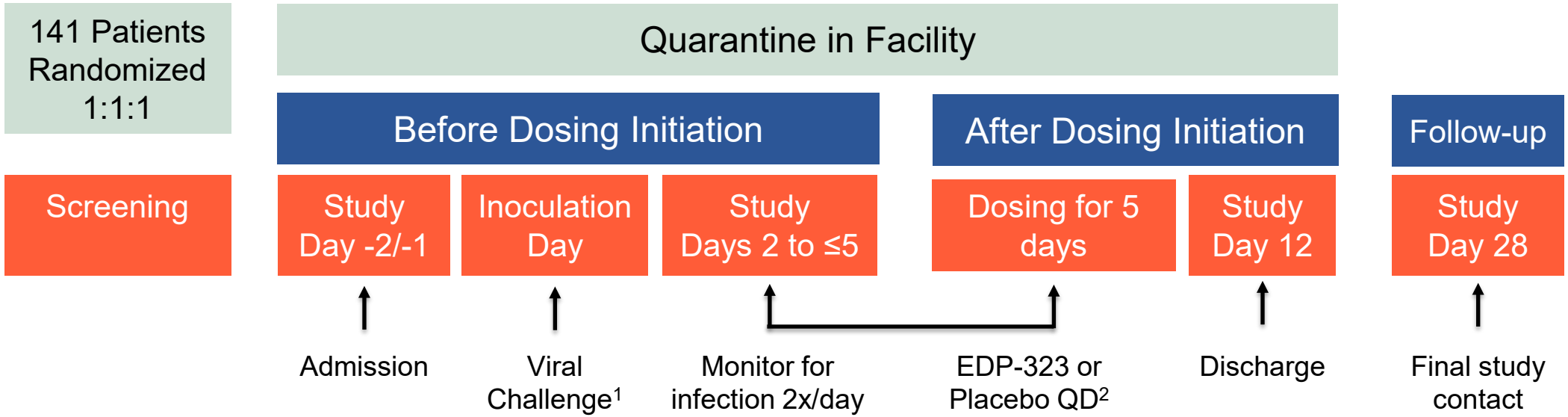
EDP-323 Phase 2a RSV Challenge Study Design



Dosing QD for 5 days:

- EDP-323 High Dose – 600mg
- EDP-323 Low Dose – 200mg (with 600mg LD)
- Placebo

Endpoints:

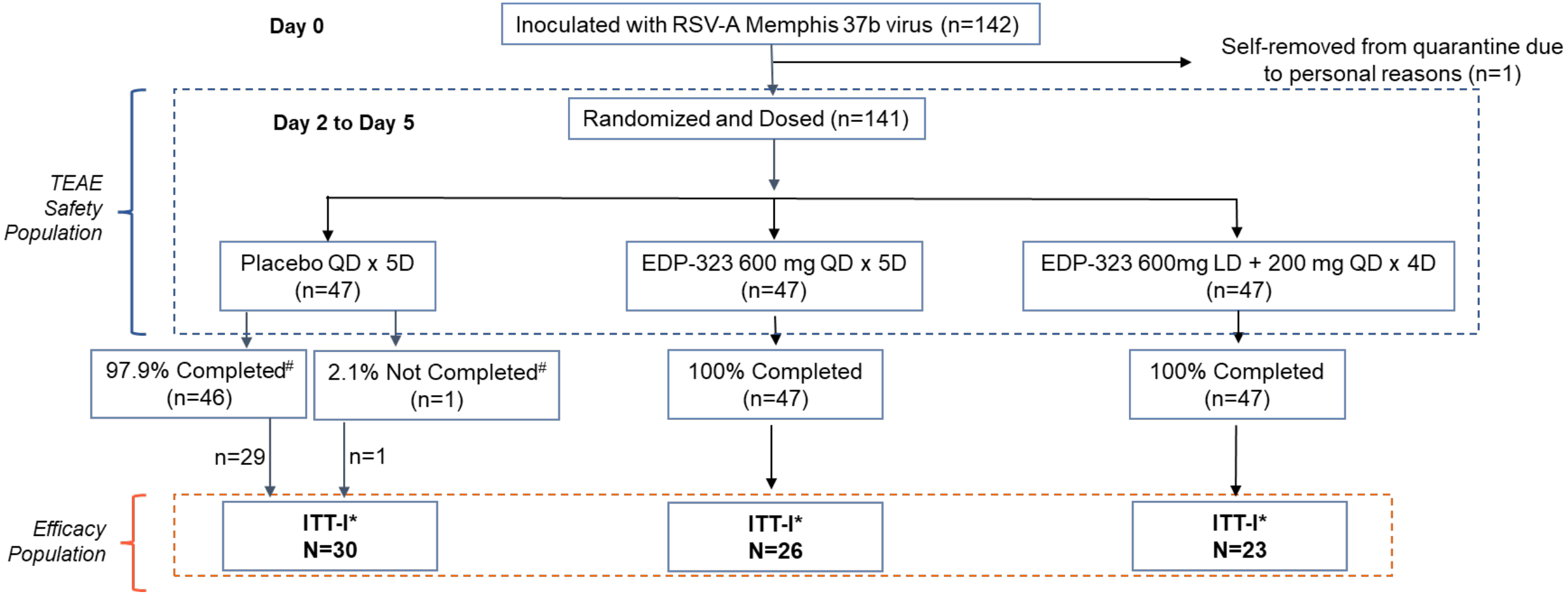
- Primary – RSV Viral Load AUC
- Secondary include
  - RSV Infectious Virus AUC
  - Total Symptom Score AUC

1 RSV-A Memphis 37b

2 Dosing initiated 12 hours after +RSV test (qualitative RT-PCR) or Day 5, whichever was first

AUC: Area Under the Curve; LD: loading dose on Day 1

EDP-323 Phase 2a Study: Participant Disposition



One participant discontinued from the study due to personal reasons on Day 9 after completing the full 5-day dosing period; data from this participant were used in analyses

*** Primary Efficacy analysis, Intent-To-Treat Infected (ITT-I):** All randomized participants receiving challenge virus and ≥1 dose of study drug and with RSV infection confirmed by RT-PCR

EDP-323 Phase 2a Study: Baseline Characteristics

- Baseline characteristics were balanced across groups

Description	EDP-323 High Dose (N=47)	EDP-323 Low Dose (N=47)	Placebo (N=47)
Age: Years – Median (Q1, Q3)	28 (24, 33)	26 (24-30)	27 (23-30)
Sex: Female – n (%)	15 (31.9)	17 (36.2)	19 (40.4)
Race: White – n (%)	39 (83.0)	35 (74.5)	38 (80.9)

Phase 2a Human Challenge Study of EDP-323: Topline Safety & Pharmacokinetic Results

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EDP-323 Demonstrated Favorable Safety Profile & Achieved Target Exposure Levels in Human Challenge Model

- EDP-323 demonstrated a favorable safety profile over a 5-day dosing period and through 28 days of follow-up
- No serious adverse events, no severe adverse events, and no adverse events leading to treatment discontinuation or study withdrawal
- Adverse events were similar between EDP-323 dosing groups and placebo
- No specific pattern of treatment-emergent adverse events was identified

Description	EDP-323 High Dose (N=47)	EDP-323 Low Dose (N=47)	Pooled EDP (N=94)	Placebo (N=47)
Any **treatment emergent** AEs	11 (23.4%)	14 (29.8%)	25 (26.6%)	13 (27.7%)
Any treatment emergent AEs considered **related** to study treatment	1 (2.1%)	1 (2.1%)	2 (2.1%)	0 (0.0%)

- EDP-323 mean trough plasma concentrations were maintained at 16- to 35-fold above the protein adjusted EC_{90} against both RSV A and B strains

Phase 2a Human Challenge Study of EDP-323: Topline Efficacy Results

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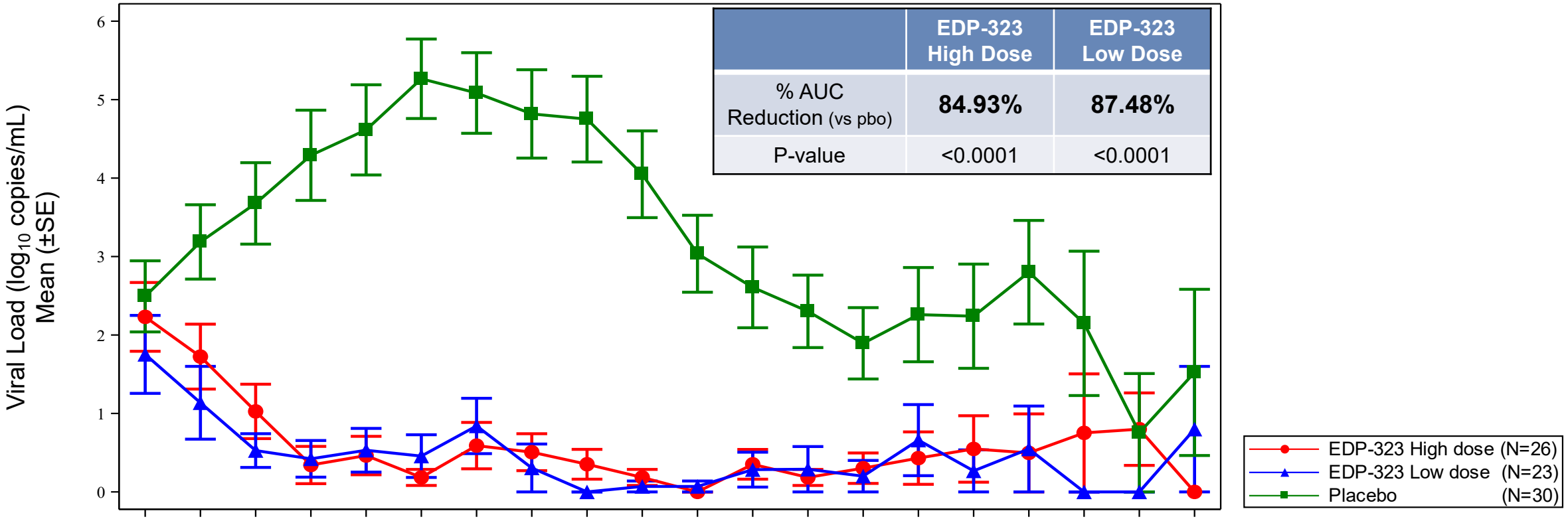
EDP-323 Results in a Rapid & Sustained Reduction in Viral Load

Primary Efficacy Endpoint: **85-87%** ↓ in VL AUC by **qRT-PCR**

- Highly statistically significant reductions in VL AUC measured by qRT-PCR compared to placebo
  - No statistically significant difference between the two EDP-323 dosing regimens

	EDP-323 High Dose	EDP-323 Low Dose
% AUC Reduction (vs pbo)	**84.93%**	**87.48%**
P-value	<0.0001	<0.0001



Number of Subjects

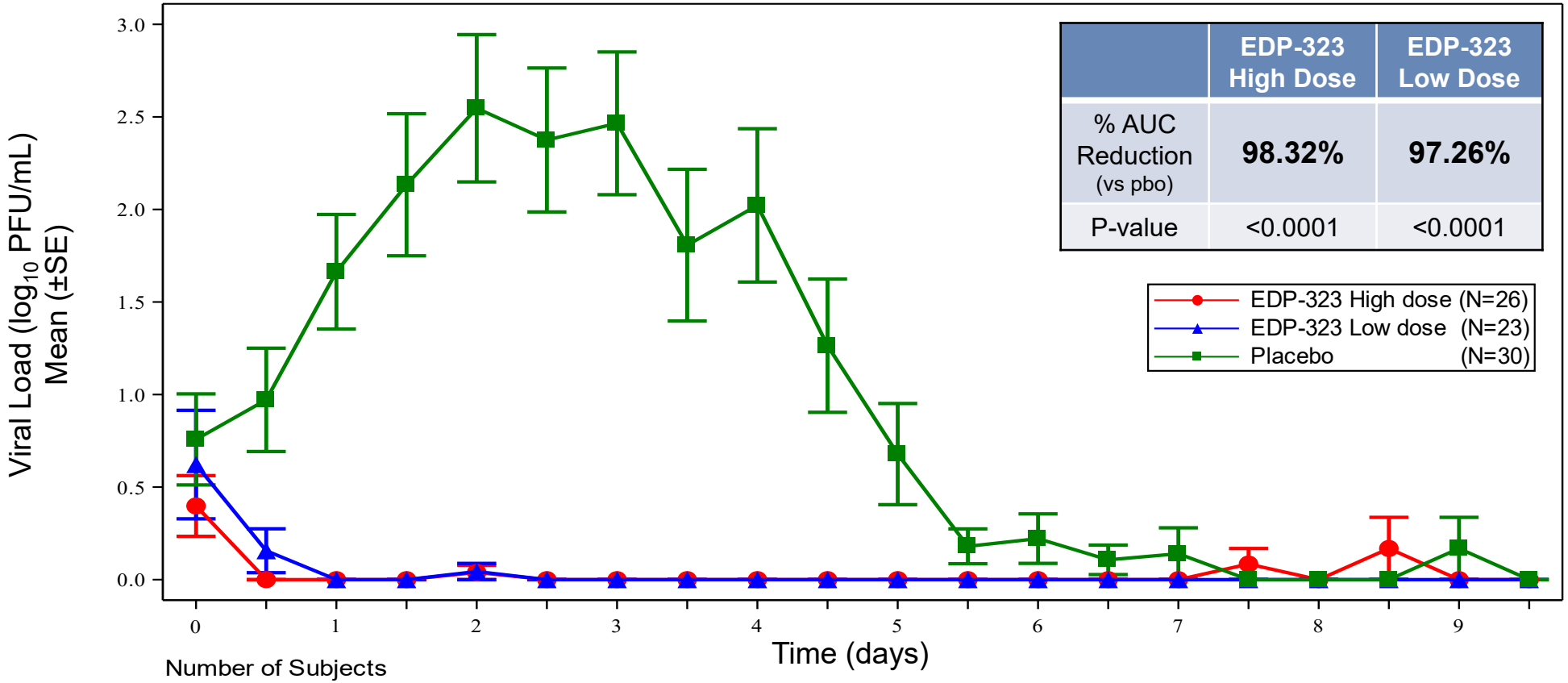
EDP-323 High dose	26	26	26	26	26	26	26	26	26	26	26	26	26	26	15	12	10	6	4	1
EDP-323 Low dose	23	23	23	23	23	23	23	23	23	23	23	23	23	23	17	16	10	5	4	2
Placebo	30	30	30	30	30	30	30	30	30	30	30	30	30	30	19	18	11	8	6	4

VL AUC: viral load area under the curve (hours x log_{10} copies/mL); qRT-PCR: quantitative reverse transcriptase polymerase chain reaction; SE: standard error

EDP-323 Results in Rapid & Sustained Reduction in Infectious Viral Load

Secondary Efficacy Endpoint: **97-98%** ↓ in VL AUC by **Viral Culture**

- Highly statistically significant reductions in infectious VL AUC measured by quantitative culture compared to placebo
  - No statistically significant difference between the two EDP-323 dosing regimens



	EDP-323 High Dose	EDP-323 Low Dose
% AUC Reduction (vs pbo)	**98.32%**	**97.26%**
P-value	<0.0001	<0.0001

Number of Subjects

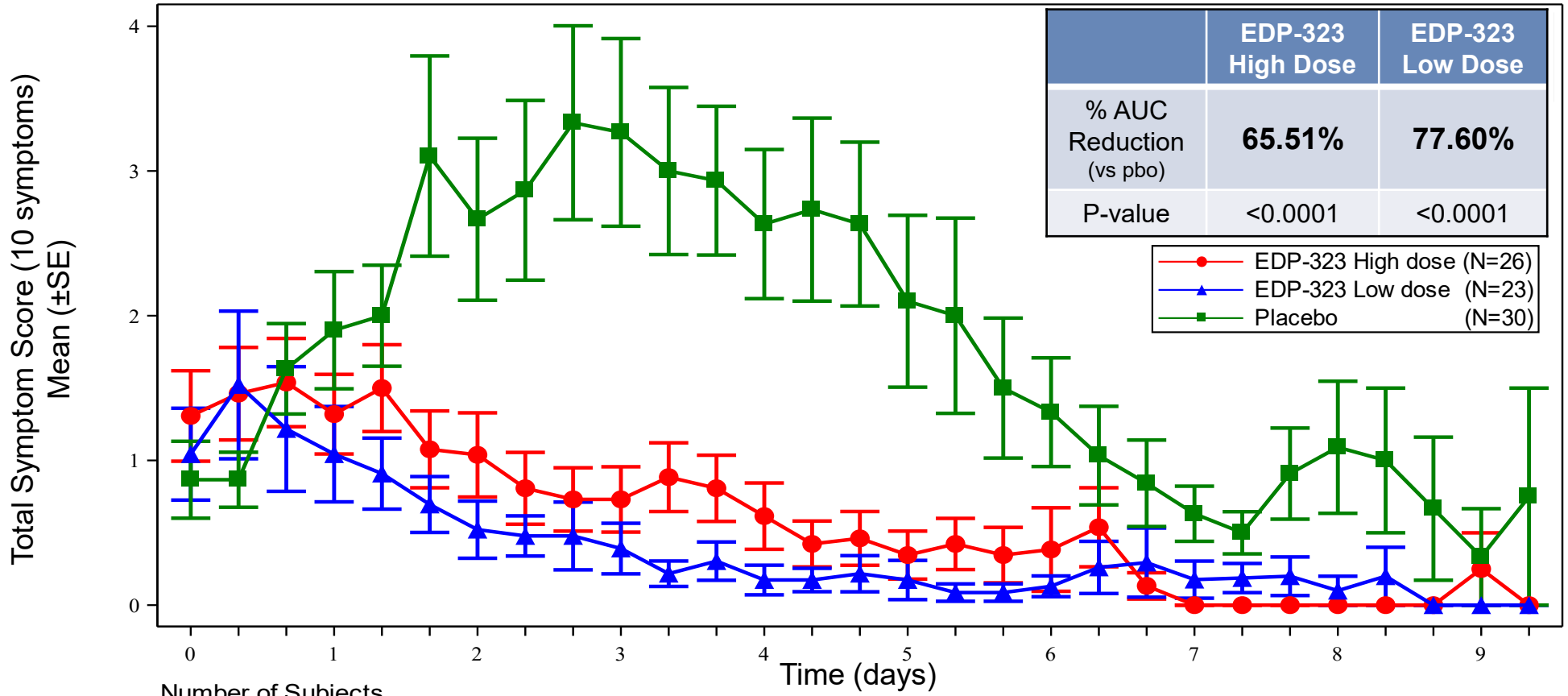
EDP-323 High dose	26	26	26	26	26	26	26	26	26	26	26	26	26	26	15	12	10	6	4	1
EDP-323 Low dose	23	23	23	23	23	23	23	23	23	23	23	23	23	23	17	16	10	5	4	2
Placebo	30	30	30	30	30	30	30	30	30	30	30	30	30	30	19	18	11	8	6	4

VL AUC: viral load area under the curve (hours x log_{10} copies/mL); PFU: plaque forming units; SE: standard error

EDP-323 Demonstrates Robust Attenuation of RSV Symptoms

Secondary Efficacy Endpoint: **66-78%** Reduction in **Symptoms**

- Highly statistically significant reductions in TSS AUC in both EDP-323 arms compared to placebo
  - No statistically significant difference between the two EDP-323 dosing regimens



	EDP-323 High Dose	EDP-323 Low Dose
% AUC Reduction (vs pbo)	**65.51%**	**77.60%**
P-value	<0.0001	<0.0001

Number of Subjects

EDP-323 High dose	26	26	26	25	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	15	15	12	10	10	6	4	4	1
EDP-323 Low dose	23	23	23	23	22	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	17	17	16	10	10	5	4	4	2
Placebo	30	30	30	30	30	29	30	30	30	30	30	30	30	30	30	30	30	30	30	30	19	19	18	11	11	8	6	6	4

TSS AUC: Area Under the Curve over time of Total Clinical Symptoms Score (10 items; hours x score); SE: standard error

EDP-323 Phase 2a RSV Challenge Study: Conclusions

- Well tolerated with safety profile similar to placebo
- Primary & key secondary efficacy endpoints achieved with high statistical significance at both dose levels compared to placebo:
  - Reduction in *viral load* of 85-87%
  - Reduction in *viral culture* of 97-98%
  - Alleviation of clinical *symptoms* by 66-78%
- Data support further clinical evaluation of EDP-323

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