Enanta Pharmaceuticals
Great Chemistry Cures

Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results

December 9, 2024

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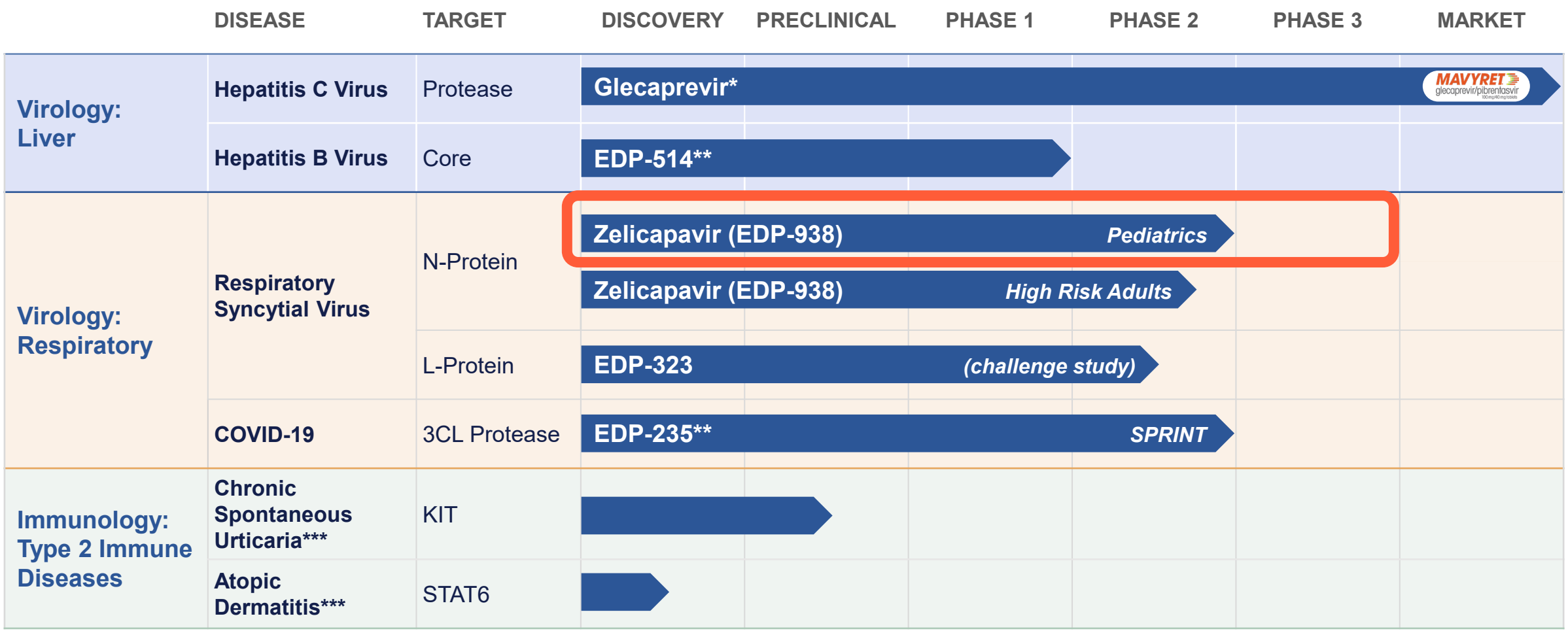
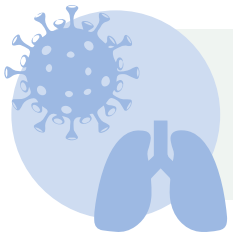
Enanta Pipeline



*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.
***Initial indications. Potential future indications include asthma, chronic inducible urticaria (CIndU), eosinophilic esophagitis (EoE), prurigo nodularis (PN), and others.

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 are currently approved.

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:

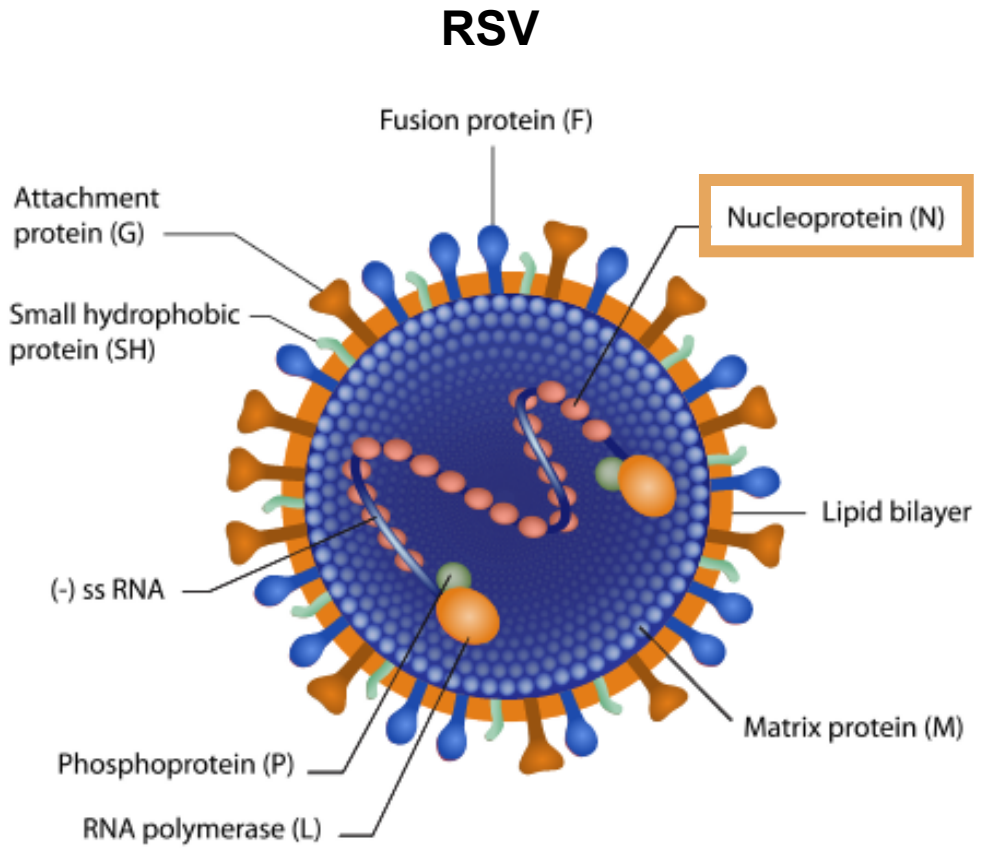
- Adoption of adult vaccines is sub-optimal and not recommended for all FDA-approved patient groups*
  - Peak adoption of vaccines for elderly range from ~35% (shingles[4]) to ~55% (flu[5])
- Pediatric prophylaxis approaches provide passive immunity; will shift first infection to next season
  - Antibody 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]
ACIP-recommended for adults age ≥75 years and age 60-74 years at increased risk of severe RSV[7]

Sources: 1. CDC RSV In Infants and Young Children. 2. Li P et al. *The Lancet*. 2022 3. Falsey AR et al. *NEJM*. 2005. 4. Terlizzi EP et al. *NCHS Data Brief*. 2020; Age 60+
5. CDC Influenza Vaccination Coverage, Adults 65+ 6. FDA-approved labels: Pfizer; GSK & Moderna 7. June 2024 ACIP recommendation

Zelicapavir (EDP-938): N-Protein Inhibitor for RSV

- Zelicapavir is currently the only N-inhibitor in clinical development for RSV
  - Replication inhibitor: shuts down the production of new virions (vs fusion inhibitors which block viral entry)
- Granted Fast Track designation by the FDA
- Strong preclinical profile
  - Nanomolar potency against RSV-A and RSV-B
  - Antiviral potency across all clinical isolates tested
  - High-barrier to resistance
  - Synergistic activity with other drug mechanisms
- Favorable safety and efficacy profile in clinical studies observed to date
  - Phase 2a challenge study showed a statistically significant ($p<0.001$) reduction in both viral load and clinical symptoms compared to placebo



Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results

A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, 2-PART STUDY TO EVALUATE EDP-938 REGIMENS IN SUBJECTS AGED 28 DAYS TO 36 MONTHS INFECTED WITH RESPIRATORY SYNCYTIAL VIRUS

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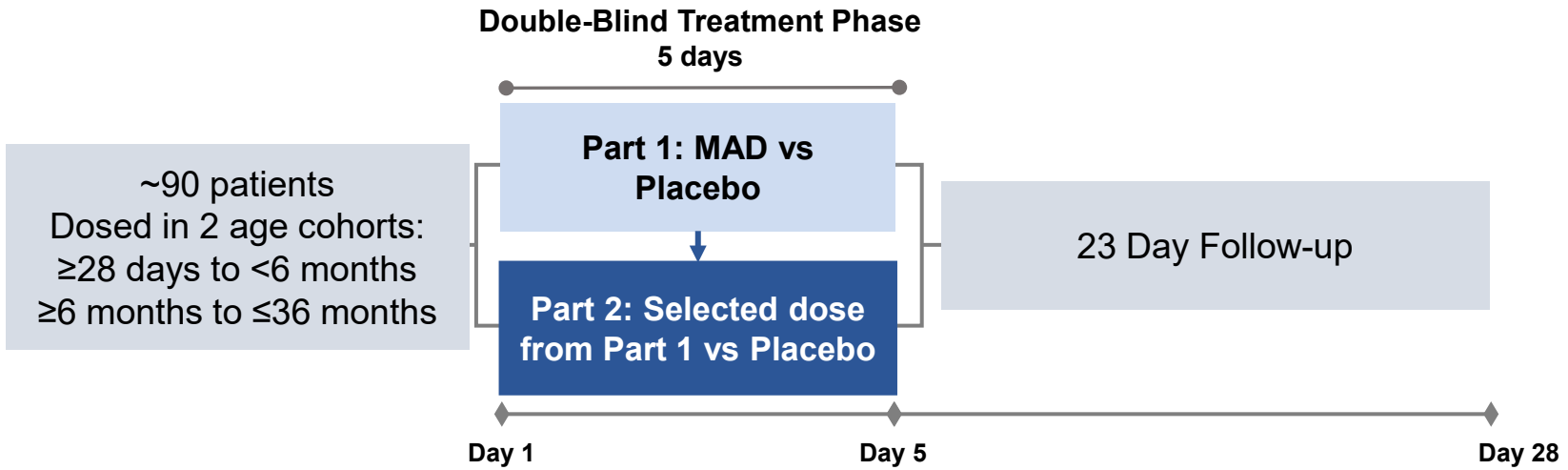
Zelicapavir Phase 2 Pediatric Study: Design & Objectives



Primary Objectives of Study

- **Overall:** Antiviral activity of zelicapavir across all patients
- **Part 1:** Safety and PK
- **Part 2:** Antiviral activity

- First zelicapavir pediatric study: safety and dose selection
- Signal finding in different patient populations to inform a potential registration-enabling trial
  - Age: ≥28 days to <6 months and ≥6 months to ≤36 months
  - Time from symptom onset to treatment
  - Hospitalized or outpatient

Zelicapavir Phase 2 Pediatric Study: Conclusions

- Well tolerated, with favorable safety profile
  - No adverse events leading to treatment discontinuation or study withdrawal
- Antiviral effect observed for the primary and secondary virology endpoints in overall population
- Viral load decline of 1.4 log at the end of treatment in Part 2
- Viral load decline of 1.2 log at Day 5 observed in prespecified subset of patients randomized within 3 days of symptom onset
- Data support further clinical development of zelicapavir

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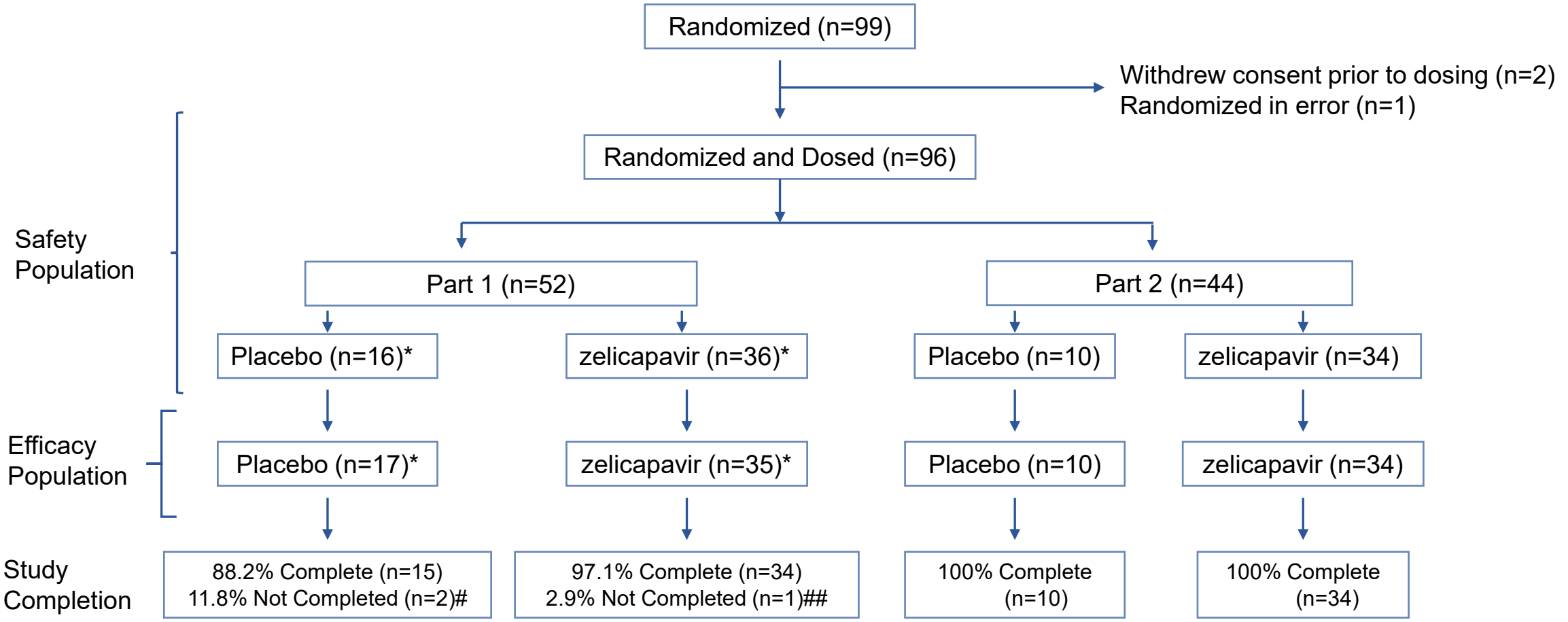
Zelicapavir Phase 2 Pediatric Study: Patient Disposition



* One patient randomized to placebo was treated with zelicapavir in error. Data for this patient are in the zelicapavir group for safety analyses and placebo group for efficacy analyses.

Two patients discontinued the study after receiving the first dose
One patient discontinued the study after receiving 2 doses

Zelicapavir Phase 2 Pediatric Study: Baseline Characteristics (Safety Population)

- Baseline characteristics were balanced across treatment groups
- Majority hospitalized at enrollment
- Mean duration of symptoms prior to randomization of 4 days

Description	**Zelicapavir** (pooled) (N=70)	**Placebo** (pooled) (N=26)
Age: Months – Median (Min, Max)	7.0 (1, 34)	7.5 (1, 27)
Sex: Female – n (%)	35 (50.0)	14 (53.8)
Race: White – n (%)	51 (72.9)	11 (42.3)
RSV Viral Load by RT-qPCR (log10 copies/mL)		
n	63	23
Mean (SD)	6.60 (1.52)	6.19 (1.44)
Duration of RSV Symptoms Prior to Randomization (Days) – Mean (SD)	4.0 (1.57)	4.1 (1.75)
Hospitalized at Enrollment – n (%)	57 (81.4)	20 (76.9)

Zelicapavir Phase 2 Pediatric Study: Exhibited Favorable Safety Profile in Children

- Adverse events (AEs) were similar between zelicapavir dosing groups and placebo
- No adverse events led to treatment discontinuation or study withdrawal

Description	**Zelicapavir** (pooled) (N=70)	**Placebo** (pooled) (N=26)
Treatment emergent AEs (TEAEs)	28 (40.0%)	13 (50.0%)
Study drug related TEAEs	6 (8.6%)	0 (0.0%)
Grade 3 or higher TEAEs	2 (2.9%)	1 (3.8%)
Serious TEAEs	1 (1.4%)	2 (7.7%)

Zelicapavir Phase 2 Pediatric Study: AEs Occurring in More than One Patient in Any Group

- Adverse events (AEs) were balanced between zelicapavir and placebo
- The two most common AEs in the zelicapavir group were diarrhea and rash

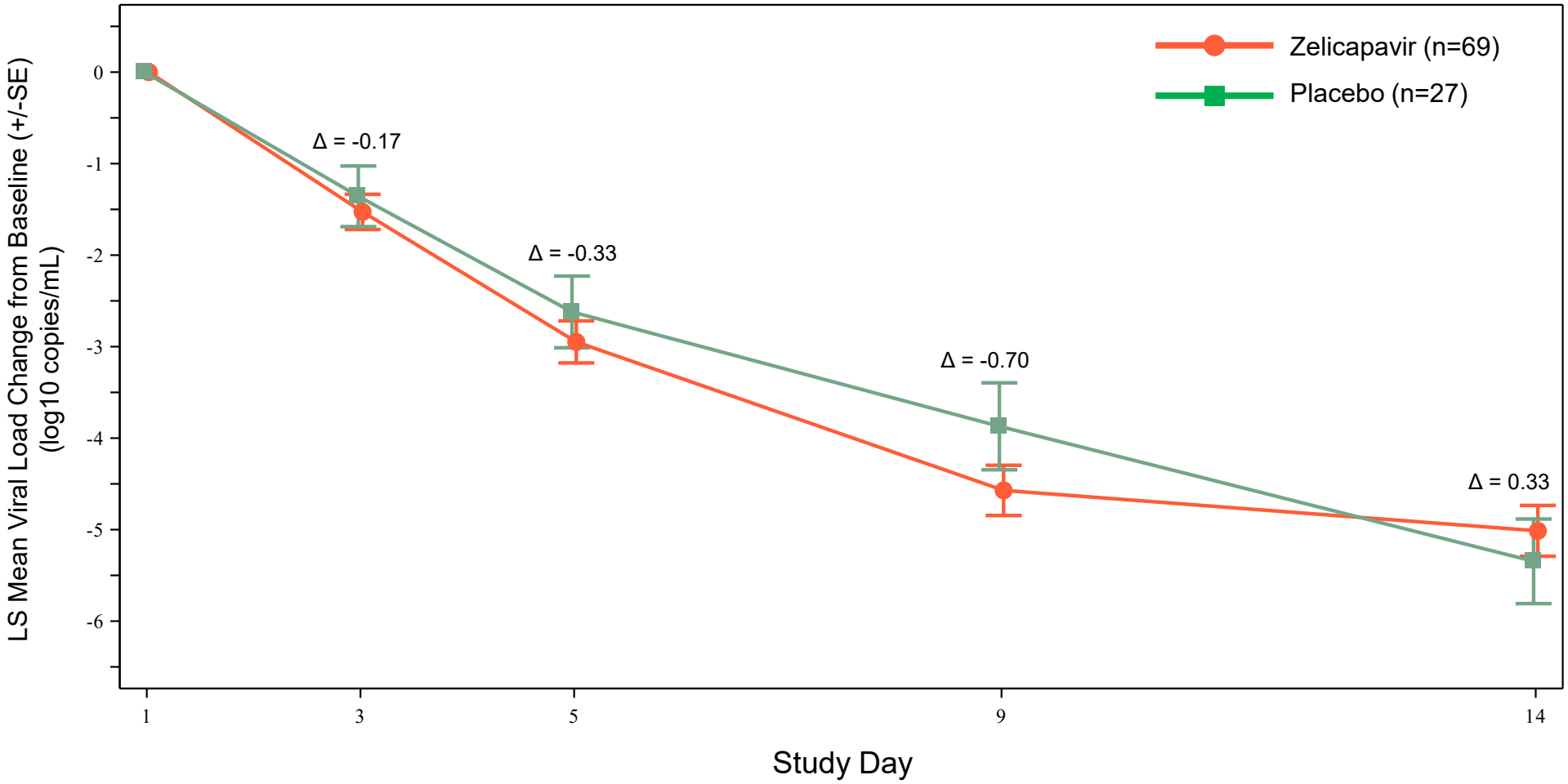
Preferred Term	Zelicapavir (pooled) (N=70)	Placebo (pooled) (N=26)
Diarrhea	7 (10.0%)	1 (3.8%)
Rash	3 (4.3%)	1 (3.8%)
Otitis media acute	2 (2.9%)	1 (3.8%)
Eczema	2 (2.9%)	1 (3.8%)
Thrombocytosis	2 (2.9%)	0 (0%)
Nasopharyngitis	1 (1.4%)	2 (7.7%)

Zelicapavir Phase 2 Pediatric Study: Achieved Target Exposure Levels in Children

- Goal was to achieve similar drug exposures to the exposures proven to be efficacious in the Phase 2 adult challenge study
- Target drug exposures achieved across all age groups and dosing cohorts (Parts 1 and 2)
  - A dose of 5 mg/kg was selected for age ≥28 days to <12 months
  - A dose of 7.5 mg/kg was selected for age ≥12 months to ≤36 months
  - Regardless of dose, all patients had model-predicted exposures above the efficacy threshold
- Exposure was similar across cohorts and all patients received a therapeutic dose
- Primary efficacy analyses were performed across all dosed patients from Parts 1 and 2 (n=96; efficacy population)

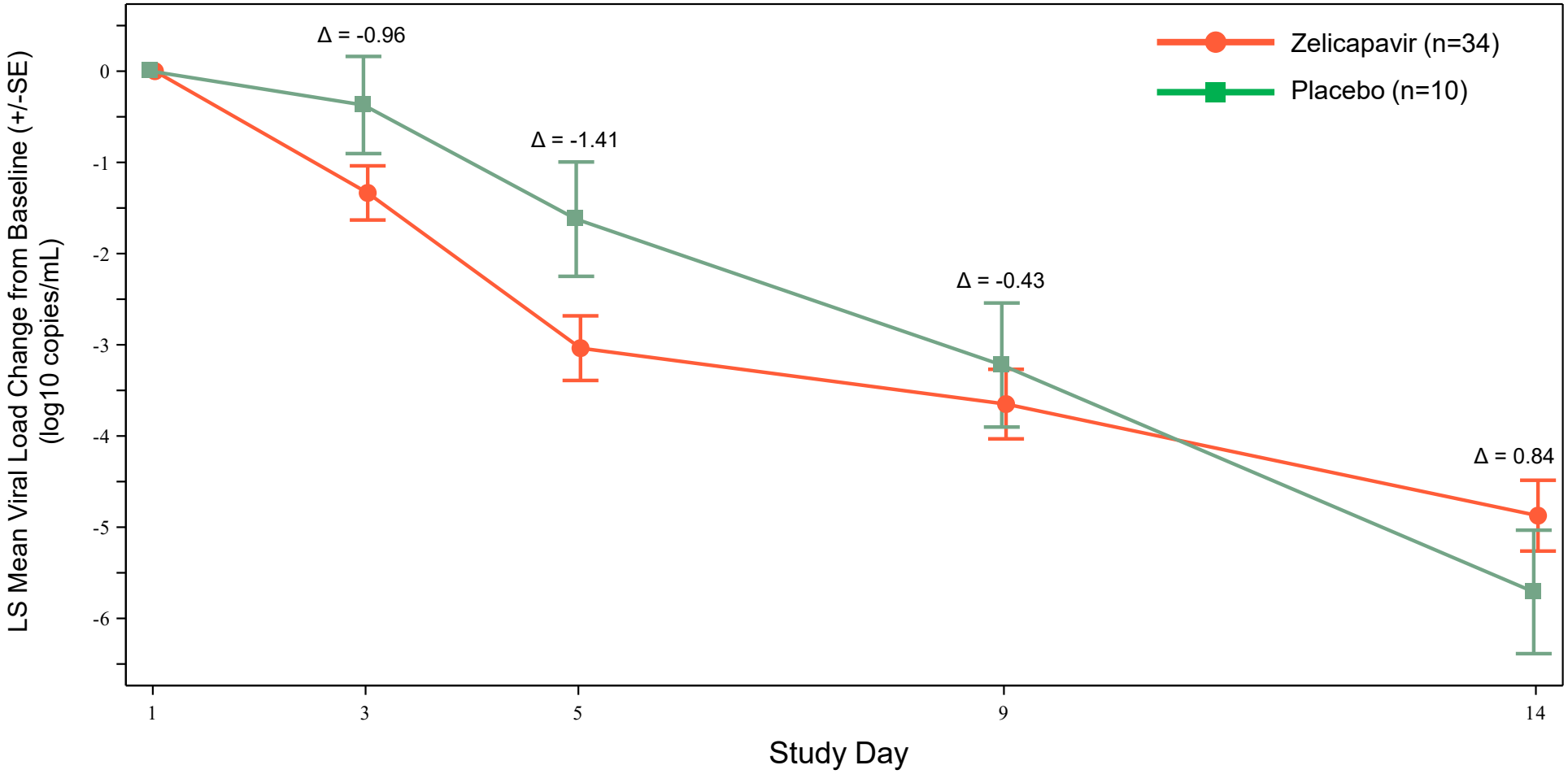
Zelicapavir Phase 2 Pediatric Study: Primary Endpoint – RSV PCR Viral Load for All Patients (Part 1 & 2)

- Trend toward greater viral load decline in patients treated with zelicapavir compared to placebo



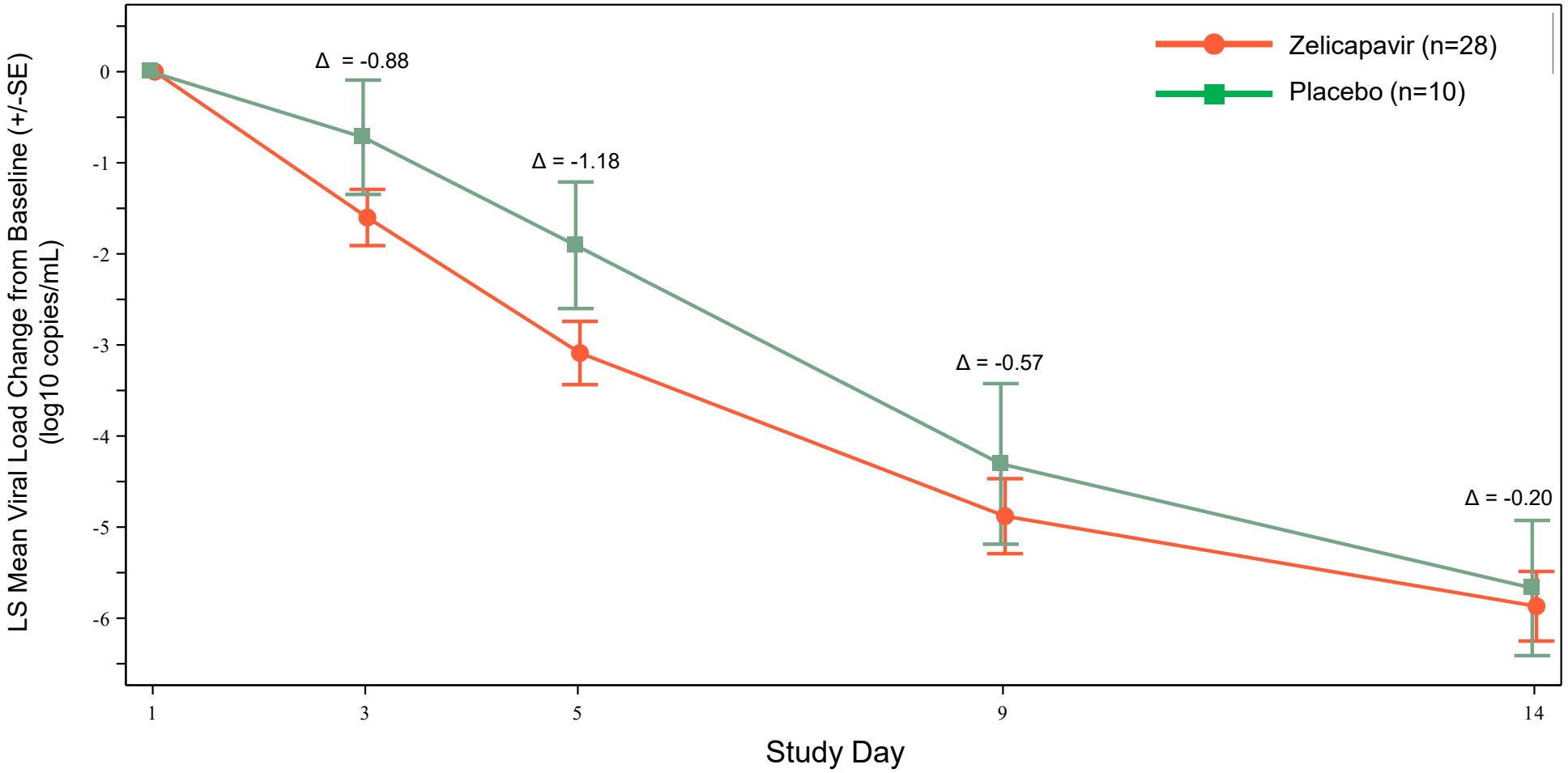
Zelicapavir Phase 2 Pediatric Study: Primary Endpoint of Part 2: RSV PCR Viral Load

- Viral load decline of **0.96 log** at Day 3 and **1.41 log** at Day 5



Zelicapavir Phase 2 Pediatric Study: Prespecified mITT-3 Population: RSV PCR Viral Load

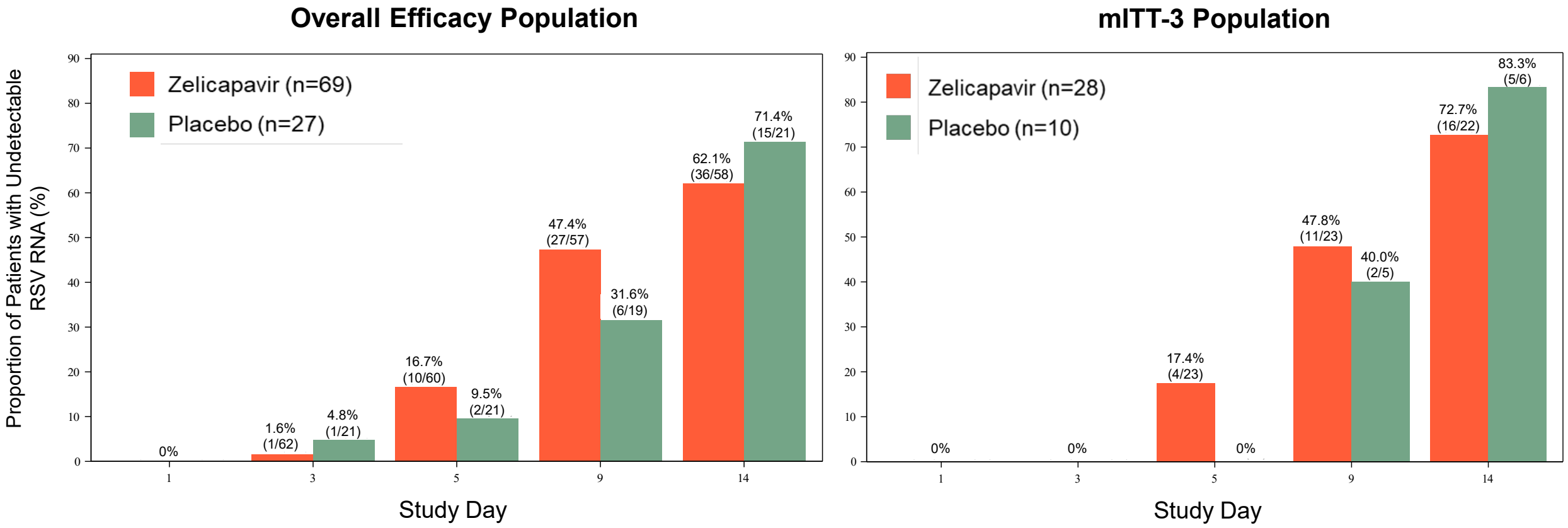
- Viral load decline of **0.88 log** at Day 3 and **1.18 log** at Day 5



mITT-3: patients randomized within 3 days of symptom onset

Zelicapavir Phase 2 Pediatric Study:
Secondary Endpoint: Proportion with Undetectable Viral Load over Time

- Greater proportion of zelicapavir treated patients had undetectable viral load at Days 5 and 9 compared to placebo

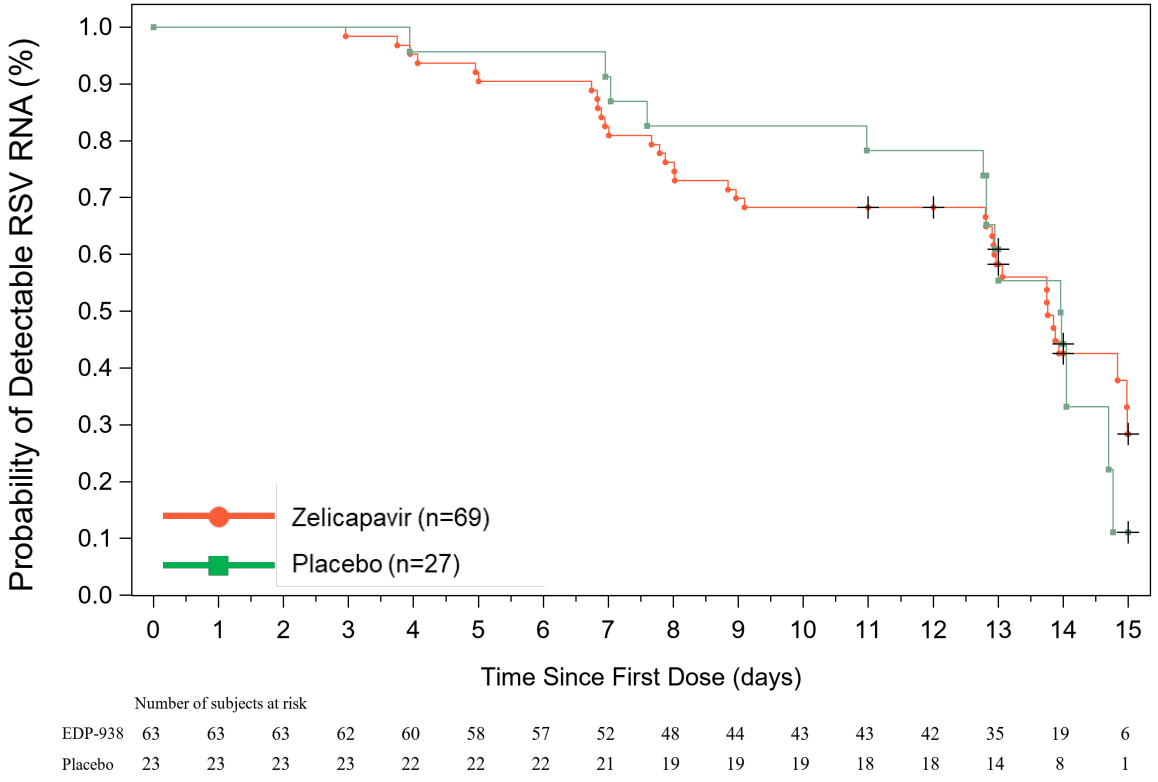


mITT-3: patients randomized within 3 days of symptom onset

Zelicapavir Phase 2 Pediatric Study: Secondary Endpoint: Time to Undetectable Viral Load

- Zelicapavir showed a qualitative improvement in time to undetectable viral load at early timepoints, although median time to undetectable viral load was similar between groups

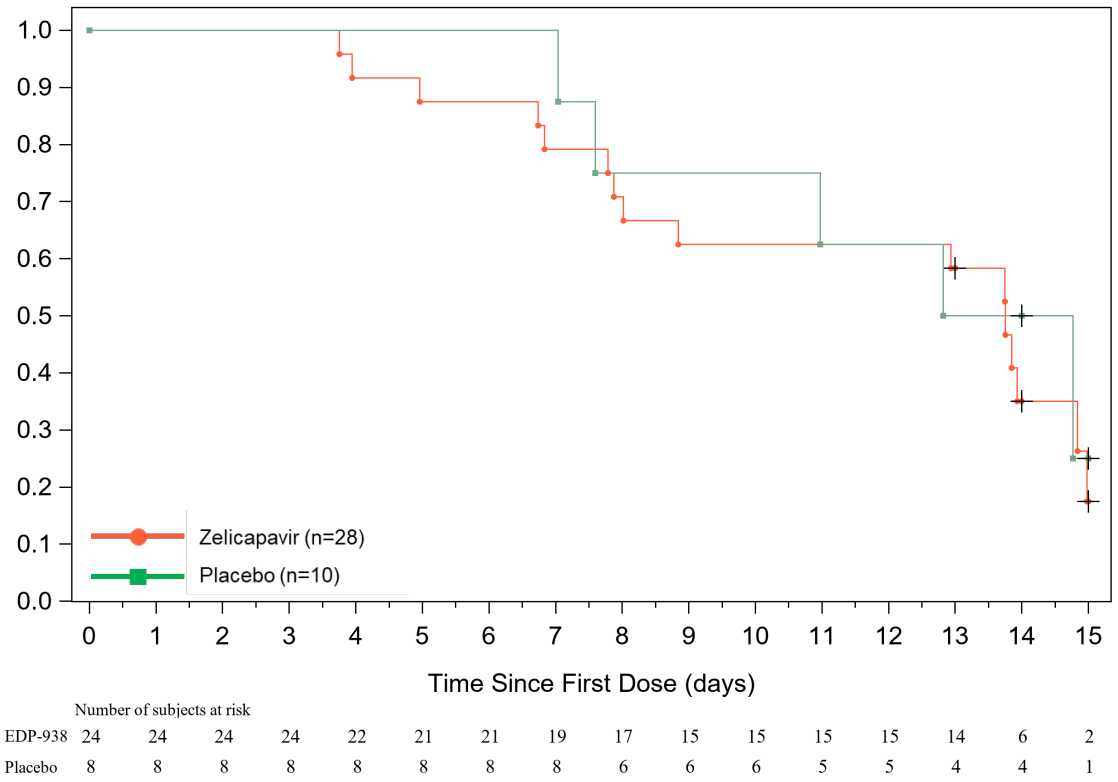
Overall Efficacy Population



Number of subjects at risk

EDP-938	63	63	63	62	60	58	57	52	48	44	43	43	42	35	19	6
Placebo	23	23	23	23	22	22	22	21	19	19	19	18	18	14	8	1

mITT-3 Population



Number of subjects at risk

EDP-938	24	24	24	24	22	21	21	19	17	15	15	15	15	14	6	2
Placebo	8	8	8	8	8	8	8	8	6	6	6	5	5	4	4	1

Time to undetectable defined as first undetectable timepoint with no further detectable timepoints
+ = Time at which data from patients were censored (patients censored at last visit)

mITT-3: patients randomized within 3 days of symptom onset

Zelicapavir Phase 2 Pediatric Study: Virology Summary

- Antiviral effect observed for the primary and secondary virology endpoints in overall population
- Viral load decline in Part 2 of 1.0 log at Day 3 and 1.4 log at Day 5 vs placebo
- Rapid and robust virology effects observed in prespecified subset of patients who were randomized within 3 days of symptom onset (mITT-3)
  - Represents ~40% of the study population (n=38/96)
  - Viral load decline of 0.9 log at Day 3 and 1.2 log at Day 5 vs placebo
  - Greater proportion of patients had undetectable viral load at Days 5 and 9 vs placebo
  - Qualitative improvement in time to undetectable viral load at early timepoints, although median time to undetectable viral load was similar between groups
  - Improvement in AUC of change from baseline for viral load at all timepoints vs placebo
- Results were similar regardless of age or setting of care (outpatient and hospitalized)

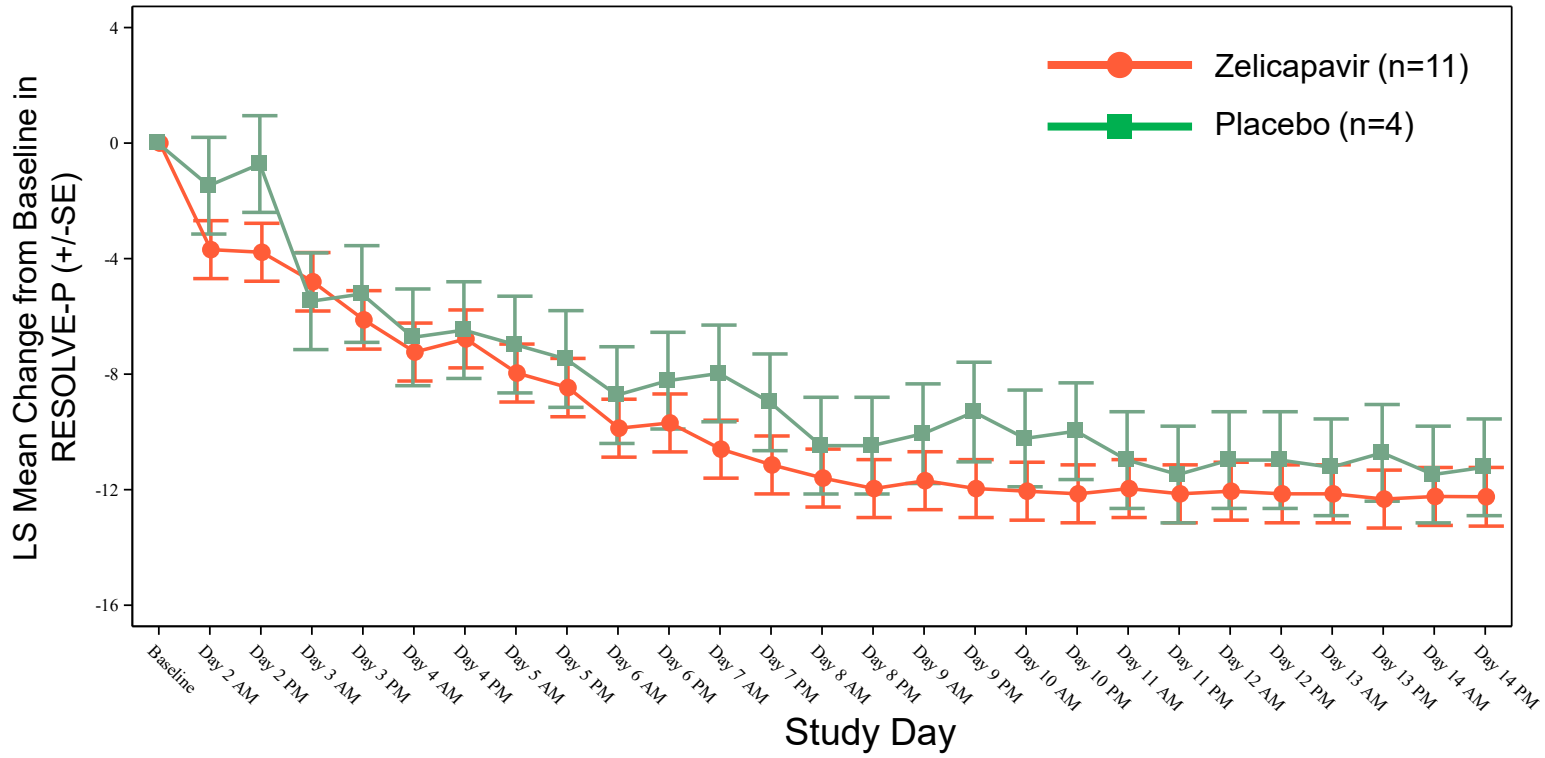
Zelicapavir Phase 2 Pediatric Study: Exploratory Endpoint: RSV Signs/Symptoms

- No validated symptom tool approved by regulatory agencies available for pediatric RSV
- RESOLVE-P (RESpiratory ObservabLE Reported Outcome-Pediatric)
  - Proprietary tool in development by Enanta in alignment with regulatory agency advice
  - Specifically designed to assess the severity of pediatric RSV infection change over time based on observations by the child's caregiver
  - Developed with input from caregivers, medical professionals and regulatory agencies
  - Finalized and introduced late in the trial, so data only available from a small number of patients (n=15)
- ReSViNET (REspiratory Syncytial VIrus NETwork)
  - Designed primarily for prophylaxis studies to assess disease severity at a single timepoint
  - Publicly available pediatric tool with caregiver assessments
  - Used as an exploratory endpoint
  - Data available from all patients

Zelicapavir Phase 2 Pediatric Study: Exploratory Endpoint – RSV Signs/Symptoms

Study was not powered to evaluate effects on signs/symptoms

- **ReSViNET**: No difference in signs/symptoms between treatment arm and placebo
- **RESOLVE-P**: Small patient dataset (n=15)
  - Trend towards greater sign/symptom reduction in patients treated with zelicapavir



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