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 9, 2024

ENANTA PHARMACEUTICALS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35839**	**04-3205099**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4 Kingsbury Avenue **Watertown, Massachusetts**	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 607-0800

Not Applicable
(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 $0.01 per share	ENTA	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 9, 2024, Enanta Pharmaceuticals, Inc. ("Enanta") issued a press release announcing positive topline data from its Phase 2 pediatric study of zelicapavir (formerly EDP-938) for the treatment of respiratory syncytial virus ("RSV"). A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by this reference. In connection with such data release, the Company compiled a presentation entitled "Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results" (the "Presentation") that includes the topline data from its Phase 2 pediatric study of zelicapavir for the treatment of RSV referenced above. A copy of the Presentation is furnished as Exhibit 99.2.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and 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 any such filing.

Item 8.01 Other Events.

As noted in Item 7.01 above, Enanta announced positive topline data from its Phase 2 pediatric study of zelicapavir for the treatment of RSV on December 9, 2024.

This Phase 2 study was a randomized, double-blind, dose ranging, placebo-controlled study in hospitalized and non-hospitalized pediatric patients with RSV aged 28 days to 36 months. The primary objective of Part 1 of the study was to evaluate the safety and pharmacokinetics of zelicapavir and to determine the optimal dosing for Part 2 of the study. The primary objective of Part 2 of the study was to evaluate the antiviral activity of zelicapavir, with assessment of symptom severity as an exploratory objective. Because exposure was similar across all cohorts and doses, and all patients received a therapeutic dose, primary efficacy analyses were able to be performed across all dosed patients from Parts 1 and 2.

A total of 96 patients received zelicapavir (n=70) or placebo (n=26). Part 1 evaluated multiple doses and patients were treated with zelicapavir (n=36) or placebo (n=16) once-daily (QD) for 5 days. In Part 2, patients received the selected dose of zelicapavir (n=34) or placebo (n=10) QD for 5 days. Demographics and baseline characteristics were balanced across treatment groups, with the majority of patients being hospitalized at enrollment, and a mean duration of RSV symptoms prior to randomization of 4 days.

Zelicapavir demonstrated a favorable safety profile over the initial 5-day dosing period and through 23 days of follow-up. Adverse events (AEs) were similar between zelicapavir and placebo, and the most common AEs (occurring in more than one patient) were diarrhea, rash, otitis media acute, eczema, thrombocytosis and nasopharyngitis with one serious adverse event (SAE) in the zelicapavir group, which was a case of community-acquired pneumonia reported 22 days after the patient began the trial and was deemed not treatment related, and two SAEs in the placebo group. There were no AEs leading to treatment discontinuation or study withdrawal. Furthermore, zelicapavir achieved target drug exposure levels across all age groups and dosing cohorts. Exposure was similar across cohorts and doses, and all patients received a therapeutic dose. A dose of 5 mg/kg was selected for age $\geq$ 28 days to <12 months, and a dose of 7.5 mg/kg was selected for age $\geq$12 months to $\leq$36 months.

An antiviral effect was observed for the primary and secondary virology endpoints in the overall pooled efficacy population, with the viral load decline peaking at 0.7 log on Day 9 compared to placebo. The primary endpoint for Part 2 of the study showed a more pronounced effect, with a viral load decline of 1.0 log at Day 3 and 1.4 log at Day 5 compared to placebo. Additionally, a rapid and robust antiviral effect was observed in the prespecified subset of patients who were randomized within 3 days of symptom onset, which represents about 40% of patients in the study (n=38/96). In these patients, a viral load decline of 0.9 log at Day 3 and 1.2 log at Day 5 was observed compared to

placebo. Furthermore, zelicapavir treatment resulted in a greater proportion of patients having undetectable viral load at Days 5 and 9 compared to placebo and improvements in AUC of change from baseline for viral load at all timepoints. Qualitative improvement in time to undetectable viral load was observed at early timepoints, although median time to undetectable viral load was similar between groups. Overall, virology results were similar regardless of age or whether patients were enrolled from a hospitalized or outpatient setting.

As there are no validated symptom tools approved by regulatory agencies for pediatric RSV, multiple methods were used to assess symptoms. ReSViNET (REspiratory Syncytial VIrus NETwork), a publicly available pediatric tool with caregiver assessments, was used as an exploratory endpoint in all patients. This tool was originally designed primarily for prophylaxis studies to assess disease severity at a single timepoint. There was no difference in symptoms between zelicapavir and placebo using ReSViNET. RESOLVE-P (RESpiratory ObservabLE Reported Outcome-Pediatric), a proprietary tool being developed by Enanta in alignment with regulatory agency input, was specifically designed to assess the severity of pediatric RSV infection change over time based on observations by the child's caregiver. As this tool was finalized and introduced late in the study, data are only available from a small number of patients (n=15). In this dataset, a trend toward greater symptom reduction in patients treated with zelicapavir was observed.

Forward Looking Statements

This Current Report on Form 8-K includes forward-looking statements, including with respect to the prospects for further development and advancement of zelicapavir for the treatment of RSV. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this report are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the development risks of early stage discovery efforts in the disease areas in Enanta's research and development pipeline, such as RSV; the impact of development, regulatory and marketing efforts of others with respect to vaccines and competitive treatments for RSV; Enanta's limited clinical development experience; Enanta's need to attract and retain senior management and research and development personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2024 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this report. All forward-looking statements contained in this report speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Enanta undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release dated December 9, 2024
99.2	Slide presentation entitled "Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results"
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 hereunto duly authorized.

Date: December 9, 2024

ENANTA PHARMACEUTICALS, INC.

By: /s/ Paul J. Mellett
Paul J. Mellett
Chief Financial and Administrative Officer

Enanta Pharmaceuticals Announces Positive Topline Results from First-in-Pediatrics Phase 2 Study Evaluating Zelicapavir for the Treatment of Respiratory Syncytial Virus (RSV)

- *Observed an antiviral effect for the primary and secondary virology endpoints in the overall population, with a viral load decline of 1.4 log at the end of treatment in Part 2*
- *Demonstrated a viral load decline of 1.2 log compared to placebo at the end of treatment in prespecified analysis of patients randomized within 3 days of symptom onset*
- *Zelicapavir was well-tolerated with a favorable safety profile*
- *Conference call and webcast to discuss data at 8:30 a.m. ET today*

WATERTOWN, Mass., December 9, 2024 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for virology and immunology indications, today announced positive topline results from the first-in-pediatrics Phase 2 study evaluating zelicapavir in hospitalized and non-hospitalized children aged 28 days to 36 months with respiratory syncytial virus (RSV). An antiviral effect was observed for the primary and secondary virology endpoints in the overall pooled efficacy population. The primary endpoint in Part 2 of the study, which focused on virology, showed a pronounced antiviral effect with a 1.4 log decline in viral load at Day 5 compared to placebo. Additionally, a rapid and robust virologic effect was observed in a prespecified subset of patients who were randomized within 3 days of symptom onset, with a 1.2 log decline in viral load at Day 5 compared to placebo. The study also showed that zelicapavir demonstrated a favorable safety profile and was well-tolerated in this pediatric population. Zelicapavir, which received Fast Track designation from the U.S. Food and Drug Administration (FDA), is a novel N-protein inhibitor in development as a once-daily oral treatment for RSV.

“We are excited to share these positive results from our first-in-pediatric Phase 2 study of zelicapavir, which we believe confirm a strong profile for our lead RSV antiviral and strengthen Enanta’s position as a leader in developing treatments for RSV. Zelicapavir demonstrated an antiviral effect on both primary endpoints, as well as secondary virology endpoints. Furthermore, patients who joined the study within 3 days of symptom onset showed a robust 1.2 log reduction in viral load at Day 5. These data provide us with continued confidence in zelicapavir and valuable insights to inform the design of a potential registration enabling trial,” said Scott T. Rottinghaus, M.D., Chief Medical Officer of Enanta Pharmaceuticals. “There is a substantial need for safe and effective oral treatments for RSV, and we believe that these important antiviral data along with the favorable safety profile observed in this young, vulnerable population support further clinical evaluation of zelicapavir.”

“In my practice, I see many children requiring hospitalization for severe RSV infection during the RSV season. The impact of RSV is felt not only by patients and caregivers, but also broadly by public health. I believe that a safe and effective antiviral therapeutic is critical in addressing this significant and unmet need,” said Jaime Deville, MD, FAAP, a Principal Investigator in the Phase 2 pediatric clinical trial of zelicapavir and Professor of Clinical Infectious Diseases in the Department of Pediatrics at the David Geffen School of Medicine, University of California, Los Angeles and UCLA Mattel Children’s Hospital. “These results support further evaluation of zelicapavir and suggest the potential for zelicapavir to improve patient outcomes. I’m excited to see this compound move forward, to possibly deliver the first safe and effective antiviral to treat children with RSV infection.”

Zelicapavir Phase 2 Study Topline Results

This Phase 2 study was a randomized, double-blind, dose ranging, placebo-controlled study in hospitalized and non-hospitalized pediatric patients with RSV aged 28 days to 36 months. The primary objective of Part 1 of the study was to evaluate the safety and pharmacokinetics of zelicapavir and to determine the optimal dosing for Part 2 of the study. The primary objective of Part 2 of the study was to evaluate the antiviral activity of zelicapavir, with assessment of symptom severity as an exploratory objective. Because exposure was similar across all cohorts and doses, and all patients received a therapeutic dose, primary efficacy analyses were able to be performed across all dosed patients from Parts 1 and 2.

A total of 96 patients received zelicapavir (n=70) or placebo (n=26). Part 1 evaluated multiple doses and patients were treated with zelicapavir (n=36) or placebo (n=16) once-daily (QD) for 5 days. In Part 2, patients received the selected dose of zelicapavir (n=34) or placebo (n=10) QD for 5 days. Demographics and baseline characteristics were balanced across treatment groups, with the majority of patients being hospitalized at enrollment, and a mean duration of RSV symptoms prior to randomization of 4 days.

Zelicapavir demonstrated a favorable safety profile over the initial 5-day dosing period and through 23 days of follow-up. Adverse events (AEs) were similar between zelicapavir and placebo and there were no AEs leading to treatment discontinuation or study withdrawal. Furthermore, zelicapavir achieved target drug exposure levels across all age groups and dosing cohorts. Exposure was similar across cohorts and doses, and all patients received a therapeutic dose. A dose of 5 mg/kg was selected for age ≥ 28 days to <12 months, and a dose of 7.5 mg/kg was selected for age ≥12 months to ≤36 months.

An antiviral effect was observed for the primary and secondary virology endpoints in the overall pooled efficacy population, with the viral load decline peaking at 0.7 log on Day 9 compared to placebo. The primary endpoint for Part 2 of the study showed a more pronounced effect, with a viral load decline of 1.0 log at Day 3 and 1.4 log at Day 5 compared to placebo. Additionally, a rapid and robust antiviral effect was observed in the prespecified subset of patients who were randomized within 3 days of symptom onset, which represents about 40% of patients in the study (n=38/96). In these patients, a viral load decline of 0.9 log at Day 3 and 1.2 log at Day 5 was observed compared to placebo. Furthermore, zelicapavir treatment resulted in a greater proportion of patients having undetectable viral load at Days 5 and 9 compared to placebo and improvements in AUC of change from baseline for viral load at all timepoints. Qualitative improvement in time to undetectable viral load was observed at early timepoints, although median time to undetectable was similar between groups. Overall, virology results were similar regardless of age or whether patients were enrolled from a hospitalized or outpatient setting.

As there are no validated symptom tools approved by regulatory agencies for pediatric RSV, multiple methods were used to assess symptoms. ReSViNET (REspiratory Syncytial VIrus NETwork), a publicly available pediatric tool with caregiver assessments, was used as an exploratory endpoint in all patients. This tool was originally designed primarily for prophylaxis studies to assess disease severity at a single timepoint. There was no difference in symptoms between zelicapavir and placebo using ReSViNET. RESOLVE-P (RESpiratory ObservabLE Reported Outcome-Pediatric), a proprietary tool being developed by Enanta in alignment with regulatory agency input, was specifically designed to assess the severity of pediatric RSV infection change over time based on observations by the child's caregiver. As this tool was finalized and introduced late in the study, data are only available from a small number of patients (n=15). In this dataset, a trend toward greater symptom reduction in patients treated with zelicapavir was observed.

Full data from the study will be presented at a future medical conference or in a peer-reviewed publication.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 8:30 a.m. ET. The live webcast can be accessed at "Events & Presentations" in the investors section of Enanta's website. To participate by phone, please register for the call here. It is recommended that participants register a minimum of 15 minutes before the call. Once registered, participants will receive an email with the dial-in information. The archived webcast will be available on Enanta's website for approximately 30 days following the event.

About Zelicapavir

Zelicapavir, Enanta's lead N-protein inhibitor, is being developed for the treatment of RSV infection, and has been granted Fast Track designation by the U.S. Food and Drug Administration. Zelicapavir is a nanomolar inhibitor of both RSV-A and RSV-B activity. Zelicapavir is differentiated from RSV fusion inhibitors as the N-protein inhibitor targets the virus' replication machinery and has demonstrated a high barrier to resistance in vitro. In preclinical studies, Zelicapavir maintained antiviral potency across all clinical isolates tested and was active against viral variants resistant to other mechanisms. Zelicapavir demonstrated a favorable safety, pharmacokinetic and drug-drug interaction profile in an extensive Phase 1 program. In a Phase 2 challenge study, zelicapavir achieved highly statistically significant ($p<0.001$) reductions in RSV viral load and clinical symptoms compared to placebo, and demonstrated a favorable safety profile and was well-tolerated, with infrequent adverse events. Zelicapavir is currently being evaluated in RSVHR, a Phase 2b study in the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease (COPD) or asthma.

About Respiratory Syncytial Virus

RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under one year of age in the United States and a significant cause of respiratory illness in older adults and immunocompromised individuals.[1] According to the Centers for Disease Control and Prevention, virtually all children in the United States get an RSV infection by the time they are two years old and one to two out of every 100 children younger than six months of age with an RSV infection may need to be hospitalized.[2] Globally, there are an estimated 33 million cases of RSV annually in children less than five years of age, with about 3 million hospitalized and up to approximately 100,000 dying each year from complications associated with the infection.[3] RSV represents a significant health threat for adults older than 65 years of age, with an estimated 177,000 hospitalizations and 14,000 deaths associated with RSV infections annually in the United States.[4]

About Enanta Pharmaceuticals, Inc.

Enanta is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs with an emphasis on indications in virology and immunology. Enanta's clinical programs are currently focused on respiratory syncytial virus (RSV) and its earlier-stage immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, including KIT and STAT6 inhibition.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic hepatitis c virus (HCV) infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from HCV products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations. Please visit www.enanta.com for more information.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including with respect to the prospects for further development and advancement of zelicapavir for the treatment of RSV. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the development risks of early stage discovery efforts in the disease areas in Enanta's research and development pipeline, such as RSV; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV; Enanta's limited clinical development experience; Enanta's need to attract and retain senior management and key scientific personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2024 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. All forward-looking statements contained in this release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Enanta undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

1. Centers for Disease Control & Prevention – Respiratory Syncytial Virus Last accessed: December 2024.
2. Centers for Disease Control & Prevention – RSV in Infants and Young Children Last accessed: December 2024.
3. Shi, Ting et al. "Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study." *Lancet (London, England)* vol. 390,10098 (2017): 946-958. doi:10.1016/S0140-6736(17)30938-8
4. Falsey, Ann R et al. "Respiratory syncytial virus infection in elderly and high-risk adults." *The New England Journal of Medicine* vol. 352,17 (2005): 1749-59. doi:10.1056/NEJMoa043951

Media and Investors Contact:

Jennifer Viera
617-744-3848
jviera@enanta.com

Exhibit 99.2

Enanta Pharmaceuticals
Great Chemistry Cures

Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results

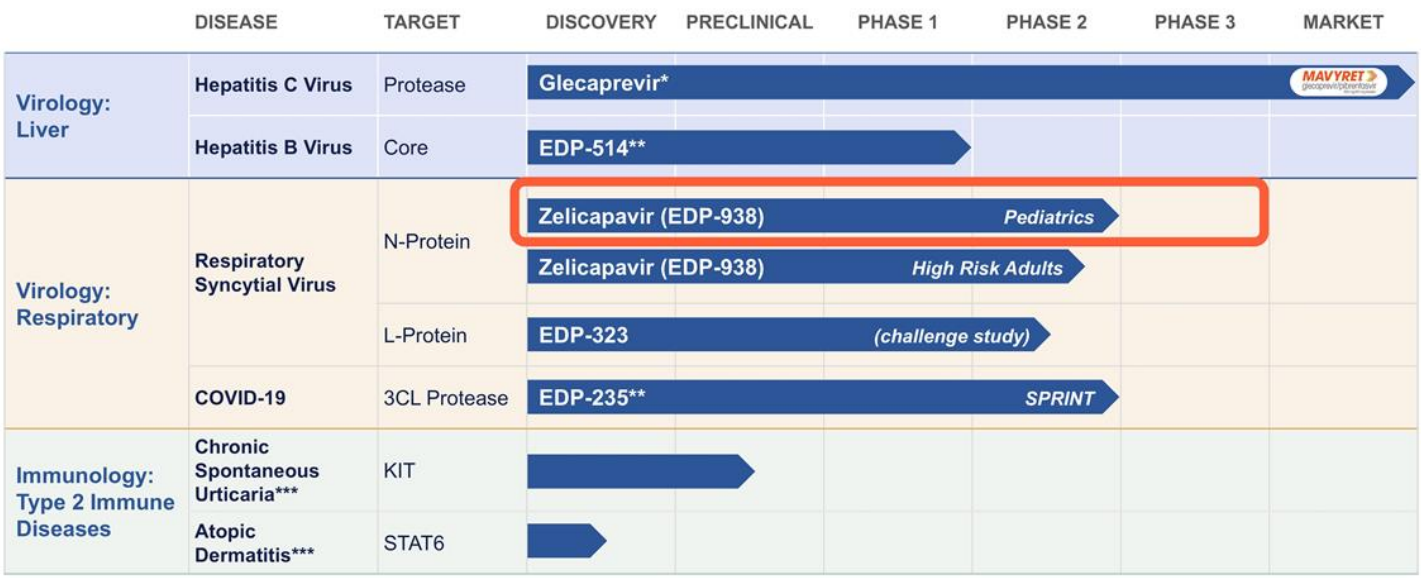
December 9, 2024

Forward Looking Statements Disclaimer

This presentation contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our research and development programs, our business and the industry in which we operate. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, as well as other comparable terminology. These forward-looking statements include, but are not limited to, statements about the potential of zelicapavir, the prospects for further development and advancement of zelicapavir for the treatment of RSV, research and clinical development plans and prospects, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends, and similar expressions. These forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management’s beliefs and assumptions. These forward-looking statements are not guarantees of future performance or results and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this presentation may turn out to be inaccurate.

Please refer to the risk factors described or referred to in “Risk Factors” in Enanta’s most recent Annual Report on Form 10-K, and other periodic reports filed with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this presentation. These statements speak only as of the date of this presentation, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

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:

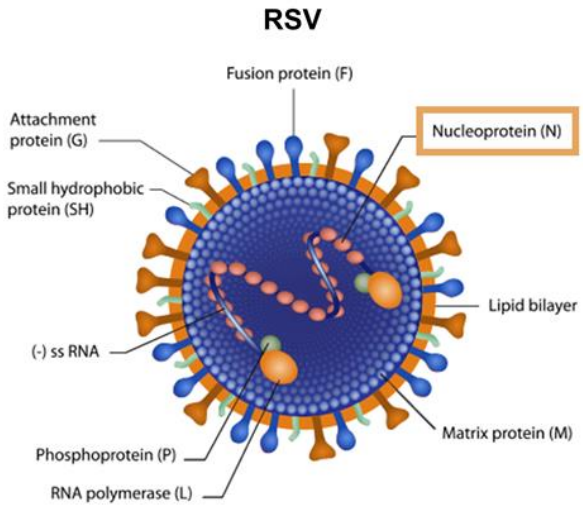
- Adoption of adult vaccines is sub-optimal and not recommended for all FDA-approved patient groups*
  - Peak adoption of vaccines for elderly range from ~35% (shingles[4]) to ~55% (flu[5])
- Pediatric prophylaxis approaches provide passive immunity; will shift first infection to next season
  - Antibody 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 in viral load and clinical symptoms compared to placebo

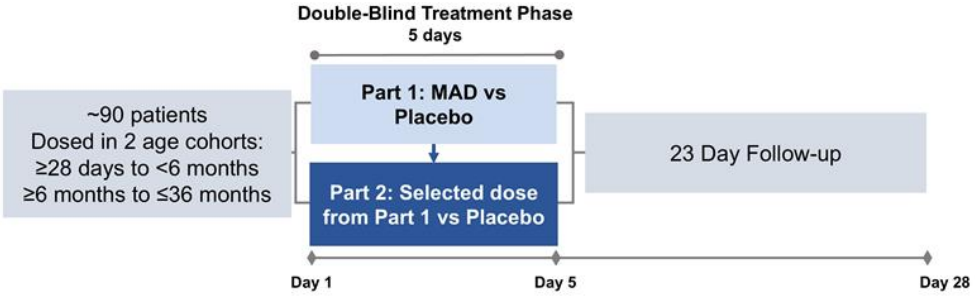


Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results

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

Enanta Pharmaceuticals

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

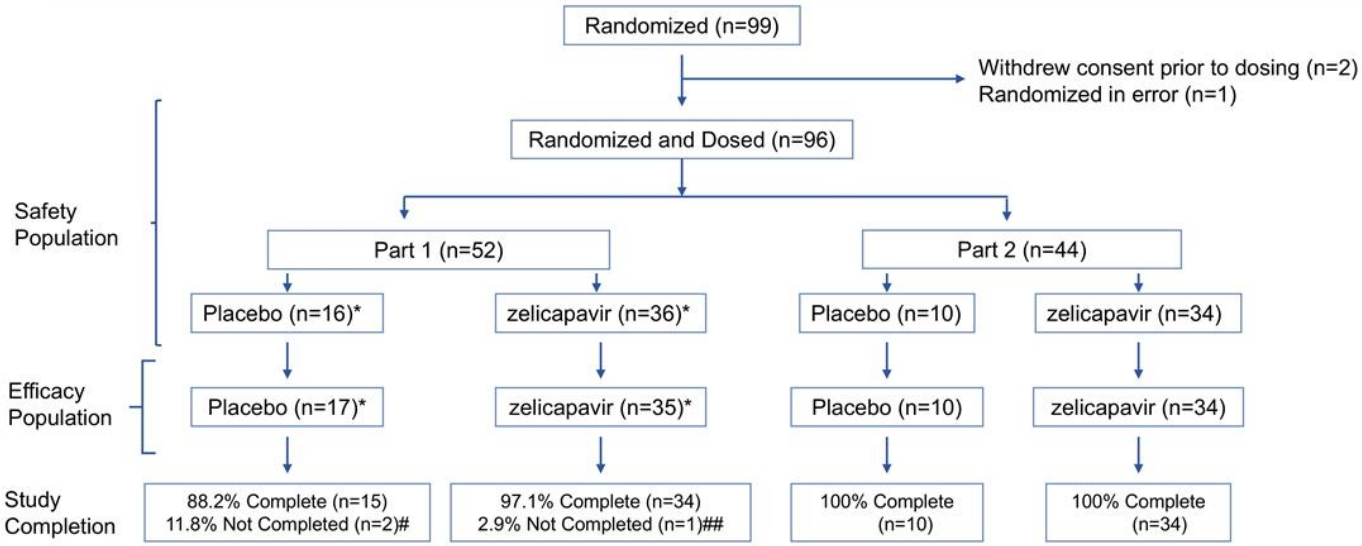
Zelicapavir Phase 2 Pediatric Study: Conclusions

- 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

Primary Objectives of Study

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

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

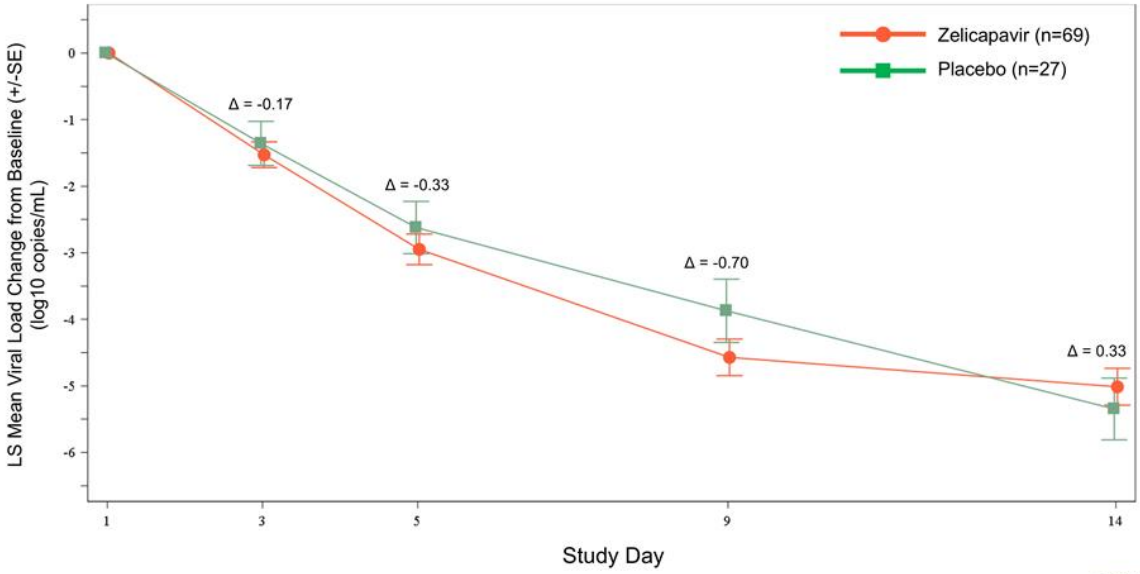
Preferred Term	Zelicapavir (pooled) (N=70)	Placebo (pooled) (N=26)
Diarrhea	7 (10.0%)	1 (3.8%)
Rash	3 (4.3%)	1 (3.8%)
Otitis media acute	2 (2.9%)	1 (3.8%)
Eczema	2 (2.9%)	1 (3.8%)
Thrombocytosis	2 (2.9%)	0 (0%)
Nasopharyngitis	1 (1.4%)	2 (7.7%)

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)

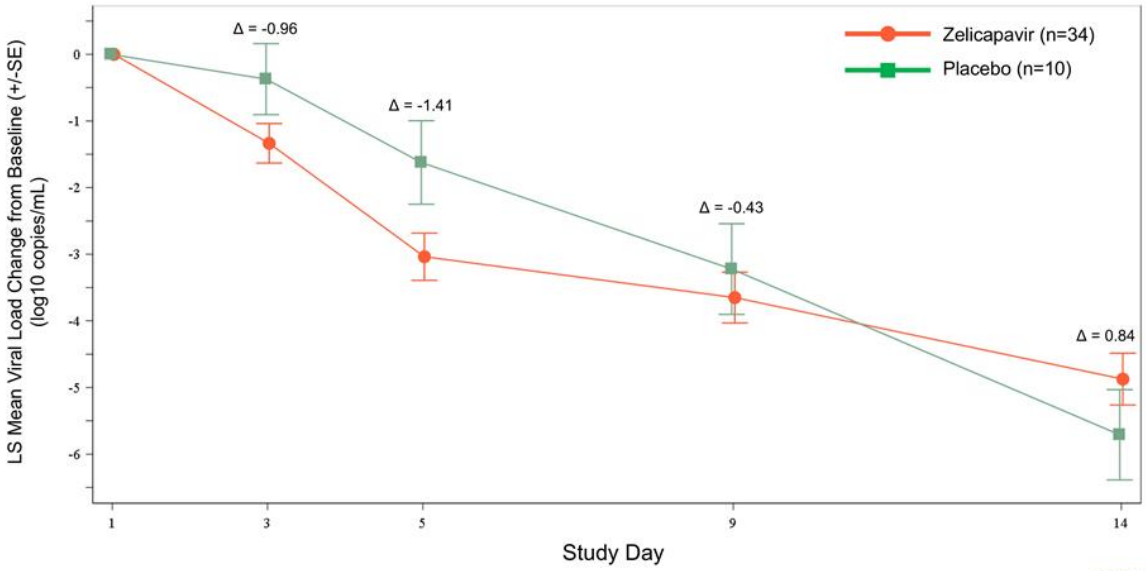
Zelicapavir Phase 2 Pediatric Study: Primary Endpoint – RSV PCR Viral Load for All Patients (Part 1 & 2)

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



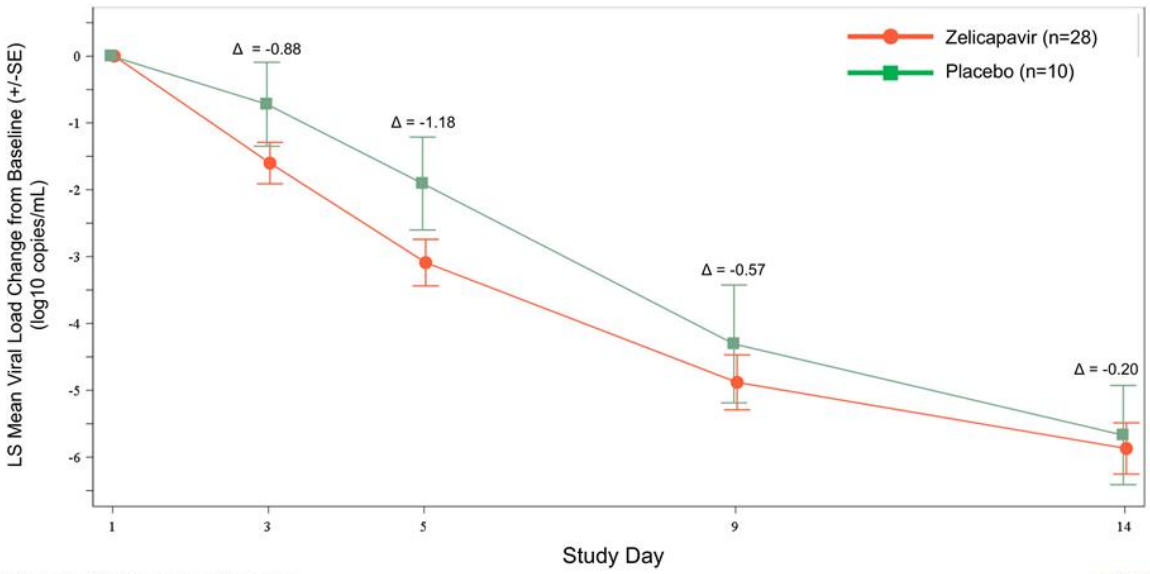
Zelicapavir Phase 2 Pediatric Study: Primary Endpoint of Part 2: RSV PCR Viral Load

- 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

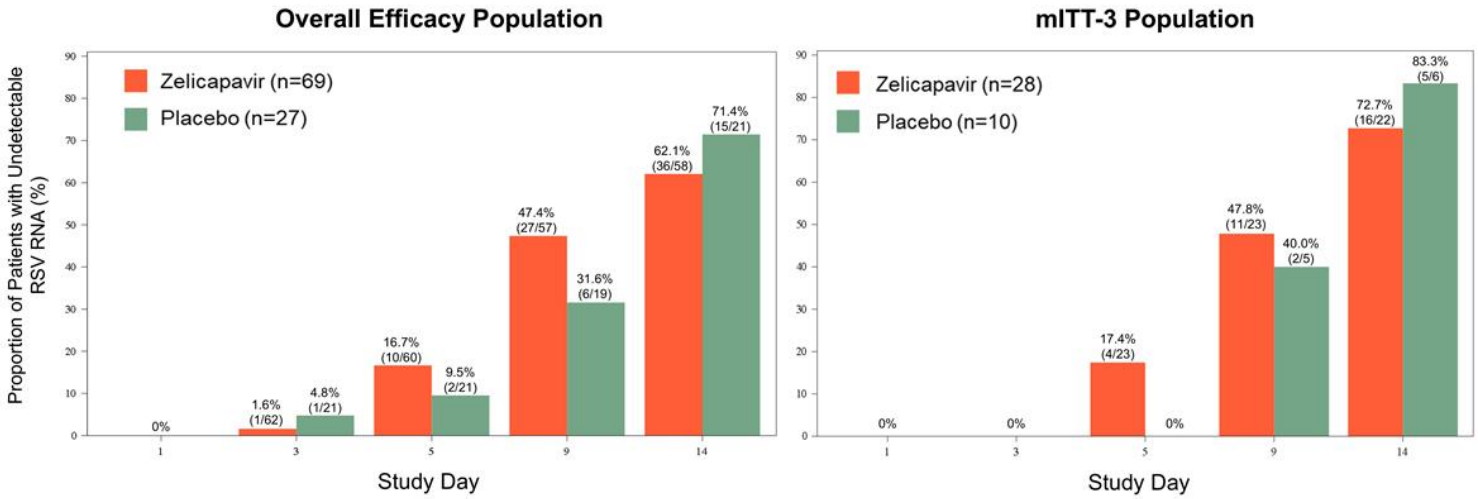
- Viral load decline of **0.88 log** at Day 3 and **1.18 log** at Day 5



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

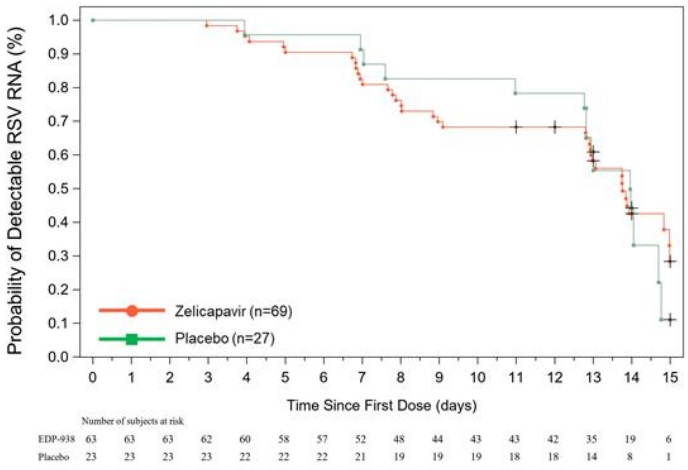


mITT-3: patients randomized within 3 days of symptom onset

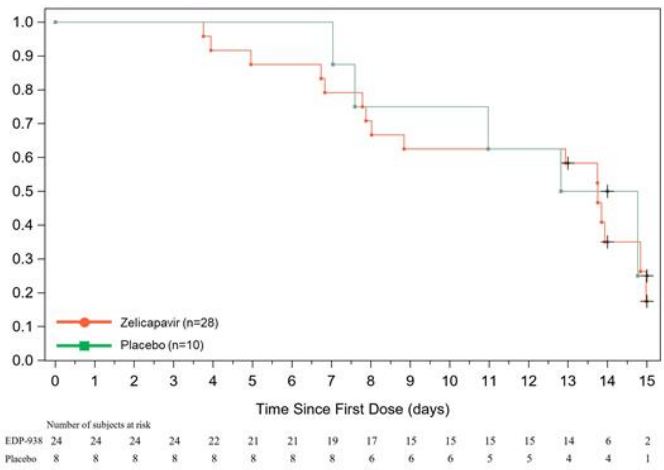
Zelicapavir Phase 2 Pediatric Study: Secondary Endpoint: Time to Undetectable Viral Load

- 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



mITT-3 Population



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 & 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 & hospitalized)

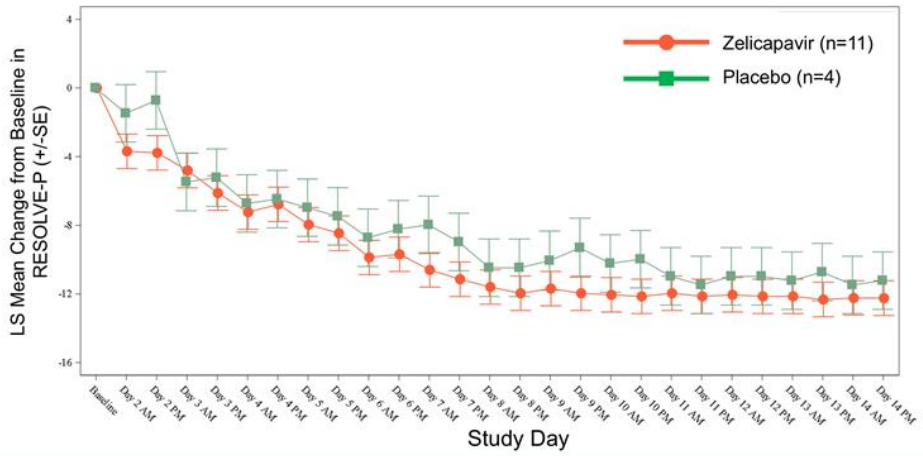
Zelicapavir Phase 2 Pediatric Study: Exploratory Endpoint: RSV Signs/Symptoms

- 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



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

Primary Objectives of Study

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

Enanta Pharmaceuticals
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Phase 2 Study of Zelicapavir in Children: RSVPEDs Topline Results

December 9, 2024