Enanta Pharmaceuticals Presents New Data for Zelicapavir, its N-Protein Inhibitor, and EDP-323, its L-Protein Inhibitor, Both in Development for the Treatment of Respiratory Syncytial Virus (RSV) at IDWeek™ 2025

October 20, 2025

- *Zelicapavir Results in Shortened Symptom Duration in Pediatric Patients*
- *EDP-323 is Highly Effective in a Post-Exposure Prophylaxis Setting*

WATERTOWN, Mass.--(BUSINESS WIRE)--Oct. 20, 2025-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical stage biotechnology company dedicated to creating novel, small molecule drugs for viral infections and immunological diseases, today announced that new data for zelicapavir, its oral, once-daily, N-protein inhibitor, and EDP-323, its oral, once-daily L-protein inhibitor, both in development for the treatment of respiratory syncytial virus (RSV), will be presented at IDWeek™ 2025 being held October 19 – 22, 2025, virtually and in Atlanta, Georgia.

"We are eager to share these new data at IDWeek™ highlighting the potential of Enanta's RSV portfolio to transform the treatment paradigm and address the unmet need for RSV therapeutics. The results presented demonstrate zelicapavir's ability to shorten symptom duration in children aged 28 days to 36 months, while another presentation underscores EDP-323's promise in post-exposure prophylaxis of RSV infection," said Scott T. Rottinghaus, M.D., Chief Medical Officer of Enanta Pharmaceuticals. "Taken together with the strong topline results from our RSVHR study of zelicapavir announced in September, these data continue to support the further clinical advancement of Enanta's RSV portfolio, including zelicapavir, our N-protein inhibitor with first-in-disease RSV treatment potential, and EDP-323, our L-protein inhibitor, a possible best-in-disease therapy."

Poster and Rapid-Fire Presentation

Zelicapavir (EDP-938) Antiviral Treatment is Associated with Shortened Duration of RSV Symptoms in a Randomized, Double-Blind, Placebo-Controlled, Clinical Trial in Children 28 Days to 36 Months of Age

- Rapid-fire presentation by Dr. Christopher Harris on Monday, October 20, 2025 at 12:35– 12:40 PM EDT in Poster Hall B4-B5 - Arena 2 (Presentation #135)
- Poster presentation by Dr. Christopher Harris on Monday, October 20, 2025 at 12:15 – 1:30 PM EDT in Poster Hall B4-B5 (Poster #523)

A post hoc analysis of a Phase 2 study of zelicapavir in children 28 days to 36 months reported in December 2024, demonstrated that treatment with zelicapavir resulted in a shorter time to complete resolution of RSV-related symptoms, as measured by ReSViNET, a parent/guardian clinical scoring system. The randomized, double-blind, placebo-controlled trial was conducted in children 28 days to 36 months of age evaluating the safety, pharmacokinetics, and antiviral activity of zelicapavir given once daily for 5 days. Caregivers reported the severity of RSV-related symptoms daily from baseline through Day 14. In the study, 96 patients were randomized and dosed (n=69 zelicapavir, n=27 placebo). Although resolution of symptom severity to mild showed no difference, a post hoc analysis of time to complete resolution of symptoms (defined as absent and discharged from hospital), showed an estimated Kaplan-Meier median of 6.99 days for zelicapavir versus 8.60 days for placebo. Similarly, an analysis of sustained resolution (defined as absent and remaining absent at all subsequent time points and discharged from hospital) resulted in 6.99 days for zelicapavir versus 10.68 days for placebo. All zelicapavir recipients achieved model-predicted target drug exposures. Adverse events (AEs) were similar between treatment groups, with none leading to treatment discontinuation or study withdrawal. These data demonstrate that treatment with zelicapavir is associated with a shorter time to complete resolution of RSV symptoms in children, thereby supporting further evaluation of zelicapavir in pediatric clinical trials.

Oral Presentation

EDP-323, a First-in-Class, Oral, RSV-Specific, Non-Nucleoside L-Protein Inhibitor Antiviral Rapidly Reduces Total RSV Symptoms, Lower Respiratory Tract RSV Symptoms and Viral Load After Human Viral Challenge

- Oral presentation by Dr. John DeVincenzo on Monday, October 20, 2025 at 4:15 – 4:27 PM EDT in B213-B214 (Presentation #235)

A randomized, double-blind, placebo-controlled human viral challenge Phase 2a study evaluated the efficacy, antiviral activity, safety and pharmacokinetics of EDP-323. Healthy volunteers were inoculated with RSV-A on Day 0. After confirmed RSV infection or 5 days later, randomized participants received EDP-323 600mg (n=47), 200mg (with 600mg loading dose, n=47), or placebo (n=47) once daily for 5 days and were followed through 28 days. Clinical symptoms were assessed once-daily using the Respiratory Infection Intensity and Impact Questionnaire (RiiQ™) and viral loads were assessed by quantitative real-time PCR on nasal washes. Participants showed rapid (within the first 24 hours) and statistically significant improvements in RiiQ™ RSV symptoms and viral load after EDP-323 dosing. Compared to placebo, there were 73% ($p=0.0012$), 61% ($p=0.0010$), and 67% ($p<0.0001$) RiiQ™ total symptom score AUC reductions in the 200mg, 600mg, and EDP-323 pooled recipients, respectively. Lower respiratory tract disease scores AUC were reduced by 95% ($p=0.0002$), 73% ($p=0.0088$), and 85% ($p=0.0002$) respectively, in the 200mg, 600mg, and pooled EDP-323 recipients versus placebo. There were 87% and 85% viral load AUC reductions in 200mg and 600mg recipients, respectively versus placebo (all $p<0.0001$). EDP-323 dosing groups showed similar efficacies. Frequencies of treatment-emergent adverse events (TEAEs) were similar across EDP-323 and placebo groups. No serious TEAEs, severe AEs, or AEs leading to treatment discontinuation or study withdrawal occurred. These findings support the further development of EDP-323 as a once-daily, oral RSV treatment.

Poster Presentation

Post-Exposure Prophylaxis (PEP) of RSV Infection After High-Inoculum RSV Human Challenge: Analysis of a Randomized Double-Blind, Placebo-Controlled Trial of EDP-323, an Oral, Non-Nucleoside Polymerase Inhibitor Antiviral

- Poster presentation by Dr. John DeVincenzo on Wednesday, October 22, 2025 at 12:15– 1:30 PM EDT in Poster Hall B4-B5 (Poster #2181)

A randomized, double-blind, placebo-controlled, human viral challenge Phase 2a study evaluated the efficacy, antiviral activity, safety and pharmacokinetics of EDP-323. Healthy volunteers were inoculated with RSV-A on Day 0. RSV real-time PCR was performed, and nasal washes were collected twice daily on Days 2-12. Study participants were randomized 1:1:1 and received either 600mg of EDP-323 orally for 5 days (high-dose group), 600mg loading dose for 1 day followed by 200mg once daily for 4 days (low-dose group), or placebo. A post exposure prophylaxis (PEP) analysis was performed in subjects who were not infected by Day 5 after RSV exposure. In this population, 68 RSV-exposed, susceptible subjects were randomized to receive EDP-323 (low dose n=24, high dose n=21) or placebo (n=23). Of these subjects, 26% (6/23) of those who received placebo became infected versus 0% (0/45) of EDP-323 recipients ($p<0.001$). Evaluated separately, the two EDP-323 dosing groups' PEP effects were statistically significant (low dose $p=0.009$, high dose $p=0.022$) versus placebo. There were no serious TEAEs, severe AEs, or AEs leading to treatment discontinuation or study withdrawal occurred. The frequency of TEAEs were similar across EDP-323 and placebo groups. These data suggest that EDP-323 is highly effective in preventing RSV infection when initiated up to 5 days after RSV exposure and further support evaluating the drug for prophylaxis.

Posters will be available to view on the conference platform and on the Company's website here after they are presented. Further information about IDWeek™ 2025 can be foundhere.

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 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.

Forward Looking Statements
This press release contains forward-looking statements, including with respect to the prospects for further development and advancement of zelicapavir and EDP-323 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.

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