



Enanta Pharmaceuticals Announces Advancement of its Zelicapavir Clinical Development Program for the Treatment of Respiratory Syncytial Virus (RSV)

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- *Registrational Ph2b/3 Trial of Zelicapavir to Initiate in High-Risk Adults with RSV in 4Q 2026, with Topline Phase 2b Data Expected in 2027*
- *Phase 2b Trial of Zelicapavir to Initiate in Pediatric Patients with RSV in 3Q 2026, with Topline Data Expected in 2027*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jun. 18, 2026-- [Enanta Pharmaceuticals, Inc.](#) (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and immunological diseases, today announced it is advancing zelicapavir into a registrational Phase 2b/3 clinical trial in adults at high risk of severe outcomes from RSV infection after a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). The Phase 2b portion of the trial will confirm the treatment effect with topline data expected in 2027. Enanta also announced plans to initiate a Phase 2b clinical trial of zelicapavir in pediatric patients with RSV, with topline data expected in 2027.

"We are thrilled to move zelicapavir into a single Phase 2b/3 registrational clinical trial in adults with RSV at high risk of progressing to severe disease, following a productive and collaborative End-of-Phase 2 meeting with the FDA. This progress, alongside the planned initiation of our pediatric Phase 2b trial, provides the opportunity for two key Phase 2b datasets next year in two important patient populations and underscores zelicapavir's potential to become the first antiviral therapy for RSV infection," said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "RSV results in a substantial global disease burden, with no available treatment options. We estimate an oral RSV antiviral for children and all high-risk adults represents a global market opportunity of over \$2 billion, with a potential total addressable population of greater than 3 million patients in the United States alone. The recent availability of at-home RSV diagnostics is expected to further drive disease awareness and increase earlier diagnosis. As we advance into late-stage development, we are well-positioned to continue our leadership in RSV and remain urgently focused on delivering zelicapavir to patients in need of treatment."

"We now have a clear and efficient pathway to advance zelicapavir into a registrational program through a single Phase 2b/3 trial. The Phase 2b part is designed to confirm the primary endpoint and treatment effect size in the targeted population and will provide a key dataset to further strengthen the body of evidence supporting the Phase 3 portion of the study. We look forward to beginning the trial in the fourth quarter of 2026, with data from the Phase 2b portion expected in 2027," said Scott T. Rottinghaus, M.D., Chief Medical Officer of Enanta Pharmaceuticals. "We are also excited to advance zelicapavir development in children, with a Phase 2b trial to be conducted in collaboration with the Penta Foundation, a leading organization dedicated to pediatric infectious disease research, and the internationally recognized AMS-PHPT Research Unit at Chiang Mai University. This trial will build on the encouraging findings from our first-in-pediatrics study and allow us to assess zelicapavir's treatment effect on symptom resolution using RESOLVE-P, our proprietary tool being developed for use as a registrational endpoint. We plan to initiate this pediatric study in the third quarter of 2026, with topline data expected in 2027."

Adult Registration Study

The Phase 2b/3 randomized, double-blind, placebo-controlled, multicenter global trial will evaluate the efficacy and safety of zelicapavir in adult outpatients who test positive for RSV and have had respiratory tract infection symptoms for no more than 3 days. Patients will have at least one of the following risk factors: 75 years of age or older, chronic obstructive pulmonary disease (COPD), or congestive heart failure (CHF). These risk factors are the same as the HR3 population in the Company's previous Phase 2 RSVHR trial where a one-week reduction in time to complete resolution of symptoms and a reduction in hospitalization was observed. Patients will receive an oral dose of 800mg of zelicapavir or placebo once daily for 7 days and be evaluated for 28 days thereafter. The primary endpoint is the time to complete resolution of all 13 RSV symptoms as measured by the RiiQ™ tool. A key secondary endpoint will evaluate hospitalization rate, with other secondary endpoints of additional clinical efficacy measures, antiviral activity and safety of zelicapavir. The Phase 2b portion of the study will include a minimum of 200 patients and is designed to confirm the primary endpoint and treatment effect size in the targeted population with the optimized dosing duration and will further support the Phase 3 portion of approximately 660 patients.

Pediatric Phase 2b Study

The Phase 2b, double-blind, placebo-controlled, multicenter trial in pediatric patients is designed to evaluate the efficacy and safety of zelicapavir in hospitalized and non-hospitalized children with up to 72 hours of respiratory tract infection symptoms who test positive for RSV. Approximately 150 participants, 28 days to 36 months of age, will receive 5mg/kg (<12 months old) or 7.5 mg/kg (≥12 months old) of zelicapavir or placebo once daily for 7 days and be evaluated for 28 days thereafter. The primary endpoint is the time to complete resolution of clinical signs of RSV as measured by the RESOLVE-P clinical scoring scale. Secondary endpoints will evaluate additional clinical efficacy measures, antiviral activity, and safety of zelicapavir. The trial is being conducted in Thailand in collaboration with the Penta Foundation, and the AMS-PHPT Research Unit at Chiang Mai University, which has deep expertise and decades of experience in conducting infectious disease trials. In addition, its network is comprised of clinical trial sites in geographies where the RSV season begins in the summer, making them an ideal partner to execute a timely start for this trial. Enanta plans to initiate this Phase 2b study in the third quarter of 2026 with topline data expected in 2027.

About Zelicapavir

Zelicapavir 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 inhibits the RSV N-protein with nanomolar activity against both RSV-A and RSV-B. This mechanism is differentiated from RSV fusion inhibitors as targeting the N-protein inhibits viral replication versus viral entry and has a high barrier to resistance *in vitro*. In a Phase 2 trial of hospitalized and non-hospitalized pediatric RSV patients aged 28 days to 3 years old, zelicapavir demonstrated an antiviral effect and shortened time to complete resolution of RSV symptoms. In a Phase 2 trial of high-risk adults, a clinically meaningful improvement in time to complete resolution of all 13 RSV symptoms was observed for zelicapavir compared to placebo, with a benefit of 6.7 days for patients with congestive heart failure, chronic

obstructive pulmonary disease, or age 75 years or older, termed the HR3 population. Importantly, zelicapavir treatment resulted in a lower hospitalization rate, with an RSV-related hospitalization rate of 5% in placebo, compared to 0% in patients who received zelicapavir. Throughout its clinical development program, zelicapavir has demonstrated a good safety profile and has been well-tolerated in more than 700 subjects to date.

About RSV

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.^{1,2} 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.³ RSV represents a significant health threat for adults older than 50 years of age, with up to 180,000 hospitalizations associated with RSV infections annually in the United States.² Overall, in the United States, RSV accounts for up to 6.8 million outpatient visits and approximately 370,000 hospitalizations, with 24,000 deaths.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 for viral infections and immunological diseases. In virology, Enanta's clinical programs are focused on the development of first-in-disease and best-in-disease treatments for RSV. The Company's immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, with KIT, STAT6 and MRGPRX2 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. Please visit www.enanta.com for more information.

Forward Looking Statements

This press release contains forward-looking statements, including statements with respect to the timeline and prospects for 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: clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, Enanta's clinical trials, including its Phase 2b/3 trial, may fail to demonstrate sufficient safety and efficacy and, if that occurs, it may be unable to commercialize our product candidates on a timely basis or ever, the impact of development, regulatory and marketing efforts of others with respect to vaccines and competitive treatments for RSV; the discovery and development risks of Enanta's programs in virology and immunology; Enanta's limited clinical development experience; Enanta's ability to partner its RSV or other programs; Enanta's need to attract and retain senior management and key 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 Form 10-K for the fiscal year-ended September 30, 2025, and any 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. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

References

1. [Centers for Disease Control & Prevention – About RSV](#). Last accessed: June 2026.
2. [Centers for Disease Control & Prevention – RSV In Adults](#). Last accessed: June 2026.
3. [Centers for Disease Control & Prevention – RSV in Infants and Young Children](#). Last accessed: June 2026.
4. [CDC Preliminary Estimates of RSV Burden for 2024-2025](#); for period: 9/29/24-9/27/25. Last accessed June 2026.

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