Atea Pharmaceuticals Initiates First-in-Human Phase 1 Clinical Trial of AT-587 for the Treatment of Hepatitis E Virus

July 14, 2026

Phase 1 Study Designed to Evaluate the Safety, Tolerability and Pharmacokinetics of AT-587 in Healthy Volunteers

AT-587 is a Potential First-in Class Treatment for Hepatitis E Virus, a Serious Liver Disease with No Approved Therapies

Study Initiation Represents an Important Milestone Advancing Atea's Antiviral Pipeline Focusing on First- or Best-in-Class Product Candidates in Areas of High Unmet Medical Need

BOSTON, July 14, 2026 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (Atea or Company), a late-stage clinical biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today announced the initiation of a first-in-human Phase 1 clinical trial evaluating AT-587, for the treatment of hepatitis E virus (HEV) infection.

AT-587 is a proprietary oral antiviral nucleotide analog being developed for the treatment of HEV, a potentially serious liver disease that can lead to chronic infection, cirrhosis and liver failure in certain patient populations. In particular, at-risk populations include immunocompromised individuals, such as transplant recipients and patients taking immunosuppressants, among others. There are currently no approved treatments for HEV.

"HEV is a significant health concern, particularly among immunocompromised patients who are at heightened risk for chronic infection and rapidly progressive liver disease, and the initiation of our Phase 1 trial represents an opportunity to address a substantial unmet need," said Jean-Pierre Sommadossi, PhD, founder and chief executive officer of Atea Pharmaceuticals. "Supported by encouraging preclinical data demonstrating potent antiviral activity, we believe AT-587 has the potential to become an important therapeutic option for patients, particularly transplant recipients and immunocompromised patients living with HEV. Advancing AT-587 into the clinic builds on our deep expertise in antiviral drug development and represents another step in expanding Atea's viral hepatitis franchise."

The Phase 1 trial is a randomized, double-blind, placebo-controlled, sequential dose-escalation study designed to evaluate the safety, tolerability and pharmacokinetics (PK) of AT-587 in healthy volunteers. The study includes both single ascending dose (SAD) and multiple ascending dose (MAD) components, as well as an embedded food-effect assessment.

Part A of the study will evaluate single ascending doses of AT-587 administered under fasting conditions, with one cohort incorporating both fasting and fed administration to assess food effect.

Part B of the study will evaluate multiple ascending doses of AT-587 administered once daily or twice daily for seven days, with dose selection informed by safety and PK data generated in Part A.

Dose escalation decisions will be guided by ongoing review of emerging safety and PK data, providing flexibility to adapt the doses as clinical experience with AT-587 evolves.

EASL 2026: AT-587 *In Vitro* Results Demonstrate High Antiviral Potency Against HEV and *In Vivo* Efficacy

Results presented at EASL Congress 2026 demonstrated the promising preclinical antiviral potency of AT-587 against HEV. Studies demonstrated that AT-587 is a potent inhibitor of HEV replication being 30- to 150-fold more potent *in vitro* against HEV than sofosbuvir and ribavirin. Ribavirin is currently used off label as a treatment for HEV. AT-587 showed no toxicity in *in vitro* studies. AT-587 was also active against flaviviruses, rubella and chikungunya. Additional data presented at EASL Congress 2026 showed that AT-587 inhibits HEV genotype 3 activity *in vivo*. Using an HEV genotype 3 infected gerbil model, samples from the treated groups had significantly lower HEV RNA levels than the control group. Notably, AT-587 also retained high potency against ribavirin (G1634R) and sofosbuvir (A1343V) clinical resistance strains *in vitro*, further underscoring the potential of AT-587 as a first-in-class therapy and differentiating its profile from existing off-label treatment options.

About HEV

HEV is a single stranded ribonucleic acid (ssRNA) virus which infects the liver and remains an under-recognized global health challenge with an estimated 20 million acute infections annually. Waterborne transmission of HEV genotypes 1 and 2 causes mostly acute self-limiting hepatitis in developing regions, whereas foodborne transmission of HEV genotype 3 predominates in the US and Europe and may cause chronic hepatitis in immunocompromised patients, which can lead to cirrhosis in three to five years. There is a growing number of immunocompromised patients, a population that includes solid organ transplant and hematopoietic stem cell transplant recipients and patients with hematologic malignancies such as multiple myeloma. Each year, in the US and Europe, 3% of the approximately 665,000 patients who have these underlying medical conditions are at risk of developing chronic HEV. There is currently no approved antiviral therapy for HEV, and current off-label treatments, including ribavirin, have limited efficacy and tolerability, underscoring a clear and urgent unmet medical need. Atea's initial HEV clinical efforts will focus on developing AT-587 for the treatment of immunocompromised patients with chronic HEV.

About Atea Pharmaceuticals

Atea is a late-stage clinical biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapies to address the unmet medical needs of patients with serious viral infections. Leveraging Atea's deep understanding of antiviral drug development, nucleos(t)ide

chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleos(t)ide prodrug platform to develop novel product candidates to treat ssRNA viruses, which are a prevalent cause of serious viral diseases. Atea plans to continue to build its pipeline of antiviral product candidates by augmenting its nucleos(t)ide platform with other classes of antivirals that may be used in combination with its nucleos(t)ide product candidates. Atea's Phase 3 program is evaluating the FDC regimen of BEM, a nucleotide analog polymerase inhibitor, and RZR, an NS5A inhibitor, to treat HCV. AT-587, a nucleotide analog, is in Phase 1 development for the treatment of HEV. For more information, please visit www.ateapharma.com

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to statements regarding the potential to develop a product for the treatment of HEV, anticipated milestone events and timelines for clinical trials, future results of operations and business strategy. When used herein, words including "expected," "should," "anticipated," "believe," "will," "plans," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Atea's current expectations and various assumptions. Atea believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Atea may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, uncertainties inherent in the drug discovery and development process and the regulatory submission or approval process, unexpected or unfavorable safety or efficacy data or results observed during clinical trials or in data readouts; delays in or disruptions to clinical trials or our business; our reliance on third parties over which we may not always have full control; dependence on the success of Atea's most advanced product candidate, in particular the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV; as well as the other important factors discussed under the caption "Risk Factors" in Atea's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While Atea may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing Atea's views as of any date subsequent to the date of this press release.

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