



Aligos Therapeutics Announces First Interim Analysis Results from the Phase 2 B-SUPREME Study of Pevifoscorvir Sodium in Participants with Chronic Hepatitis B Virus Infection and Grant of FDA Fast Track Designation

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- Received FDA Fast Track Designation for pevifoscorvir sodium for the treatment of chronic hepatitis B virus infection
- HBeAg- cohort sample size increased to optimize powering; futility criteria not met
- Study drugs were well-tolerated by participants
- Topline data expected in 2027, guidance remains unchanged

SOUTH SAN FRANCISCO, Calif., April 14, 2026 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, "Aligos") a clinical stage biopharmaceutical company focused on improving patient outcomes through best-in-class therapies for liver and viral diseases, today announced the first interim analysis results of the Phase 2 B-SUPREME study of pevifoscorvir sodium in participants with chronic hepatitis B virus (HBV) infection for the Part 2a (HBeAg- cohort) where the independent Data Safety Monitoring Review Board (DSMB) has recommended continuation of the study with an increase in sample size for this cohort in order to optimize statistical powering; futility criteria for the cohort was not met. Additionally, Aligos announced that the United States Food and Drug Administration (FDA) has granted Fast Track Designation to pevifoscorvir sodium, a potential best/first-in-class capsid assembly modulator (CAM-E) under investigation for the treatment of chronic hepatitis B virus (HBV) infection.

Interim Analysis

The study design for the Phase 2 B-SUPREME study includes pre-specified sample size re-estimations for both Parts 1a and 2a to ensure sufficient power to demonstrate a statistically significant treatment effect at the primary endpoint. The first pre-specified interim analysis of the Phase 2 B-SUPREME study was performed after approximately 60% of HBeAg- participants (N=34, Part 2a) reached Week 12 or later. In addition, safety data was reviewed for all participants enrolled in the study (N=174) at the time the interim analysis was performed.

Findings from the first interim analysis include:

- The DSMB recommended increasing the sample size of Part 2a from 74 currently enrolled to 100 participants. A futility analysis was performed; the prespecified futility criteria was not met, per the statistical analysis plan.
- The study drugs were well-tolerated with no clinically concerning laboratory, physical examination, vital sign, or ECG abnormalities. No viral breakthrough related to study drugs has been observed in the study to date.

Aligos remains blinded to participant-level data. Completion of enrollment in the HBeAg- cohort is expected in the second half of 2026. Currently, there are 74 participants enrolled in the HBeAg- cohort (Part 2a), with 103 participants enrolled in the HBeAg+ cohort (Part 1a). Topline data remains on track for 2027.

"We are encouraged by this recommendation from the DSMB to increase the sample size in order to increase the probability for success of the study's primary endpoint," stated Lawrence Blatt, Ph.D., M.B.A., Chairman, President, and Chief Executive Officer at Aligos Therapeutics. "We believe we can enroll the necessary study participants in the coming months, with topline data on track for 2027. Additionally, I am thrilled to share that pevifoscorvir sodium has been granted Fast Track Designation. Aligos' mission since its founding has been to improve outcomes for patients with unmet needs in liver and viral diseases and being granted Fast Track Designation for pevifoscorvir sodium is the next step in our journey to make this a reality. As we progress the Phase 2 B-SUPREME study, we look forward to working with regulators to determine the appropriate path forward."

Fast Track Designation

The FDA Fast Track Designation was supported by the 96-Week Phase 1 (NCT04536337) data evaluating pevifoscorvir sodium monotherapy in patients with chronic HBV infection, which were presented at The Liver Meeting® 2025, along with the 8-Week nucleoside analog follow-up data. This study demonstrated that pevifoscorvir sodium was well tolerated by study participants and the data demonstrated potential best-in-class reductions across clinically relevant viral markers.

Fast Track Designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. It enables more frequent meetings and communication with the FDA to ensure alignment on development plans and the collection of clinical data needed to support approval. Furthermore, clinical programs with Fast Track Designation may be eligible for Rolling Review, Accelerated Approval and Priority Review if relevant criteria are met.

For conditions where an available treatment exists, a drug candidate must show some advantage over available therapy, such as superior effectiveness, to be granted Fast Track Designation¹.

About B-SUPREME

The Phase 2 B-SUPREME study (NCT06963710) is a randomized, double-blind, active-controlled multicenter study evaluating the safety and efficacy of pevifoscorvir sodium monotherapy compared with tenofovir disoproxil fumarate in approximately 200 untreated HBeAg+ and HBeAg- adult subjects with chronic HBV infection for 48 weeks. The primary endpoint in the HBeAg+ part is HBV DNA <LLOQ (10 IU/mL, target detected [TD] or target not detected [TND]) and the primary endpoint in the HBeAg- part is HBV DNA <LLOQ (10 IU/mL, target not detected [TND]). The study will also evaluate the safety, pharmacokinetics, and other secondary and exploratory biomarkers, including reductions in HBV antigens and other markers of HBV infection. The second interim analysis is expected in the second half of 2026 and topline data is expected in 2027.

About pevifoscorvir sodium

Pevifoscorvir sodium (formerly known as ALG-000184) was derived from initial IP licensed from the laboratory of Dr. Raymond Schinazi at Emory University, which was further optimized by Aligos. Pevifoscorvir sodium is a potent potential best/first-in-class oral small molecule capsid assembly modulator (CAM-E) being developed for chronic hepatitis B virus (HBV) infection. Phase 1 studies have demonstrated after single and multiple daily doses that pevifoscorvir sodium was well-tolerated by study participants, with no safety signals observed, and demonstrated linear PK and promising antiviral activity. In longer term Phase 1 studies, pevifoscorvir sodium 300mg QD x ≤96 weeks monotherapy has demonstrated sustained reductions in HBV DNA, RNA, HBsAg, HBeAg, and HBcrAg. Pevifoscorvir sodium has a regulatory path, as acknowledged by the FDA, EMA, and NMPA (China), for subsequent studies utilizing the chronic suppressive pathway.

About Chronic HBV Infection

Chronic hepatitis B virus (HBV) infection is a life-threatening viral infection that primarily affects the liver with 254 million patients worldwide and approximately 1.2 million individuals become newly infected every year despite the availability of a prophylactic vaccine. Complications include cirrhosis, end-stage liver disease, and hepatocellular carcinoma, which collectively resulted in approximately 1.08 million deaths in 2022, according to the European Association for the Study of the Liver's 2025 clinical practice guidelines. Chronic HBV infection is the primary cause of liver cancer worldwide, and the mortality associated with HBV-related liver cancer continues to increase.

About Aligos

Aligos Therapeutics, Inc. (NASDAQ: ALGS) is a clinical stage biopharmaceutical company founded with the mission to improve patient outcomes by developing best-in-class therapies for the treatment of liver and viral diseases. Aligos applies its science driven approach and deep R&D expertise to advance its purpose-built pipeline of therapeutics with high unmet medical needs such as chronic hepatitis B virus (HBV) infection, metabolic dysfunction-associated steatohepatitis (MASH), obesity, and coronaviruses.

For more information, please visit www.aligos.com or follow us on LinkedIn or X.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release that are not historical facts may be considered "forward-looking statements," including without limitation, statements regarding Aligos' mission to improve patient outcomes by developing best-in-class therapies for the treatment of liver and viral diseases; the expected pace of enrollment in the B-SUPREME study, timing for enrollment completion, expectations for second interim analysis in the second half of 2026, and expectations for topline data in 2027; whether the planned increase in enrollment will lead to success in meeting the study's primary endpoint; expectations regarding what the B-SUPREME study will evaluate in the future; and whether the granting of Fast Track Designation by the FDA for pevifoscorvir sodium will lead to improved outcomes for patients with unmet needs in liver and viral diseases. Such forward-looking statements are subject to substantial risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties inherent in the drug development process, including Aligos' clinical stage of development, the process of designing and conducting clinical trials and the regulatory approval processes. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of Aligos in general, see Aligos' Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2026 and its future periodic reports to be filed or submitted with the Securities and Exchange Commission. Except as required by law, Aligos undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

1. <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track> (Accessed April 14, 2026)

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