Aligos Therapeutics Announces First Subject Dosed in the Phase 2 B-SUPREME Study of ALG-000184 in Subjects with Chronic HBV Infection

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SOUTH SAN FRANCISCO, Calif., Aug. 13, 2025 (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 that dosing in the Phase 2 B-SUPREME study of its investigational compound ALG-000184 has been initiated in subjects with chronic hepatitis B virus (HBV) infection.

“Despite available treatments for chronic HBV infection, better therapies are needed to stem the progression to end-stage liver disease and liver cancer,” said Nezam Afdhal, MD, DSc, Chief of Gastroenterology, Hepatology, and Nutrition at Beth Israel Deaconess Medical Center and Charlotte & Irving Rabb Distinguished Professor of Medicine at Harvard Medical School. “I am pleased that therapies such as Aligos’ ALG-000184 are continuing to progress. The impressive antiviral activity seen in clinical trials to date provides hope for patients in need.”

“Dosing the first subjects in our Phase 2 B-SUPREME study is an important milestone for Aligos,” said Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer at Aligos Therapeutics. “We are pleased by the engagement of the clinicians and subjects, as they recognize the need for improved treatment regimens for chronic HBV infection. We believe that ALG-000184 has first/best-in-class potential based on the exciting data seen across viral markers of HBV to date. We look forward to continuing to advance ALG-000184 for patients in need of better outcomes.”

The Phase 2 B-SUPREME study (NCT06963710) is a randomized, double-blind, active-controlled multicenter study evaluating the safety and efficacy of ALG-000184 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 will be HBV DNA <LLOQ (10 IU/mL, target detected [TD] or target not detected [TND]) and the primary endpoint in the $HBeAg^-$ part will be 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. Interim data is projected in 2026, and topline data is anticipated in 2027.

About ALG-000184

ALG-000184 was derived from initial IP licensed from the laboratory of Dr. Raymond Schinazi at Emory University, which was further optimized by Aligos. ALG-000184 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 ALG-000184 was well-tolerated by study participants, with no safety signals observed, and demonstrated linear PK and excellent antiviral activity. In longer term Phase 1 studies, ALG-000184 300mg QD x ≤96 weeks ± entecavir (ETV) and ALG-000184 monotherapy have demonstrated sustained reductions in HBV DNA, RNA, HBsAg, HBeAg, and HBcrAg. ALG-000184 has a regulatory path, as acknowledged by the FDA, EMA, and NMPA (China), for subsequent studies utilizing the chronic suppressive pathway. Phase 1 96-week dosing of ALG-000184 has been completed with the final and post-treatment follow up data expected at the American Association for the Study of Liver Disease’s The Liver Meeting® in 2025. The Phase 2 B-SUPREME study initiated in August 2025, with interim data projected in 2026, and topline data anticipated in 2027.

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 biotechnology 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 for high unmet medical needs such as chronic hepatitis B virus (HBV) infection, metabolic dysfunction-associated steatohepatitis (MASH), 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’ financial results and performance as well as research and development activities, including regulatory status and the timing of announcements and updates relating to our regulatory filings and clinical trials. Such forward looking statements are subject to substantial risks and uncertainties that could cause our development programs, future results, performance, or achievements 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, the regulatory approval processes, and other matters that could affect the sufficiency of Aligos’ capital resources to fund operations. 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’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 6, 2025 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.

Aligos Therapeutics

Contact
Jordyn Tarazi
Vice President, Investor Relations & Corporate Communications
+1 (650) 910-0427
jtarazi@aligos.com

Media Contact
Inizio Evoke
Jake Robison
Vice President
Jake.Robison@inzioevoke.com