



Aligos Therapeutics Presents Positive Data at the AASLD Liver Meeting® 2023 Demonstrating that Treatment with ALG-000184 (CAM-E) Results in Significant Multi-log Reductions in Hepatitis B Antigens (HBsAg, HBcrAg and HBeAg)

Hepatitis B virus e antigen positive (HBeAg+) subjects dosed with once-daily 300mg ALG-000184 ± entecavir for up to 48 weeks demonstrated:

- Dose dependent mean reductions of up to 2 log₁₀ IU/mL for HBV antigens
- Mean DNA reductions of up to 6.8 log₁₀ IU/mL
- No viral DNA breakthroughs in subjects receiving ALG-000184 monotherapy
- Data suggest ALG-000184 may lower cccDNA levels via both mechanisms of action for CAM-E drugs
- A well tolerated safety profile

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today announced that emerging hepatitis B antigen lowering data for its capsid assembly modulator – empty (CAM-E) drug, ALG-000184, are available as a late breaking poster at The Liver Meeting® of the American Association for the Study of Liver Diseases (AASLD), being held in Boston, Massachusetts, November 10 – 14, 2023.

Poster (#5028-C), “Long-term dosing with the capsid assembly modulator ALG-000184 results in multi-log reductions of DNA, RNA, HBsAg, HBeAg, and HBcrAg in untreated HBeAg positive chronic hepatitis B subjects,” is now accessible at The Liver Meeting® and on the “Scientific Presentations & Conferences” section of the Aligos website (www.aligos.com). The data will be presented by Dr. Man-Fung Yuen, Chair and Professor of Gastroenterology and Hepatology at the University of Hong Kong, in Poster Hall C on Monday November 13 from 1-2 pm ET.

Important highlights from the poster, which summarizes safety and antiviral activity data in HBeAg positive subjects receiving once-daily 300 mg ALG-000184 ± entecavir (ETV) x ≤48 weeks, include:

1. Mean HBsAg, HBeAg, and HBcrAg reductions of 1.2 log₁₀ IU/mL, 1.7 log₁₀ PEI U/L and 2.0 log₁₀ U/mL, respectively, at Week 48. These reductions were dose-dependent, independent of co-administration of ETV, and suggest that ALG-000184 may reduce cccDNA levels via both the 1st and 2nd mechanisms of action of CAM-E drugs
2. Greater mean DNA reductions were observed for ALG-000184 ± ETV vs. ETV monotherapy after treatment for 12 weeks; maximum mean DNA reductions of 6.8 log₁₀ IU/mL for the ALG-000184 + ETV combination were observed at Week 48
3. Mean DNA reductions were comparable for 300 mg ALG-000184 with or without ETV, indicating ETV did not further impact DNA lowering. No viral DNA breakthroughs were observed in subjects receiving ALG-000184 monotherapy
4. ALG-000184 with or without ETV was well tolerated with no safety signals identified

“I have been one of the physicians overseeing this Phase 1a/1b study of ALG-000184 for several years now and continue to be impressed with the antiviral activity that ALG-000184 has demonstrated, particularly in HBeAg+ subjects,” noted Dr. Yuen. “ALG-000184 appears to have best-in-class antiviral properties which are also unique compared to other drug classes being evaluated for the treatment of chronic hepatitis B (CHB). If the trends observed to date continue, ALG-000184 has the potential to become a cornerstone therapy in the treatment of CHB. I look forward to sharing these exciting data at the Liver Meeting.”

“The effort to raise the rate of functional cure and improve outcomes in CHB subjects has been very challenging,” noted Ira Jacobson, M.D., Director of Hepatology Research at New York University. “We believe that more profound suppression of the virus or an enhanced immune response to it, or a combination of the two is probably necessary. The antiviral effects of ALG-000184 presented at AASLD indicate that this drug is achieving significant viral suppression, likely via inhibition of cccDNA synthesis. If these effects continue, ALG-000184, in combination with complementary mechanisms of action, may take us a step closer in our effort to achieve higher functional cure rates.”

“We are pleased to see reductions in all HBV viral markers associated with prolonged dosing of ALG-000184, with or without entecavir, continue to trend so favorably,” said Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. “The data suggest that ALG-000184 is the first CHB drug to affect cccDNA antigen expression levels via two mechanisms of action and may play a central role in future efforts to achieve higher rates of chronic DNA suppression or functional cure. Accordingly, we have initiated Phase 2 enabling activities in preparation for future studies and look forward to continuing to share emerging data from these ongoing cohorts at future scientific conferences. We are proud of our team for this important accomplishment, and we are also grateful to our collaborators at Emory University (Professor Raymond Schinazi) for their contributions to this effort.

About Aligos

Aligos Therapeutics, Inc. is a clinical stage biopharmaceutical company that was founded in 2018 with the mission to become a world leader in the treatment of liver and viral diseases. Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver and viral diseases to discover and develop potentially best in class therapeutics for nonalcoholic steatohepatitis (NASH) and viruses with high unmet medical need such as coronaviruses and chronic hepatitis B (CHB).

Forward-Looking Statement

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 that the mean HBsAg, HBeAg, and HBcrAg reductions were dose-dependent, independent of co-administration of ETV and suggest that ALG-000184 may reduce cccDNA levels via both the 1st and 2nd mechanisms of action of CAM-E drugs; that ALG-000184 appears to have best-in-class antiviral properties which are unique compared to other drug classes being evaluated for the treatment of CHB and that if the trends observed to date continue, ALG-000184 has the potential to become a cornerstone therapy in the treatment of CHB; the belief that more profound suppression of the virus or an enhanced immune response to it or a combination of the two is probably necessary; statements that the antiviral effects of ALG-000184 presented indicate that this drug is achieving more significant viral suppression likely via inhibition of cccDNA synthesis and that if these effects continue, ALG-000184, in combination with complementary mechanisms of action, may be a step closer in the effort to achieve higher functional cure rates; statements that the data suggest that ALG-000184 is the first CHB drug to affect cccDNA antigen expression levels via two mechanisms of action and may play a central role in future efforts to achieve higher rates of chronic DNA suppression or functional cure; and the company looking forward to sharing emerging data from ongoing cohorts at future scientific conferences. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology indicating future results. 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, the risks and uncertainties associated with market conditions, 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, the timing of regulatory filings, the challenges associated with manufacturing drug products, Aligos' ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos' capital resources to fund operations, reliance on third parties for manufacturing and development efforts, and the impact of global events and other macroeconomic conditions on the Aligos business. 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 November 2, 2023 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.

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