Aligos Therapeutics Presents Positive Data at APASL 2025

Mar 26, 2025

SOUTH SAN FRANCISCO, Calif., March 26, 2025 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today announced positive data from three oral presentations at the 34th Annual Meeting of the Asian Pacific Association for the Study of the Liver (APASL) 2025, being held March 26 - 30, 2025 in Beijing, China.

“We are pleased to present preliminary data out to 96 weeks in our Phase 1 study of ALG-000184, which continues to demonstrate first-/best-in-class reductions in important HBV markers,” stated Lawrence Blatt, PhD, MBA, Chairman, President, & CEO of Aligos Therapeutics. “Additionally, the HERALD data from the Phase 2a study of ALG-055009 in MASH subjects demonstrated robust reductions in liver fat, with a subgroup analysis in subjects on stable GLP-1 agonist therapy, showing a potential role for ALG-055009 in combination with other therapies.”

Two oral presentations will highlight the continued potent antiviral activity of ALG-000184 for chronic hepatitis B virus (HBV) infection in both HBeAg-positive and HBeAg-negative subjects, demonstrating the potential for the molecule to become first-line therapy for chronic suppression and the backbone for regimens aimed at functional cure.

Data from ≤84 weeks following an oral daily dose of 300 mg ALG-000184 monotherapy demonstrated HBV DNA suppression (<LLOQ <10 IU/mL) in 9/9 (100%) HBeAg+ subjects. All HBeAg- subjects achieved sustained HBV DNA suppression by Week 24 and 11/11 (100%) subjects achieved sustained HBV DNA <LLOQ at Week 48 with 10/11 (91%) subjects further achieving HBV DNA below the lower limit of detection (LLOD <4.29 IU/mL). Importantly, no subject demonstrated viral resistance to ALG-000184 monotherapy and suppression was maintained throughout the dosing period.

All subjects achieved HBV RNA < LLOQ by Week 52 in HBeAg+ subjects and Week 8 in HBeAg- subjects. Multi-$\log_{10}$ reductions in HBsAg, HBeAg, and HBcrAg were observed in HBeAg+ subjects, and HBcrAg decline was observed in HBeAg- subjects. These reductions demonstrate the activation of the CAM-E second mechanism. In both patient populations, ALG-000184 continues to be well tolerated with no viral breakthrough observed in subjects ≤96 weeks and no known CAM resistant mutations identified with monotherapy treatment.

Additionally, the third oral presentation will highlight the best-in-class potential of ALG-055009, a purpose built THR-β agonist discovered by Aligos scientists. 12-weeks of once daily ALG-055009 treatment in MASH patients met the primary endpoint, with robust reductions in liver fat content at Week 12. Doses of 0.5 mg to 0.9 mg ALG-055009 demonstrated statistically significant reductions in liver fat at Week 12, with placebo-adjusted median relative reductions up to 46.2% as measured by MRI-PDFF. Up to 70% of subjects achieved ≥30% relative reduction in liver fat compared to baseline, a positive prognostic indicator of histological improvements in MASH resolution and fibrosis reduction. Eighteen subjects who were on stable GLP-1 agonist therapy qualified for enrollment in the study, with liver fat content meeting the inclusion criteria of ≥10% at baseline as measured by MRI-PDFF. Notably, 11/14 subjects on stable GLP-1 agonists treated with ALG-055009 had liver fat decreases, whereas 4/4 subjects on stable GLP-1 agonists treated with placebo had increases in liver fat over the 12-week dosing period. Treatment with ALG-055009 was well-tolerated, with rates of gastrointestinal-related AEs similar to placebo.

Details of the presentations are as follows:

ALG-000184: Potential first-/best-in-class small molecule CAM-E for chronic hepatitis B (CHB)

Abstract #: 0094

Title: *Monotherapy with the Capsid Assembly Modulator ALG-000184 Results in Rapid Viral Load Reduction and High Viral Suppression Rates in Untreated HBeAg-Negative Subjects with Chronic Hepatitis B Virus Infection*

Presenter: Ed Gane, MBChB, MD, FRACP, FAASLD, MNZM, Professor of Medicine at the University of Auckland, New Zealand, Hepatologist and Deputy Director of the New Zealand Liver Unit at Auckland City Hospital

Date/Time: March 28, 2025, 3:30pm – 4:30pm GMT+8

Abstract #: 0394

Title: *Monotherapy with the Capsid Assembly Modulator ALG-000184 Results in High Viral Suppression Rates in Untreated HBeAg-Positive Subjects with Chronic Hepatitis B Virus Infection*

Presenter: Professor Man-Fung Yuen, MBBS, MD, PhD, DSc, Chair and Chief of the Division of Gastroenterology and

Hepatology, University of Hong Kong

Date/Time: March 29, 2025, 11:00am – 12:00pm GMT+8

ALG-055009: Potential best-in-class small molecule THR-β for Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Abstract #: 0257

Title: *ALG-055009, a Novel Thyroid Hormone Receptor Beta (THR-β) Agonist, was Well-tolerated with Significant Reductions in Liver Fat at Week 12 in Non-cirrhotic MASH Patients in the Randomized, Double-Blind, Placebo-controlled Phase 2a HERALD Study*

Presenter: Stanley Wang, MD

Date/Time: March 29, 2025 at 2:30pm – 3:30pm GMT+8

The presentations can be found on the Posters & Presentations section of the Aligos website (www.aligos.com) after the live event.

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 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’ Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 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.

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