Aligos Therapeutics Presents Positive Data at the EASL Congress 2025

May 8, 2025

SOUTH SAN FRANCISCO, Calif., May 08, 2025 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on improving patient outcomes through best-in-class therapies for liver and viral diseases, today announced positive data from eight presentations at the European Association for the Study of the Liver (EASL) Congress 2025, being held May 7 – 10, 2025 in Amsterdam, Netherlands.

“We are pleased to have eight presentations at this year’s EASL Congress from programs across our pipeline,” stated Lawrence Blatt, PhD, MBA, Chairman, President, & CEO of Aligos Therapeutics. “In particular, we are excited to share an update on the 96-week data from the monotherapy cohort receiving 300 mg ALG-000184. All subjects in both the $HBeAg^+$ and $HBeAg^-$ cohorts have achieved HBV DNA viral suppression < LLOQ (10 IU/mL) and continue to demonstrate sustained log_{10} reductions in viral antigens such as HBcrAg. These data further strengthen our belief that ALG-000184 is a first-/best-in-class asset with the potential to improve patient outcomes. Additionally, we will present biomarker and subgroup analyses from the Phase 2a HERALD study. These data continue to demonstrate the best-in-class potential of ALG-055009 across the cardio-metabolic space.”

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

In $HBeAg^+$ subjects with a very high mean HBV DNA level of 8.0 log_{10} IU/mL at baseline, all experienced profound and persistent HBV DNA reductions after receiving an oral daily dose of 300 mg ALG-000184 monotherapy. At Week 48, 6 of 10 subjects (60%) achieved HBV DNA < LLOQ (10 IU/mL, target detected or target not detected). With treatment extension, this rate increased to 9 of 9 subjects (100%) at Week 96. Additionally, HBV DNA level continuously declined to < LLOQ (target not detected, <4.29 IU/mL) in 5 of 9 subjects at Week 96.

In $HBeAg^-$ subjects, all 11 (100%) had rapid decline in HBV DNA levels and achieved sustained HBV DNA suppression (HBV DNA < LLOQ, target detected or target not detected) by Week 24. The HBV DNA suppression level was maintained in the ALG-000184 monotherapy cohort for up to 96 weeks, with further decline in HBV DNA to < LLOQ, target not detected, observed in all subjects (8/8) at Week 96.

Importantly, no viral breakthrough was observed in any chronic HBV infection subjects receiving ALG-000184 monotherapy for up to 96 weeks. The resistant analysis reported no known CAM resistant mutations had been identified with ALG-000184 monotherapy.

HBV RNA level achieved < LLOQ (10 copies/mL) in all $HBeAg^+$ and $HBeAg^-$ subjects by Week 52 and Week 8, respectively. Furthermore, concurrent multi-log_{10} reductions in HBV antigens (HBsAg, HBeAg, and HBcrAg) in $HBeAg^+$ subjects and HBcrAg decline in $HBeAg^-$ subjects were observed, suggesting the potential inhibition of cccDNA establishment by CAM-E 2^{nd} mechanism of action of ALG-000184.

A favorable tolerability profile has been demonstrated in untreated $HBeAg^+$ and $HBeAg^-$ subjects receiving 300 mg ALG-000184 for up to 96 weeks.

Additionally, two presentations will showcase the best-in-class potential of ALG-055009, a purpose built THR-β agonist discovered by Aligos scientists. As previously presented at AASLD’s The Liver Meeting in 2024, 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. 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.

New data being presented at the EASL congress will demonstrate substantial, dose-dependent reductions in liver fat were observed across all key subgroups with 12 weeks of once daily ALG-055009 treatment. In addition, statistically significant improvements in atherogenic lipids were achieved with 12 weeks of ALG-055009 treatment. Reductions in lipids/lipoproteins were observed even in the context of stable GLP-1 agonist or statin use. This data suggests an added benefit of ALG-055009 for patients at risk for cardiovascular disease in addition to the previously reported liver fat lowering properties in a MASLD/MASH population.

Details of the presentations are as follows:

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

Poster #: THU-261
Title: *Monotherapy with the Novel Capsid Assembly Modulator ALG-000184 for up to 96 Weeks Results in Profound and Sustained HBV DNA Suppression in Untreated Subjects with Chronic HBV 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: May 8, 2025 at 4:15pm – 5:00pm CET; May 8, 2025 at 8:30am – 5:00pm CET
Session: Poster Tour; Poster - Viral Hepatitis B and D: New therapies, unapproved therapies or strategies

Poster #: THU-256
Title: *The Safety and Antiviral Effect of Oral Daily 300 mg ALG-000184 in Combination with Entecavir for up to 96 Weeks in Untreated HBeAg-Positive Subjects with Chronic Hepatitis B Virus Infection*
Presenter: Professor Jinlin Hou, MD, Chairman and Professor of the Hepatology Unit and Department of Infectious Diseases, Nanfang Hospital, Southern Medical University
Date/Time: May 8, 2025 at 8:30am – 5:00pm CET
Session: Poster - Viral Hepatitis B and D: New therapies, unapproved therapies or strategies

Poster #: THU-242
Title: *Viral kinetics and sequence analysis of a phase I monotherapy study in subjects with chronic hepatitis B reveals a high barrier of resistance to the capsid assembly modulator ALG-000184*
Presenter: Andreas Jekle, PhD
Date/Time: May 8, 2025 at 8:30am – 5:00pm CET
Session: Poster - Viral Hepatitis B and D: New therapies, unapproved therapies or strategies

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

Poster #: SAT-451
Title: *ALG-055009, a novel thyroid hormone receptor beta agonist, demonstrated significant reductions in atherogenic lipids/lipoproteins, including lipoprotein (a), in patients with presumed metabolic dysfunction-associated steatohepatitis in the Phase 2a HERALD*
Presenter: Stanley Wang, MD, PhD
Date/Time: May 8, 2025 at 9:45am – 10:30am CET; May 10, 2025 at 8:30am – 4:00pm CET
Sessions: Poster tour; Poster - MASLD: Therapy

Poster #: SAT-450
Title: *ALG-055009, a novel thyroid hormone receptor beta (THR-beta) agonist, demonstrated robust reductions in liver fat at Week 12 across subgroups including glucagon-like peptide-1 (GLP-1) receptor agonist users in non-cirrhotic MASH patients in the Phase 2a HERALD study*
Presenter: Megan Fitzgerald, PhD
Date/Time: May 10, 2025 at 8:30am – 4:00pm CET
Session: Poster - MASLD: Therapy

Poster #: SAT-430
Title: *Population pharmacokinetic/pharmacodynamic modelling of novel thyroid hormone receptor beta agonist ALG-055009 reveals statistically significant correlation between exposure and key efficacy endpoints*
Presenter: Kha Le, PhD
Date/Time: May 10, 2025 at 8:30am – 4:00pm CET
Session: Poster - MASLD: Therapy

Poster #: FRI-450
Title: *ALG-055009, a potent and selective thyroid hormone receptor beta agonist for the treatment of metabolic dysfunction-associated steatohepatitis, induces pro-metabolic and anti-fibrotic gene expression in the liver of diet-induced obese mice*
Presenter: Xuan Luong, PhD
Date/Time: May 9, 2025 at 8:30am – 5:00pm CET
Session: Poster - MASLD: Experimental and pathophysiology

Preclinical

Poster #: FRI-257
Title: *Next generation hepatitis B virus antisense oligonucleotides incorporating novel chemistries demonstrated significantly improved properties compared to current clinical candidates*
Presenter: Jin Hong, PhD
Date/Time: May 9, 2025 at 8:30am – 5:00pm CET
Session: Poster - Viral Hepatitis: Experimental and pathophysiology

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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 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.

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