Aligos Therapeutics Presents Positive Data at The Liver Meeting (TLM) 2024

Nov 19, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 19, 2024 (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 one late-breaker oral and three poster presentations at the American Association for the Study of Liver Disease’s (AASLD) The Liver Meeting (TLM) 2024, being held November 15 – 19, 2024 in San Diego, CA.

The clinical poster presentation highlighted the continued potent antiviral activity of ALG-000184 for chronic hepatitis B (CHB) virus 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 sustained HBV DNA suppression (<LLOQ <10 IU/mL) in 7/7 (100%) HBeAg-positive CHB 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 <4.92 IU/mL). Importantly, no subject demonstrated viral resistance to ALG-000184 monotherapy and suppression was maintained throughout the dosing period.

All subjects achieved sustained HBV RNA < LLOQ by Week 44 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. In both patient populations, ALG-000184 continues to be well tolerated with no viral breakthrough observed and no known CAM resistant mutations identified with monotherapy treatment.

Additionally, the late-breaker oral presentation highlighted 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.

Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a) and apolipoprotein B and dose-dependent increases in SHBG were observed. In particular, ALG-055009 demonstrated a dose-dependent reduction from baseline of up to 26.8% at Week 12 for lipoprotein (a), which is an established risk factor for cardiovascular disease that has been resistant to treatment with statin therapy. Treatment with ALG-055009 was well-tolerated, with rates of gastrointestinal-related AEs similar to placebo.

“The presentation of longer duration dosing of ALG-000184 in CHB patients strengthens our belief that this therapy will become both first-line for chronic suppression as well as the backbone of next generation HBV treatments aimed at functional cure,” stated Lawrence Blatt, PhD, MBA, Chairman, President, & CEO of Aligos Therapeutics. “Additionally, we are pleased to have presented the HERALD data, showing robust reductions in liver fat for patients treated with ALG-055009. The subgroup analysis in patients enrolled in the study on stable GLP-1 agonist therapy suggests a role for ALG-055009 to augment liver fat reductions in patients receiving incretin therapy.”

Details of the presentations are as follows:

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

Abstract #: 1213

Title: *Monotherapy with the Capsid Assembly Modulator, ALG-000184, Results in High Viral Suppression Rates in Untreated HBeAg+ and HBeAg- 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: November 15, 2024, 8:00am – 5:00pm PT

Abstract #: 1266

Title: *Capsid Assembly Modulators Such as ALG-001075 Induce Profound HBV DNA Knockdown and Directly Target HBeAg In Vitro*

Presenter: Cheng Liu, PhD

Date/Time: November 15, 2024, 8:00am – 5:00pm PT

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

Format: Oral presentation

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 Ongoing Randomized, Double-Blind, Placebo-controlled Phase 2*

Presenter: Rohit Loomba, MD, MHSc, Chief, Division of Gastroenterology and Hepatology, University of California, San Diego

Date/Time: November 19, 2024 at 10:30am – 10:40am PT

Abstract #: 3226

Title: *Nonclinical Toxicology Profile of ALG-055009, a Novel and Potent Thyroid Hormone Receptor β Agonist, for the Treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH)*

Presenter: Dinah Misner, PhD

Date/Time: November 17, 2024, 8:00am – 5:00pm PT

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

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 for metabolic dysfunction-associated steatohepatitis (MASH) and viruses with high unmet medical need such as hepatitis B 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 November 6, 2024 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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