



Aligos Therapeutics Presents Positive Clinical Data at Hep-DART 2023 from Phase 1 Studies in HBV (ALG-000184) and NASH (ALG-055009)

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SOUTH SAN FRANCISCO, Calif., Dec. 07, 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, delivered oral presentations of clinical data for its capsid assembly modulator-empty (CAM-E), ALG-000184, and its thyroid hormone receptor-beta (THR- β) drug candidate, ALG-055009, at the Hep-DART 2023 meeting, held in Cabo San Lucas, Mexico, from December 3 – 7, 2023. The presentations can be found on the “Scientific Presentations & Conferences” section of the Aligos website (www.aligos.com).

“We’re greatly encouraged by the substantial and consistent reductions in HBV viral markers observed during prolonged dosing of ALG-000184 and are grateful for the opportunity to share these results with the scientific community at the Hep-DART 2023 meeting,” said Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. “Consistent with the data that we recently presented at this year’s AASLD meeting, these promising results, including ALG-000184’s unique ability to affect cccDNA antigen expression, affirm our belief that it may have the potential to play a central role in enhancing rates of chronic suppression and/or functional cure in HBV.”

Dr. Blatt continued: “We are also pleased for the opportunity to present findings from the Phase 1 trial of our THR- β agonist, ALG-055009, including favorable safety, lipid-lowering activity and differentiated pharmacology and pharmacokinetics, compared to competitor THR- β agonists. As presented at AASLD, ALG-055009 appears to have best-in-class potential. We look forward to the opportunity to demonstrate this promise for patients with NASH in the Phase 2a study, expected to begin in Q1 2024.”

Presentation details:

Title: Long-term Dosing with ALG-000184 in HBeAg Positive Subjects Results in Unprecedented Multi-log Reductions in HBV Markers Including HBsAg

Presenter: Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics

Key Highlights:

- Oral dosing with 300 mg of ALG-000184 \pm entecavir (ETV) for up to 48 weeks in untreated HBeAg positive chronic hepatitis B patients demonstrated a favorable safety profile and greater suppression of HBV DNA and RNA versus ETV alone
- No viral breakthroughs occurred when ALG-000184 was given as a monotherapy for up to 44 weeks
- Dose dependent, multi-log reductions were seen in HBsAg, HBeAg and HBcrAg
- ALG-000184 appeared to lower cccDNA levels via 1st and 2nd mechanisms of action of CAM-E drugs
- ALG-000184 may play an important role in enhancing rates of chronic suppression and/or functional cure in CHB patients

Title: Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Oral Doses of ALG-055009, a Thyroid Hormone Receptor Beta Agonist, in Hyperlipidaemic Subjects and Relative Bioavailability/Food Effect of a Solid Formulation in Healthy Volunteers

Presenter: Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics

Key Highlights:

- In the Phase 1 study, ALG-055009 was well tolerated with a favorable PK profile that is differentiated from VK-2809 and resmetrom
- Expected thymimetic effects were observed: dose-dependent increases in sex hormone binding globulin levels (SHBG) and decreases in lipid levels
- No food effect using Phase 2a gel cap formulation in healthy volunteers
- Demonstrates best-in-class properties as a THR- β agonist

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, with respect to ALG-000184, statements around the company being encouraged by the substantial and consistent reductions in HBV viral markers observed during prolonged dosing of ALG-000184, including ALG-000184’s unique ability to affect cccDNA antigen expression, all of which affirm the company’s belief that it may have the potential to play a central role in enhancing rates of chronic suppression and/or achieving a functional cure in HBV and, with respect to ALG-055009, statements around ALG-055009 appearing to have best-in-class potential, based on higher levels of β -selectivity, compared to other THR- β agonist programs and the company looking forward to demonstrate this promise for patients with NASH in the Phase 2a study, expected to begin in Q1 2024. 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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