Aligos Therapeutics Presents Program Updates at the 32nd Conference of the Asian Pacific Association for the Study of the Liver

SOUTH SAN FRANCISCO, Calif., Feb. 16, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in NASH and viral diseases, today announced that the company is delivering several oral and poster presentations at the 32nd Conference of the Asian Pacific Association for the Study of the Liver (APASL), being held Feb 15 – 19 in Taipei, Taiwan at the Taipei International Convention Center. Data is being presented for ALG-055009, Aligos' THR-β agonist in clinical development for nonalcoholic steatohepatitis (NASH), as well as for several clinical and nonclinical stage investigational agents from its chronic hepatitis B (CHB) portfolio.

"At this year's meeting, we look forward to sharing data demonstrating that ALG-055009, our thyroid hormone receptor-beta (THR-β) agonist in development for NASH, showed promising anti-lipid effects in subjects with hyperlipidemia," said Lawrence Blatt, Ph.D., MBA, CEO and Chairman of the Board at Aligos. "In addition, we have several presentations which demonstrate the potentially best-in-class antiviral activity of our CAM-E compound, ALG-000184, where notable reductions in HBsAg levels have been observed with higher and longer-term dosing in subjects with HBeAg-positive CHB."

Presentation details, including summaries of data presented, follow below. Posters will be available for viewing throughout the conference for attendees and are also available on Aligos' corporate website's Scientific Presentations & Conferences page.

NASH program

Poster presentation

Title: Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Single and Multiple Ascending Oral Doses of ALG-055009, a Thyroid Hormone Receptor Beta (THR-β) Agonist for the Treatment of Non-Alcoholic Steatohepatitis (NASH), in Healthy Volunteers and Subjects with Hyperlipidaemia
Presenter: Hakim Charfi, M.D., Medical Director, Biotrial, France
Poster number: PH-025
Summary: Single ascending oral doses of ALG-055009 up to 4 mg in healthy volunteers as well as multiple doses up to 1 mg for 14 days in subjects with hyperlipidemia were generally well tolerated and were not associated with clinically significant changes in thyroid hormones or cardiovascular parameters. Additionally, ALG-055009 demonstrated favorable pharmacokinetics and anti-lipid effects with dose-proportional increases in exposure.

Chronic hepatitis B program

Oral presentations

Title: The Capsid Assembly Modulator ALG-000184 Dosed for 28 Days Was Well Tolerated and Rapidly Reduced Viral Markers in Subjects with Chronic Hepatitis B, Including HBsAg in a Subset of HBeAg Positive Subjects with Elevated Baseline ALT
Presenter: Professor Ed Gane, MBChB, M.D., University of Auckland, New Zealand
Presentation date/time: Thursday, February 16, 14:40 – 14:55 Taipei Standard Time (TST)
Presentation location: 3F North Lounge
Session title: HBV (Clinical) and HCV
Presentation number: FP03-16
Summary: Oral daily dosing with 10 – 300 mg of ALG-000184 for 28 days resulted in substantial declines in HBV DNA and RNA at all doses, regardless of whether subjects were HBeAg-positive or negative. HBsAg declines as high as 0.78 $\log_{10}$ IU/mL were seen in subjects achieving drug exposures corresponding to 300 mg for 28 days.

Title: ALG-000184, a Capsid Assembly Modulator, Demonstrates Superior Antiviral Activity in Combination with Entecavir Compared to Entecavir in HBeAg Positive Subjects with Chronic Hepatitis B Infection
Presenter: Professor Jinlin Hou, M.D., Nanfang Medical University, Guangzhou, China
Presentation date/time: Thursday, February 16, 14:55 – 15:10 TST
Presentation location: 3F North Lounge
Session title: HBV (Clinical) and HCV
Presentation number: FP03-17
Summary: In untreated subjects with CHB who were HBeAg-positive, ALG-000184 combined with entecavir (compared to entecavir alone) demonstrated superior antiviral activity as measured by HBV DNA and RNA reductions, as well as superior reductions in HBsAg, particularly in the 300 mg arm. These data demonstrate that ALG-000184 has best-in-class properties and a potential role in combination therapeutic regimens for CHB.

Title: Preclinical Profile of ALG-125755, a GalNAc-siRNA Targeting HBV
Presenter: Jin Hong, Ph.D., Aligos Therapeutics
Presentation date/time: Saturday, February 18, 11:35 – 11:50 TST
Presentation location: 3F South Lounge
Session title: HBV (Basic)
Presentation number: FP11-59
Summary: Aligos' Phase 1-stage siRNA candidate in development for chronic hepatitis B was designed using proprietary chemistries and exclusively licensed liver-targeting technology that may confer safety, stability, and potency advantages relative to other siRNA products. A summary of the preclinical *in vitro* and *in vivo* potency, efficacy and safety of ALG-125755 will be presented.

Poster presentations

Title: Effect of the Capsid Assembly Modulator (CAM) ALG-000184 on HBsAg Levels in Subjects with HBeAg Positive Chronic Hepatitis B (CHB)
Presenter: Professor Jinlin Hou, Nanfang Medical University, Guangzhou, China
Poster number: PC-019
Summary: In subjects with CHB who were HBeAg-positive, oral daily dosing for 28 days with 100 mg and 300 mg of ALG-000184 yielded rapid and profound declines in HBV DNA and RNA. Additionally, subjects achieving drug exposures corresponding to 300 mg for 28 days demonstrated HBsAg declines up to 0.78 $\log_{10}$ IU/mL.

Title: Preclinical Antiviral, Pharmacological and Toxicological Characteristics of ALG-000184, a Prodrug of the Novel HBV Capsid Assembly Modulator ALG-001075
Presenter: Andreas Jekle, Ph.D., Aligos Therapeutics
Poster number: PB-007
Summary: The capsid assembly modulator ALG-001075 (of which Aligos' CAM-E candidate ALG-000184 is a prodrug) demonstrated potent antiviral activity in cell-based assays and in a mouse model. In primary human hepatocytes, ALG-001075 was shown to functions via both mechanisms that CAMs can engage: inhibiting the encapsidation of pregenomic RNA (pgRNA) and preventing the formation of covalently closed circular DNA (cccDNA).

Title: Safety, Tolerability and Pharmacokinetics (PK) of Single Ascending Doses of ALG-125755, a GalNAc-Conjugated Small Interfering RNA (siRNA), in Healthy Volunteers (HV)
Presenter: Professor Ed Gane, MBChB, M.D., Auckland University, New Zealand
Poster number: PPB-043
Summary: In healthy volunteers, single doses of up to 200 mg of Aligos' siRNA candidate ALG-125755 were well tolerated, and exposures increased dose-proportionally. A dose range that is predicted to achieve antiviral activity in CHB patients has been identified, at 40 – 100 mg.

Title: Discovery of a Liver-Targeted PD-L1 Small Molecule Inhibitor for the Treatment of Chronic Hepatitis B and Liver Cancer
Presenter: Heleen Roose, Ph.D., Aligos Therapeutics
Poster number: PB-010
Summary: Aligos' small molecule liver-targeted PD-L1 inhibitor, ALG-093702, was shown to block the PD-1/PD-L1 interaction while reducing cell surface PD-L1. The compound also demonstrated similar potency to the PD-L1 antibody drug durvalumab. ALG-093702's potential to mitigate immune-related systemic toxicity makes it a candidate for use in CHB or other indications in the liver.

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 diseases and viral infections. Aligos is leveraging its expertise in liver and infectious diseases to create targeted therapeutics for nonalcoholic steatohepatitis (NASH) and for the discovery and development of targeted antiviral therapies for coronaviruses. Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver and infectious disease, to rapidly advance its pipeline of potentially best-in-class molecules.

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 ALG-055009 is showing promising anti-lipid effects in subjects with hyperlipidemia and statements that with respect to Aligos' CAM-E, ALG-000184, notable reductions in HBsAg levels have been observed with higher and longer-term dosing in subjects with HBeAg positive CHB. 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 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, changes in the competitive landscape and the effects on our business of the worldwide COVID-19 pandemic and the ongoing conflict between Russia and Ukraine. 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, 2022 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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