Aligos Therapeutics to Present Nonclinical and Clinical Data for its Chronic Hepatitis B and NASH Portfolio at AASLD's The Liver Meeting® 2022

SOUTH SAN FRANCISCO, Calif., Oct. 21, 2022 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases, today announced seven upcoming poster presentations at The Liver Meeting® (November 4-8, 2022), hosted by the American Association for the Study of Liver Diseases (AASLD).

All posters, which cover drug candidates targeting chronic hepatitis B (CHB) and nonalcoholic steatohepatitis (NASH), will be available on the Aligos website at Scientific Presentations & Conferences following the conclusion of the conference.

"The Liver Meeting® 2022 will showcase the breadth and depth of Aligos' portfolio of potential treatments for CHB and the continued progress in our NASH program," said Lawrence Blatt, Ph.D., MBA, CEO and Chairman of the Board at Aligos. "We are excited to provide an update at the conference on our clinical-stage drug candidates, particularly our Class 2 capsid assembly modulator (CAM) for CHB, ALG-000184, which continues to show best-in-class declines in a variety of viral markers. We will also present preclinical data for ALG-125755, our siRNA drug candidate which is designed to reduce HBsAg and is currently being dosed in healthy volunteers in Phase 1. Finally, we are excited to share the excellent pharmacokinetic (PK) properties, well tolerated safety profile and reductions in various lipid levels we have observed after hyperlipidemic subjects received multiple doses of our thyroid hormone beta agonist, ALG-055009."

Dr. Blatt continued, "We are also pleased to share preclinical findings for two early-stage CHB programs, including a second class of small molecule CAMs and two modalities of PD-L1 inhibitors."

Chronic Hepatitis B

Capsid Assembly Modulator-2 (CAM-2)

Title: Safety, pharmacokinetics (PK), and antiviral activity of the capsid assembly modulator (CAM) ALG-000184 in subjects with HBeAg positive chronic hepatitis B (CHB)
Poster Number: 33693
Presenter: JinLin Hou, M.D.
Summary: In currently not treated or treatment-naïve CHB subjects who were HBeAg positive, 100 and 300 mg of ALG-000184 given for up to 28 days was well tolerated. Both dose levels also exhibited predictable PK properties and resulted in rapid and substantial declines in multiple viral markers. Data showing the effects of ALG-000184 on HBV DNA, RNA and HBsAg levels are discussed in the poster.

CAM-1

Title: Non-HAP class I capsid assembly modulators have distinct profiles and a differentiated mechanism of action
Poster Number: 37007
Presenter: Yannick Debing, Ph.D.
Summary: Non-HAP (heteroaryldihydropyrimidine) CAM-1 compounds ALG-005398 and ALG-006162 have a profile that is clearly distinct from known HAP CAM-1s. As optimized non-HAP CAM-1s have suitable ADME/toxicity profiles, they represent an attractive class of molecules for further development as a part of potential functional cure regimens for CHB.

Title: HAP Class I capsid assembly modulators clear hepatitis B virus-infected hepatocytes through core-dependent hepatocyte death and subsequent proliferation
Poster Number: 36810
Presenter: Dieudoneé Buh Kum, Ph.D.
Summary: HAP CAM-1s were shown to act through two mechanisms, possibly complemented by an immune response, that result in a sustained loss of HBV-positive cells. First, HAP CAM-1s were shown to induce hepatitis B virus (HBV) core protein (HBc) aggregation and hepatocyte apoptosis in HBc-expressing cells. Second, compensatory hepatocyte proliferation was shown to lead to an additional loss of AAV-HBV episomes.

siRNA

Title: Nonclinical efficacy, pharmacokinetic profile and pharmacokinetic/pharmacodynamic (PK/PD) correlation of ALG-125755, a GaINAc-conjugated siRNA, for functional cure of chronic hepatitis B
Poster Number: 35097
Presenter: Kusum Gupta
Summary: ALG-125755 demonstrates encouraging preclinical pharmacology, PK properties, and a long half-life in the liver, which predicts monthly or less frequent dosing in human subjects.

PD-L1 inhibitor: siRNA

Title: Suppression of PD-L1 expression by a novel liver-targeted siRNA leads to potential restoration of immune responses against HBV
Poster Number: 36189
Presenter: Dawei Cai, Ph.D.
Summary: Liver-targeted PD-L1 siRNA therapy may lead to restoration of immune responses against HBV and consequent clearance of HBV infection, which is considered critical for CHB cure. Multiple siRNAs with sub-nanomolar PD-L1 mRNA inhibition EC_{50} values have been identified. Efforts to identify siRNAs with greater PD-L1 expression knockdown efficiency as well as greater anti-HBV activity are ongoing.

PD-L1 inhibitor: small molecule

Title: Discovery of liver-targeted oral PD-L1 small molecule inhibitors for the treatment of chronic hepatitis B and liver cancers
Poster Number: 34890
Session Title: Novel Therapeutic Approaches Aimed at Functional Cure of Hepatitis B and D
Presenter: Tongfei Wu, Ph.D.
Summary: The authors rationally designed liver-targeted oral PD-L1 small molecule inhibitors to localize T cell activation in the liver and thereby potentially mitigate systemic toxicity, toward an effort to develop better tolerated PD1/PD-L1 inhibitors for CHB patients. Lead molecules developed to date show similar *in vivo* efficacy to approved antibodies but were more efficacious than antibodies in a liver metastatic tumor model.

NASH

THR-β agonist

Title: Safety, Pharmacokinetics, and Pharmacodynamics of multiple ascending oral doses of ALG-055009, a thyroid hormone receptor beta agonist, in hyperlipidaemic subjects
Poster Number: 2354
Presenter: Hakim Charfi, M.D.
Summary: Thyroid hormone receptor-beta (THR-β) agonist drugs have been shown to rapidly reduce atherogenic lipids, decrease hepatic fat content and improve liver histology, and thus represent a promising approach to treat patients with fatty liver disease. ALG-055009 is a novel THR-β agonist with high THR-β selectivity and potency. As part of an ongoing Phase 1 study (ALG-055009-301, or NCT05090111), in subjects with hyperlipidemia, multiple daily doses of ALG-055009 given for 14 days were well tolerated with a favorable PK profile and evidence of lipid lowering activity.

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 viral infections and liver diseases. Aligos is focused on the discovery and development of targeted antiviral therapies for chronic hepatitis B (CHB) and coronaviruses as well as leveraging its expertise in liver diseases to create targeted therapeutics for nonalcoholic steatohepatitis (NASH). Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver disease, particularly viral hepatitis, 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 regarding ALG-000184 continuing to show best-in-class declines in a variety of viral markers; and with respect to ALG-055009, the PK properties being excellent, the safety profile being well tolerated and the reductions in various lipid levels being observed after hyperlipidemic subjects received multiple doses of ALG-055009. 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 August 4, 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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