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

ALG-055009, a THR-β agonist drug candidate in development as a treatment for NASH, demonstrated dose-dependent reductions in several atherogenic lipids and a favorable pharmacokinetic profile in subjects with hyperlipidemia

Aligos' oral and poster presentations also collectively highlight new data from the company's drug candidates targeting PD-L1 inhibition and the CAM-A (CAM-aberrant) mechanism for the treatment of chronic hepatitis B (CHB)

SOUTH SAN FRANCISCO, Calif., Nov. 04, 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 that the company is presenting several posters and an oral presentation at The Liver Meeting® (November 4-8, 2022), hosted by the American Association for the Study of Liver Diseases (AASLD).

Notably, poster 2354 provides new data on the activity of ALG-055009, Aligos' thyroid hormone receptor beta (THR-β) agonist in development for nonalcoholic steatohepatitis (NASH). Multiple ascending dose (MAD) data from the ongoing Phase 1 study ALG-055009-301 (NCT05090111) demonstrate that treatment for 14 days in subjects with hyperlipidemia resulted in reduced triglyceride, low-density lipoprotein (LDL), and apolipoprotein B levels in a generally dose-dependent manner. ALG-055009 was well tolerated and resulted in favorable dose-proportional pharmacokinetics with low inter-subject variability across the therapeutic range.

"We are pleased with the emerging clinical profile of ALG-055009," said Lawrence Blatt, Ph.D., MBA, CEO and Chairman of the Board at Aligos. "THR-β agonists continue to have the potential to become a cornerstone therapy in the treatment of NASH and ALG-055009 appears to benchmark favorably with other drugs in this class. Moving forward, we plan to evaluate its ability to reduce fat in the livers of subjects with NASH over a twelve-week period in a Phase 2 study funded internally or through a partnership."

Aligos' oral and poster presentations at The Liver Meeting collectively highlight new data from the company's drug candidates targeting chronic hepatitis B (CHB) and nonalcoholic steatohepatitis (NASH) and are available on the Aligos website at Scientific Presentations & Conferences. Presentation details are described below.

Aligos has highlighted new Phase 1 clinical data on its CAM-E drug candidate, ALG-000184, in a separate press release.

Presentation Details

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
Publication Number: 2354
Presenter: Hakim Charfi, M.D.
Summary: See above.

Chronic Hepatitis B

PD-L1 inhibitor: small molecule

Title: Discovery of liver-targeted oral PDL1 small molecule inhibitors for the treatment of chronic hepatitis B and liver cancers
Presentation Number: 34890
Publication Number: 26
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.

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
Publication number: 1186
Presenter: Jin Hong, 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.

CAM-A

Title: Non-HAP class I capsid assembly modulators have distinct profiles and a differentiated mechanism of action
Poster Number: 37007
Publication number: 1208

Presenter: Yannick Debing, Ph.D.
Summary: Non-HAP (heteroaryldihydropyrimidine) CAM-1 (CAM-A, or CAM-aberrant) compounds ALG-005398 and ALG-006162 have a profile that is clearly distinct from known HAP CAM-1s. Data presented here suggest that non-HAP CAM-1s can promote HBsAg reduction via a mechanism distinct from that of 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
Publication Number: 1202
Presenter: Dieudoneé Buh Kum, Ph.D.
Summary: In vivo and in vitro HAP CAM-1 (CAM-A, or CAM-aberrant) RG7907 was shown to act through two mechanisms, possibly complemented by an immune response, that result in a sustained loss of HBV-positive cells. First, RG7907 was 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. This represents an attractive mechanism for regimens intended to introduce functional cure in CHB.

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
Publication Number: 1155
Presenter: Kusum Gupta
Summary: ALG-125755 demonstrates encouraging preclinical pharmacology, PK/PD properties, and a long half-life in the liver, which predicts monthly or less frequent dosing in human subjects. A Phase 1 study of ALG-125755 began dosing in healthy volunteers in Oct 2022.

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 THR-β agonists continuing to have the potential to become a cornerstone therapy in the treatment of NASH; ALG-055009 appearing to benchmark favorably with other drugs in this class and our plan to evaluate its ability to reduce fat in the livers of subjects with NASH over a twelve-week period in a Phase 2 study funded internally or through a partnership. 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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