



Aligos Therapeutics Presents Data for its Chronic Hepatitis B (CHB) and Nonalcoholic Steatohepatitis (NASH) Portfolio at The Liver Meeting® 2021

Nov 12, 2021

Several clinical and nonclinical posters to be presented at the conference

Aligos' capsid assembly modulator (CAM) candidate, ALG-000184, achieved rapid, substantial reductions in hepatitis B virus DNA and RNA in CHB patients after 28 daily doses

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2021 (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, will present several poster presentations at The Liver Meeting® 2021, hosted by the American Association for the Study of Liver Diseases (AASLD). All of these posters will also be available on the Aligos website at [Scientific Presentations & Conferences](#) as of today and following the conclusion of the conference.

"As we continue to progress our pipeline with a multifaceted approach to addressing chronic liver diseases, we are pleased to showcase our progress with posters covering our CHB drugs, including STOPS™, CAM, ASO, and siRNA drug candidates, as well as encouraging results from a preclinical study showing additive to synergistic activity when several of these modalities are combined," said Lawrence Blatt, Ph.D., MBA, Chairman and Chief Executive Officer of Aligos. "We believe that combining multiple modalities that reduce hepatitis B virus S-antigen together with drugs that inhibit viral replication will be the key to achieving enhanced functional cure rates in people living with CHB."

Dr. Blatt continued, "We are especially pleased to present preclinical data further elucidating the molecular mechanism of action for our STOPS molecules as well as clinical data for our CAM drug candidate, ALG-000184, demonstrating good tolerability and significant reductions in HBV DNA and RNA after 28 days of oral dosing. We are also excited to present our THR-β agonist drug candidate, ALG-055009, that has a favorable preclinical pharmacokinetic profile that is supportive of once-daily dosing in humans and appears to have a low risk of drug-drug interactions."

Chronic Hepatitis B

S-antigen Transport-inhibiting Oligonucleotide Polymers (STOPS™)

Title: S-antigen Transport-inhibiting Oligonucleotide Polymers, (STOPS™) Sequester Cellular Proteins to Reduce Hepatitis B Virus S-Antigen Expression and Increase Its Proteasomal Degradation

Publication Number: 845

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: C. Cheng Kao

Summary: As part of an *in vitro* study to elucidate STOPS' mechanism of action in the context of hepatitis B virus (HBV) infection, five host proteins were identified as binding to STOPS. The proteins are known to be involved in RNA processing, translation, and protein folding and degradation, supporting the premise that STOPS molecules likely inhibit HBV infection and hepatitis B virus surface antigen (HBsAg) production by sequestering host proteins needed to express and properly fold the antigen.

STOPS are Aligos' proprietary single-stranded oligonucleotides that are designed to improve functional cure rates by reducing HBsAg, which is thought to suppress antiviral immune responses in CHB subjects.

Capsid Assembly Modulator (CAM)

Title: Safety, Pharmacokinetics (PK), and Antiviral Activity of the Capsid Assembly Modulator (CAM) ALG-000184 in Subjects with Chronic Hepatitis B (CHB)

Publication Number: 843

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: Ed Gane

Summary: ALG-000184 is Aligos' class II CAM candidate in development to inhibit HBV infection by interfering with HBV capsid assembly and viral replication by causing the formation of non-infectious empty viral particles.

As part of the ongoing, three-part, multicenter, double-blind, randomized, placebo-controlled study (NCT04536337), Cohorts 1 and 2 (n=10/cohort; 8 active:2 placebo) of E-antigen (HBeAg)-negative, currently not treated (CNT)/treatment naïve (TN) CHB subjects received 50-mg or 100-mg daily oral doses of ALG-000184 or placebo for 28 days. In both cohorts, ALG-000184 administration was associated with similar rapid, substantial reductions in HBV DNA and RNA through the 28-day period, with ≥75% and 100% of evaluable subjects achieving HBV DNA and RNA reductions below the lower limit of quantitation (LLOQ), respectively.

Antisense Oligonucleotide (ASO)

Title: Best-in-Class Antisense Oligonucleotides Against Hepatitis B Virus: Next Generation Bridged Nucleic Acid Chemistries Significantly Increase *In Vivo* Efficacy and Reduce Hepatotoxicity in Mice

Publication Number: 820

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: Dinah Misner

Summary: Aligos' application of next-generation Bridged Nucleic Acid (BNA) chemistries to ASO candidates already using Locked Nucleic Acid (LNA) technology stands to yield a best-in-class ASO candidate in terms of efficacy relative to hepatotoxicity.

Aligos is advancing ASO drug candidates as part of a combination approach to reducing HBsAg, which suppresses the patient's antiviral immune response in CHB. Historically, hepatotoxicity has been a major side effect of ASOs; however, next-generation BNA chemistries, when used in ASOs that contain LNA components, can reduce hepatotoxicity while maintaining efficacy.

Title: ALG-020572, a GalNAc-Conjugated Antisense Oligonucleotide, Demonstrates *In Vivo* Efficacy and Favorable Preclinical Profile for the Treatment of Chronic Hepatitis B

Publication Number: 819

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: Kusum Gupta

Summary: Aligos' ASO therapeutic candidate ALG-020572 was shown to potently inhibit HBsAg *in vitro* and *in vivo*. The antiviral activity, hepatocyte targeting and a favorable PK profile of ALG-020572 following SC administration warrants its advancement into clinical development as a potential treatment for CHB.

siRNA

Title: Incorporation of Novel siRNA Chemistries Significantly Improves the Potency and Durability of HBV siRNAs in the AAV-HBV Mouse Model

Publication Number: 831

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: Jin Hong

Summary: Aligos' nonclinical small interfering RNA (siRNA) therapeutic candidates in development for CHB demonstrated improved potency and/or durability *in vitro* and *in vivo* when modified with novel siRNA chemistries.

Combinations

Title: Triple Combination of Anti-Hepatitis B Virus Drugs Demonstrates Synergistic Activity *In Vitro*

Publication Number: 852

Session Title: Hepatitis B: Therapeutics: New Agents

Presenter: Hua Tan

Summary: Aligos' siRNA compound in development against hepatitis B virus, ALG-125755, in combination with the company's ASO, ALG-020572, and STOPS™ molecule, ALG-010133, demonstrated synergistic activity in cell culture with respect to reducing HBsAg when added to various triple-combination groupings with nucleos(t)ide analogs (NA), CAM or interferon.

Triple combinations of the siRNA ALG-125755 and STOPS ALG-010133 with the ASO ALG-020572 showed additive activity in reducing HBsAg and demonstrated a dose-dependent response with respect to the ASO. When interferon or STOPS were added to the ASO-siRNA combination, the effect was enhanced, indicating the possibility of lowering doses needed to treat HBV when combined with other HBV therapies. Additionally, when tested in pairwise combinations with a NA or CAM, the compounds demonstrated additive to synergistic interactions on inhibition of HBV DNA.

NASH

Title: Preclinical Pharmacokinetic Profiling of ALG-055009, a Potent and Selective Thyroid Hormone Receptor Beta Agonist for the Treatment of Nonalcoholic Steatohepatitis, and Prediction of its Human Pharmacokinetics

Publication Number: 1932

Session Title: NAFLD and NASH: Therapeutics

Presenter: Kusum Gupta

Summary: The nonclinical pharmacokinetic properties of ALG-055009 in several animal model species indicate efficacious doses in the clinic are likely to be once daily doses in the sub- to low milligram range and there is likely a with low risk of drug-drug interactions.

Title: Development of a Novel Seven-Day Dosing Mouse Efficacy Model to Evaluate Thyroid Hormone Receptor Agonists for the Treatment of NASH

Publication Number: 1907

Session Title: NAFLD and NASH: Therapeutics

Presenter: Xuan Luong

Summary: Authors developed a high-cholesterol diet (HCD) mouse model for efficient *in vivo* screening of THR-β agonists as potential therapeutic agents in nonalcoholic steatohepatitis (NASH). The model appears to be predictive of patient response at clinically relevant exposures and provides a rapid alternative to the time-consuming standard efficacy models developed through

high-fat diet administration.

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's 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 our belief that that combining multiple modalities that reduce hepatitis B virus S-antigen together with drugs that inhibit viral replication will be the key to achieving enhanced functional cure rates in people living with CHB and that the preclinical pharmacokinetic profile of our THR- β agonist drug candidate, ALG-055009, will support once-daily dosing in humans and have a low risk of drug-drug interactions. 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's 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's ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos's 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. 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's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 4, 2021, and its future periodic reports to be filed 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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