Aligos Therapeutics Presents Data on Chronic Hepatitis B, NASH and Hepatocellular Carcinoma Programs at AASLD's The Liver Meeting Digital Experience™ 2020

SOUTH SAN FRANCISCO, Calif., Nov. 16, 2020 (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 has delivered six poster presentations and an oral presentation at this year's American Association for the Study of Liver Diseases (AASLD) Liver Meeting Digital Experience™ (TLMdX) 2020, held virtually on November 13-16, 2020. The data presented includes updates from three of Aligos' assets in its lead chronic hepatitis B (CHB) combination therapy platform, as well as data from the company's nonalcoholic steatohepatitis (NASH) and hepatocellular carcinoma (HCC) programs.

"We are proud of the progress we have made for the Aligos' liver disease programs as outlined in our presentations during this year's AASLD Liver Meeting," said Lawrence Blatt, Ph.D., MBA, Chief Executive Officer of Aligos. "We are working towards producing a combination regimen of promising therapeutics that have the potential to lead to functional cures for patients living with chronic hepatitis B. Additionally, our team has made substantial progress on ALG-055009, a potent and selective purpose built THR beta agonist for the treatment of NASH. Two of our drug candidates, ALG-010133 (STOPS™) and ALG-000184 (CAM), aimed at the treatment of chronic hepatitis B have already begun Phase 1 clinical trials and we look forward to advancing the remainder of our liver disease portfolio towards clinical development over the coming year."

Chronic hepatitis B

Antisense oligonucleotide (ASO)
Title: Development of a Best-in-Class HBV ASO, ALG-020572, for the Treatment of Chronic Hepatitis B: Potential for Combination with other Anti-HBV Agents
Authors: Jin Hong, et al.
Presentation type: Oral presentation
Summary: Aligos' ASO candidates for chronic hepatitis B significantly improve upon other ASOs in terms of nonclinical safety. ALG-020572, which targets the open reading frame (ORF) of the small HBsAg, demonstrates excellent *in vivo* potency and safety profiles in an AAV-HBV mouse efficacy model. ALG-020572 or its unconjugated form demonstrated additive to synergistic activity when combined with other anti-HBV agents *in vivo* or *in vitro*.

Capsid assembly modulator (CAM)
Title: Best-in-class preclinical characteristics of ALG-000184, a prodrug of the capsid assembly modulator ALG-001075 for the treatment of chronic hepatitis B
Abstract number: 0823
Presentation type: Poster
Authors: Andreas Jekle, et al.
Summary: The *in vitro* antiviral profile and ADME characteristics of ALG-000184, Aligos' capsid assembly modulator (CAM) candidate for chronic hepatitis B, are described. ALG-001075 is a class-II CAM with broad and potent anti-HBV activity.
In cell-based assays, both compounds inhibited HBV DNA with nanomolar EC_{50} values. ALG-001075 had broad antiviral activity against 37 clinical isolates of the hepatitis B virus and retained activity against 6 known CAM resistance mutations, while T33N reduced ALG-001075's antiviral activity 28-fold.
Oral administration of ALG-000184 in a tablet formulation at doses of 1 to 12.6 mg/kg resulted in complete oral absorption and high exposure to ALG-001075.

S-antigen Transport-inhibiting Oligonucleotide Polymer (STOPS™)
Title: ALG-010133, a Representative S-Antigen Transport-inhibiting Oligonucleotide Polymer (STOPS™) Effectively Inhibits Hepatitis B Surface Antigen (HBsAg) Secretion in Multiple Hepatitis B Virus (HBV) Cell Models
Abstract number: 0821
Presentation type: Poster
Authors: Yuchun Nie et al.
Summary: ALG-010133 demonstrated robust inhibition of HBsAg release in multiple cell lines and infected liver cells across HBV genotypes, with enhanced activity compared to the structurally similar clinical-stage nucleic acid polymer REP-2139. Additionally, intracellular HBsAg was also reduced, suggesting that HBsAg was degraded inside the cell rather than trapped intracellularly.
ALG-010133 inhibited HBsAg release with the following EC_{50} values in respective cell models:

- 3.9 nM in HepG2.2.15
- 23.7 nM in PLC/PRF 5
- 3.2 nM in HBV-infected HepG2-NTCP cells
- 5.9 nM in HBV-infected PHH cells

Title: The S-Antigen Transport-Inhibiting Oligonucleotide Polymer (STOPS™) ALG-010133 Demonstrates a Favorable Preclinical Profile for the Treatment of Chronic Hepatitis B
Abstract number: 0831
Presentation type: Poster
Authors: Vikrant Gohil, et al.
Summary: Aligos' STOPS candidate for use in chronic hepatitis B, currently in a Phase 1a/b trial, was evaluated for pharmacokinetic and overall safety profile in nonclinical species through subcutaneous or intravenous dosing.
Results included the following:

- 2-week repeat dose studies with weekly SC dosing in nonclinical species showed that ALG-010133 was well tolerated to up to the highest dose tested (50 mg/kg).
- Rapid uptake and long half-life were demonstrated, with significant recovery in all tissues four weeks after the final dose in nonclinical species.

NASH

Title: Characterization of Thyroid Hormone Receptor (THR) Agonists for the Treatment of Non-Alcoholic Steatohepatitis (NASH) by Quantification of Gene Transcription in Human Hepatocytes
Abstract number: 1665
Presentation type: Poster
Authors: Xuan Luong, et al.
Summary: A fast, high-throughput strategy to rank THR agonist compound efficacy was implemented by using human-derived hepatocytes and quantifying changes in the hepatocytes' transcription of specific genes specific to cholesterol and fatty acid biosynthesis and metabolism directly downstream of THR binding and activation. The ability of three THR agonists to modulate the expression of genes specific to cholesterol and fatty acid biosynthesis and metabolism were compared to one another *in vitro* and replicated *in vivo* in a high fat diet-fed rat model for confirmation. Using human-derived hepatocytes provides more biologically relevant data compared to biochemical or non-hepatocyte screening assays.

Title: ALG-055009, a Potent and Selective THR Beta Agonist for the Treatment of NASH, Demonstrates Significant Cholesterol Reduction in a Diet-Induced Obese (DIO) Mouse Efficacy Model
Abstract number: 1656
Presentation type: Poster
Authors: Kusum Gupta, et al.
Summary: Aligos' THR-β agonist candidate ALG-055009 in development for NASH is highly efficacious in a diet-induced obese mouse model. With its high and selective potency combined with projected low doses in humans, ALG-055009 has the potential to be a best-in-class THR-β agonist for the treatment of NASH.
In DIO mouse models, the minimum efficacious dose of 0.15 mg/kg/dose twice daily resulted in 17% and 34% reductions in total and LDL cholesterol, respectively. None of the doses induced any significant changes in gene expression in the heart, indicating a potentially wide safety margin.

Hepatocellular carcinoma

Title: Tumor Regression in a Mouse Model of Hepatocellular Carcinoma Upon Treatment with the STING Agonist ALG-031048
Abstract number: 1118
Authors: Andreas Jekle, et al.
Summary: Aligos' novel STING agonist ALG-031048 was evaluated in the Hepa1-6 HCC mouse model, for potential use in the treatment of advanced hepatocellular carcinoma.
Three intratumorally administrated doses of ALG-031048 induced robust dose-dependent anti-tumor activity, resulting in an average 14% tumor reduction (TR) at 25 µg dosing, with tumor regression achieved in 7 of 10 mice; and 88% tumor regression at 100 µg dosing, with tumor regression achieved in all 10 mice. Both were an improvement over single agent anti-PD-1 treatment.
After intratumoral and subcutaneous administration in CT26 and MC38-hPD-L1 murine models of colon carcinoma, ALG-031048 showed strong anti-tumor activity, which was augmented in combination with antibodies against the immune checkpoint inhibitor CTLA-4 in the CT26 model or in combination with the anti-PD-L1 antibody, atezolizumab, in the MC38-hPD-L1 model.

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 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 workforce has in liver disease, particularly viral hepatitis, to rapidly advance its pipeline of potentially best-in-class molecules.

Forward Looking Statements

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 working towards producing a combination regimen of therapeutics that may lead to functional cures for patients living with CHB and our looking forward to advancing the remainder of our liver disease portfolio towards clinical development over the coming year. 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 prospectus filed with the Securities and Exchange Commission on October 19, 2020, 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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