Aligos Presents Update of Chronic Hepatitis B Pipeline Portfolio at HEP DART 2021

New data from HBeAg-positive patients receiving 100 mg of ALG-000184 demonstrates similar PK and potent antiviral activity to previously reported data for HBeAg-negative patients

New preclinical data with a novel oral small molecule PD-1/PD-L1 antagonist shows potential to induce immune responses that together with HBsAg reduction and inhibition of viral replication could provide a multifactorial combination approach to achieve functional cure in CHB patients

SOUTH SAN FRANCISCO, Calif., Dec. 07, 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, today announced that company management, will deliver an invited oral presentation at the 2021 HEP DART meeting, being held December 5 – 9, 2021 in Cabo San Lucas, Mexico.

Titled “Combination Approaches Towards a Functional Cure for Chronic Hepatitis B”, the presentation provides new clinical and preclinical data as well as details on Aligos’ strategic approach in developing a combination portfolio of multiple therapeutics designed to provide a functional cure for chronic hepatitis B (CHB). Aligos’ portfolio includes several oligonucleotide modalities (ALG-010133, a proprietary STOPS ^{TM} molecule, ALG-020572, an antisense oligonucleotide (ASO), and ALG-125755, a siRNA), a small molecule capsid assembly modulator (CAM) and a newly announced program to discover an orally available small molecule PD-1/PD-L1 antagonist.

“We’re very proud of the progress Aligos has made since the last HEP DART meeting in 2019 toward building a portfolio of purpose-built therapeutic candidates that target clinically validated mechanisms of CHB infection and persistence,” said Lawrence M. Blatt, Ph.D., MBA, Chairman and CEO of Aligos. “The current standard of care in CHB effectively blocks viral replication, but it falls short of providing a functional cure as it must be administered for life. We believe that by targeting HBV antigen reduction, inhibiting viral replication and boosting immune responses, we can find one or more combinations of in-house candidates that can produce high rates of functional cure in CHB patients.”

New data were shown at HEP DART from Aligos’ Phase 1b study (ALG-000184-201, NCT04536337) of the company’s CAM candidate ALG-000184. Cohort 4 enrolled 10 hepatitis B E-antigen positive chronic hepatitis B patients (8 ALG-000184: 2 placebo). HBeAg-positive cases of CHB are typically marked by active hepatitis B virus replication with high viral loads at baseline. After once daily oral dosing for 28 days with 100 mg of ALG-000184, there was an average reduction of 4 $\log_{10}$ IU/mL of HBV DNA and >3 $\log_{10}$ copies/mL of HBV RNA. This is similar to the responses recently observed in two cohorts of HBeAg-negative patient who received 50 mg or 100 mg doses of ALG-000184. ALG-000184 was well tolerated in CHB subjects regardless of HBeAg status. Evaluation of a 10 mg dose in HBeAg-negative subjects is ongoing.

Additionally, the presentation highlighted initial preclinical data on an oral small molecule PD-1/PD-L1 antagonist derived from the company’s internal discovery engine, for potential addition of this immune boosting mechanism to Aligos’ CHB portfolio. Proof-of-concept in CHB patients with anti-PD1 or PD-1 antibodies has been previously established in multiple clinical studies in the published literature where they demonstrated reductions in HBsAg. In addition to the other portfolio candidates’ effects on HBsAg reduction and viral replication inhibition, Aligos’ newly announced program is designed to promote endogenous T-cell activity against HBV to enhance viral clearance. An early lead compound, ALG-093453, is a small molecule PD-1/PD-L1 antagonist with excellent in vitro biochemical and cell-based potency and has been selected for further preclinical profiling and optimization.

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 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, but not limited to, statements regarding Aligos’ belief that by targeting HBV antigen reduction, inhibiting viral replication and boosting the immune responses, the company can find one or more combinations of in-house candidates that can produce high rates of functional cure in CHB patients and its new program around PD-1/PD-L1 antagonist being a potential addition to Aligos’ CHB portfolio with its early lead compound, ALG-093453, undergoing further preclinical profiling and optimization. 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. 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 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.

Media Contact
Amy Jobe, Ph.D.
LifeSci Communications
+1 315 879 8192
ajobe@lifescicomms.com

Investor Contact
Corey Davis, Ph.D.
LifeSci Advisors
+1 212 915 2577
cdavis@lifesciadvisors.com