Aligos Therapeutics Begins Dosing with Capsid Assembly Modulator Drug Candidate, ALG-000184, in First Cohort of Chronic Hepatitis B Patients in a Phase 1 Proof-of-Concept Study

Aligos now evaluating two of its four Chronic Hepatitis B (CHB) portfolio drug candidates in patients

SOUTH SAN FRANCISCO, Calif., April 14, 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 the company has started dosing in the first cohort of chronic hepatitis B (CHB) patients in the ongoing ALG-000184-201 study (NCT04536337). The trial is evaluating ALG-000184, a proprietary Class II capsid assembly modulator (CAM) designed to inhibit viral replication, as determined by HBV DNA and RNA levels.

"To fully suppress the hepatitis B virus, we believe you must not only remove the immunosuppressive effects of high S-antigen levels using oligonucleotide drug candidates such as our STOPS™ molecule, ALG-010133, but also inhibit replication of the virus using small molecule drug candidates such as our CAM, ALG-000184," said Lawrence Blatt, Ph.D., MBA, Chief Executive Officer of Aligos. "We believe combination approaches such as giving ALG-010133 and ALG-000184 together with a nucleos(t)ide analog therapy have the potential to achieve higher rates of functional cure than with current standard of care."

Matthew W. McClure, M.D., Chief Medical Officer of Aligos, added, "ALG-000184 has demonstrated potent inhibition of HBV DNA and RNA levels in preclinical studies. This observation, coupled with the drug's clinical profile to date, led us to initiate dosing with ALG-000184 in CHB patients to assess its ability to suppress HBV DNA and RNA levels. We expect to begin reporting safety, pharmacokinetic, and antiviral activity data for ALG-000184 from the initial patient cohorts of this study in the second half of 2021."

Professor Ed Gane, MB ChB, Principal Investigator for the ALG-000184-201 study, added, "I believe that combinations of drugs that collectively reduce S-antigen and HBV DNA/RNA levels have the potential to achieve significantly higher rates of functional cure than the current standard of care. By advancing their STOPS molecule drug candidate, ALG-010133, and now their CAM drug candidate, ALG-000184, separately into CHB patients, Aligos is laying the groundwork for future combination studies in CHB, where we can test this important hypothesis."

ALG-000184-201 (NCT04536337) is a multi-part umbrella trial that is evaluating the safety, pharmacokinetics (PK) and antiviral activity of up to 28 daily oral doses of ALG-000184 in treatment-naïve CHB patients as well as CHB patients not currently being treated. The study also previously evaluated the safety and PK of up to 7 oral daily doses of ALG-000184 in 48 healthy volunteers and preliminary data indicate that ALG-000184 has a good safety and PK profile and can achieve drug levels expected to confer antiviral activity.

Aligos' CAM program represents one of several in the company's CHB portfolio that target different clinically validated mechanisms of action in the hepatitis B virus life cycle. The portfolio also includes
S-antigen Transport-inhibiting Oligonucleotide Polymer (STOPS^{TM}) molecules, antisense oligonucleotide (ASO), and small interfering RNA (siRNA) drug candidates. The properties of these candidates indicate that their use in combination could yield potentially best-in-class treatment regimens that may achieve higher rates of functional cure than current standard of care. For each of these drug candidates, Aligos plans to initially establish proof of concept as monotherapy in Phase 1 umbrella trials before evaluating them in combination in subsequent trials.

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 Aligos' expectation of reporting safety, pharmacokinetic, and antiviral activity data for ALG-000184 from the initial patient cohorts of the study in the second half of 2021; the achievement of higher rates of functional cure than the current standard of care through the combinations of drugs that collectively reduce S-antigen and HBV DNA/RNA levels; plans of future combination studies in CHB by advancing Aligos' STOPS molecule drug candidate, ALG-010133, and now its CAM drug candidate, ALG-000184, separately into CHB patients; the expectation that the drug levels achieved at doses evaluated in healthy volunteers will result in antiviral activity and thus supporting further evaluation of ALG-000184 in CHB patients; and Aligos' plans to initially establish proof of concept as monotherapy in Phase 1 umbrella trials for each of its CAM, STOPS, ASO and siRNA candidates before evaluating them in combination in subsequent trials. 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' Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 23, 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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