Aligos Therapeutics Begins Dosing with STOPS™ Molecule Drug Candidate, ALG-010133, in First Cohort of Chronic Hepatitis B Patients in a Phase 1 Proof-of-Concept Study

The first drug candidate in Aligos's chronic hepatitis B portfolio to be administered to CHB patients

SOUTH SAN FRANCISCO, Calif., March 10, 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-010133-101 study (NCT04485663). This trial is evaluating ALG-010133, a proprietary oligonucleotide S-antigen Transport-inhibiting Oligonucleotide Polymer (STOPS™) molecule, which was developed to reduce viral S-antigen (or HBsAg) levels in CHB patients.

"S-antigen suppresses immune responses and plays a major role in maintaining HBV replication in patients with CHB," said Lawrence Blatt, Ph.D., MBA, Chief Executive Officer of Aligos. "Our lead STOPS candidate, ALG-010133, has demonstrated potent inhibition of S-antigen levels in preclinical studies. This observation, coupled with the drug's clinical profile to date, led us to initiate dosing with ALG-010133 in CHB patients to assess its ability to suppress S-antigen levels. It is exciting to have taken the first step in evaluating ALG-010133 in CHB patients. Our goal is to develop a therapeutic regimen that can lead to functional cure for patients living with CHB."

ALG-010133-101 (NCT04485663) is a multi-part umbrella trial that is evaluating the safety, pharmacokinetics and antiviral activity of up to twelve weekly doses of subcutaneously administered ALG-010133 in healthy volunteers (HVs) and virologically suppressed patients with CHB. Seventy-two healthy volunteers have been dosed to date, and preliminary data indicate that ALG-010133 has an acceptable safety and PK profile after as many as three weekly subcutaneous doses. The drug levels achieved at doses evaluated in HVs are expected to result in antiviral activity, thus supporting further evaluation of ALG-010133 in CHB patients.

Matthew W. McClure, M.D., Chief Medical Officer of Aligos, added, "This is an exciting next step for Aligos. We have now entered an important phase in the ALG-010133-101 study where we will define the clinical profile of ALG-010133 in our target population, patients with CHB. We expect to begin reporting safety, pharmacokinetic, and antiviral activity data for ALG-010133 from the initial patient cohorts of this study in the second half of 2021."

Professor Ed Gane, MB ChB, Principal Investigator for the ALG-010133-101 study, added, "I believe that drugs that reduce S-antigen levels will play an important role in achieving much higher rates of functional cure than can be achieved with current therapies and look forward to evaluating the potential role that this promising drug candidate may play in future treatment regimens."

Aligos' STOPS 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 capsid assembly modulator (CAM), 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's goal to develop a therapeutic regimen that can lead to functional cure for patients living with CHB; expectations that the drug levels achieved at doses evaluated in HVs will result in antiviral activity and thus supporting further evaluation of ALG-010133 in CHB patients; plans to define the clinical profile of ALG-010133 in patients with CHB in its ALG-010133-101 study; expectations to begin reporting safety, pharmacokinetic, and antiviral activity data for ALG-010133 from the initial patient cohorts of the study in the second half of 2021; use of Aligos' candidates in its CHB portfolio in combination yielding potentially best-in-class treatment regimens that may achieve higher rates of functional cure than current standard of care; plans to initially establish proof of concept as monotherapy in Phase 1 umbrella trials before evaluating its CHB candidates in combination in subsequent trials; belief that drugs which reduce S-antigen levels will play an important role in achieving much higher rates of functional cure than can be achieved with current therapies; and evaluation of the potential role that ALG-010133 may play in future treatment regimens. 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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