Aligos Therapeutics Begins Dosing with Antisense Oligonucleotide Drug Candidate, ALG-020572, in Healthy Volunteers in a Phase 1 Proof-of-Concept Study

Aligos now evaluating three of its four chronic hepatitis B (CHB) portfolio drug candidates in clinical trials

SOUTH SAN FRANCISCO, Calif., Oct. 11, 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 healthy volunteers in Study ALG-020572-401 (NCT05001022). The trial is evaluating ALG-020572, a proprietary antisense oligonucleotide (ASO) therapeutic candidate that is designed to reduce circulating HBsAg (Hepatitis B surface antigen) levels.

“This is the second drug candidate we have advanced to clinical development that targets HBsAg reductions in chronic hepatitis B patients,” said Lawrence Blatt, Ph.D., MBA, Chairman and Chief Executive Officer of Aligos. “The mechanism of our ASO molecule is specifically designed to selectively seek out and destroy viral messenger RNA and utilizes third generation XNA chemistry devised to improve the pharmacological characteristics of the molecule. We are hopeful these enhanced properties will augment the candidate’s antiviral activity in the clinic.”

Professor Ed Gane, MB ChB, Principal Investigator for the ALG-020572-401 study, added, “I believe that reducing HBsAg levels is an essential step in achieving functional cure. Other ASOs have demonstrated substantial HBsAg reductions in the clinic. Given that ALG-020572 appears to have more potent antiviral activity and enhanced hepatocyte targeting via GalNAc than other ASOs, a combination regimen containing ALG-020572 may have the potential to achieve higher rates of functional cure.”

Study ALG-020572-401 is a two-part umbrella protocol. In Part 1, it will evaluate the safety, tolerability and pharmacokinetics (PK) of single subcutaneous (SC) doses of ALG-020572 in healthy volunteers. In Part 2, it will evaluate the safety, PK, and antiviral activity of multiple SC doses given over 28 days in multiple chronic hepatitis B (CHB) subpopulations.

Aligos’s ASO 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, capsid assembly modulators (CAMs), 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’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 the ability of the mechanism of Aligos’s ASO molecule to selectively seek out and destroy viral messenger RNA, the use of third generation XNA chemistry in such molecule improving the pharmacological characteristics and the hope of such enhanced properties augmenting the candidate’s antiviral activity in the clinic; the potential of ALG-020572 having have more potent antiviral activity and enhanced hepatocyte targeting via GalNAc than other ASOs and the potential of a combination regimen containing ALG-020572 achieving higher rates of functional cure; the evaluation of the safety, tolerability and pharmacokinetics (PK) of single subcutaneous (SC) doses of ALG-020572 in healthy volunteers in Part 1 of Study ALG-020572 and the evaluation of the safety, PK, and antiviral activity of multiple SC doses given over 28 days in multiple CHB subpopulations in Part 2 thereof; the properties of the CHB candidates in Aligos’s portfolio potentially yielding best-in-class treatment regimens that may achieve higher rates of functional cure than current standard of care; and Aligos’s plans with respect to each CHB drug candidate to initially establish proof of concept as monotherapy in Phase 1 umbrella trials 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’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 August 5, 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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