



Aligos Halting Further Development of STOPS™ Drug Candidate, ALG-010133

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Phase 1 data at projected efficacious dose (400 mg) indicate insufficient activity against hepatitis B virus to justify further development

SOUTH SAN FRANCISCO, Calif., Jan. 06, 2022 (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 it has halted further development of its STOPS™ drug candidate, ALG-010133, in development to address chronic hepatitis B (CHB). This decision is based on emerging data from the Phase 1 Study ALG-010133-101 that indicate that at the projected efficacious dose (400 mg, estimated to achieve liver exposures $>3 \times EC_{90}$ for HBsAg inhibition) there is no meaningful HBsAg reduction. Furthermore, higher doses levels (maximum feasible dose is 600 mg) that were planned to be evaluated in a subsequent cohort are very unlikely to reach the 1 log₁₀ IU/mL HBsAg reduction level that Aligos had previously defined as necessary to advance the program. No dose-limiting safety findings have been identified in CHB subjects dosed at any dose level. Based on this information, Aligos management reviewed the data with members of the study's Study Review Committee (SRC) and jointly concluded that these data were not sufficient to support further development of ALG-010133 and that dosing should be discontinued.

"We are disappointed that the antiviral activity data from this study indicate that ALG-010133 cannot meaningfully contribute to achieving functional cures in CHB," said Lawrence M. Blatt, Ph.D., MBA, Chairman and CEO of Aligos. "Hepatitis B is a very challenging virus that will likely require combination regimens involving distinct mechanisms of action (MOAs) in order to achieve functional cure. Aligos' pipeline is deep, with multiple additional MOAs – ASO, siRNA, CAM 1, CAM-2 and PD-L1 inhibitors – many of which are clinically validated and have potentially best-in-class properties. Two drug candidates with these MOAs – ALG-000184 (CAM-2) and ALG-020572 (ASO) – are currently in the clinic and a third (ALG-125755, siRNA) is projected to be in the clinic mid-year 2022. We continue to be confident that Aligos' pipeline has the potential to enhance functional cure rates in patients with CHB."

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.

Aligos' CHB portfolio includes an antisense oligonucleotide (ASO), small interfering RNA (siRNA) drug candidates, Class 1 and 2 capsid assembly modulators (CAM-1, CAM-2) and small molecule inhibitors of programmed death ligand 1 (PD-L1). 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.

Aligos' NASH portfolio includes a small molecule thyroid hormone receptor beta (THR-B) agonist, ALG-055009, as well as an oligonucleotide with an undisclosed target that is partnered with Merck.

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 hepatitis B likely requiring combination regimens involving distinct MOAs to achieve functional cure; Aligos' deep pipeline with multiple additional MOAs having potentially best-in-class properties; that the properties of Aligos' CHB portfolio of drug 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; the third drug candidate (ALG-125755, siRNA) projected to be in the clinic mid-year 2022; Aligos' plan for 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; and Aligos' confidence that its pipeline has the potential to enhance functional cure rates in patients with CHB. 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 candidates, 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, as well as other documents Aligos files from time to time 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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