Aligos Therapeutics Begins Dosing in Chronic Hepatitis B Patients in its Phase 1 Antisense Oligonucleotide Study (ALG-020572-401)

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Administration of single ascending doses up to 480 mg in healthy volunteers nearly complete

First chronic hepatitis B patient dosed in initial cohort, each of which will be administered 7 subcutaneous doses over 29 days

SOUTH SAN FRANCISCO, Calif., Jan. 26, 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 the first chronic hepatitis B (CHB) patient has been dosed in the multiple ascending dose (MAD) portion of Study ALG-020572-401 (NCT05001022) which is evaluating antisense oligonucleotide (ASO) ALG-020572.

“We are pleased to have initiated the MAD phase of this study in CHB patients,” said Lawrence M. Blatt, Ph.D., MBA, Chairman and CEO of Aligos. “As with our earlier CHB portfolio drugs entering Phase 1 studies, we plan to evaluate multiple dose levels in patients to determine the risk-benefit profile for ALG-020572 before advancing it into combination studies with other drugs.”

Study ALG-020572-401 is a Phase 1a/1b umbrella study, which is evaluating the safety, pharmacokinetics, and pharmacodynamics (Phase 1b) of the ASO ALG-020572 when given subcutaneously as single doses to healthy volunteers (HVs) or 7 doses over 29 days in CHB patients. Dosing in HVs is nearly complete, with the highest administered dose level being 480 mg. Multiple cohorts are planned in the MAD portion of the study to evaluate the risk-benefit profile of ALG-0202572, including its dose-response effect on viral markers, potentially in multiple CHB subpopulations. The first MAD cohort will evaluate a dose of 210 mg in HBeAg negative, virologically suppressed CHB patients. Results of this and subsequent cohorts will be presented at a future scientific conference.

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 oligonucleotides with respect to two undisclosed targets that are 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, Aligos’ plan to evaluate multiple dose levels in patients to determine the risk-benefit profile for ASO ALG-020572 before advancing it into combination studies with other drugs; multiple cohorts being planned in the MAD portion of the study to evaluate the risk-benefit profile of ALG-0202572, including its dose-response effect on viral markers, potentially in multiple CHB subpopulations; results from the first MAD cohort to evaluate a dose of 210 mg in HBeAg negative, virologically suppressed CHB patients as well as from subsequent cohorts being presented at a future scientific conference; and the 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. 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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