Aligos Discontinues Development of its Antisense Oligonucleotide Drug Candidate ALG-020572 in Subjects with Chronic Hepatitis B and Pivots Internal Strategic Emphasis to its Small Molecule Portfolio

Dosing in the first cohort discontinued after multiple reports of ALT flares suggestive of drug-induced liver toxicity

Funds will be redirected to support ongoing clinical programs, including ALG-000184 (Class-II CAM for CHB) and ALG-055009 (THR- agonist for NASH), and to accelerate internal oral small molecule development programs, including a SARS-CoV-2 protease inhibitor, a Class-I CAM for CHB and a PD-L1 inhibitor for CHB

SOUTH SAN FRANCISCO, Calif., March 22, 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 discontinued development of its drug candidate, ALG-020572, which was being studied in subjects with chronic hepatitis B (CHB). Dosing in the first CHB cohort of Study ALG-020572-401 (NCT05001022) was stopped after one subject experienced a serious adverse event (SAE) with significant increase in alanine aminotransferase (ALT) following multiple dosing of 210 mg ALG-020572 that resulted in a brief hospitalization. This is one of four CHB subjects in this first cohort who experienced potentially drug-related ALT flares, which were unexpected based on prior experience in nonclinical studies and single dose safety data in healthy volunteers. In all four CHB subjects, laboratory parameters and symptoms are improving and the hospitalized subject has been discharged.

“Patient safety is our number one priority, and we are gratified to see that these unanticipated ALT elevations are improving and subjects are on the path to recovering,” said Lawrence M. Blatt, Ph.D., MBA, Chairman and CEO of Aligos. “We will continue to follow emerging safety and antiviral activity data as these subjects complete their off-treatment follow-up to understand these events further. Although this is undeniably a setback, our team remains committed to developing drug candidates with the potential to improve the lives of patients living with viral and liver diseases. In particular, we will continue to focus on advancing our clinical development programs, including:

- ALG-000184 (capsid assembly modulator; CAM), which is being dosed orally for 28 days in CHB subjects and is progressing towards longer duration studies aimed at chronic suppression of HBV DNA and RNA;
- ALG-055009 (THR- agonist), which is currently being dosed orally in healthy volunteers (HVs) and subjects with hyperlipidemia;
- ALG-125755 (HBV siRNA), our remaining internal oligonucleotide program which is due to start subcutaneous dosing in HVs in Q3; and
- Our ritonavir-free oral, highly potent SARS-CoV-2 protease inhibitor, which is due to start Phase 1 enabling nonclinical studies in Q3.

“We will also focus on accelerating our internal oral small molecule preclinical development programs, including:

- a Class-I CAM for CHB; and
- a PD-L1 inhibitor for CHB

“Finally, we remain committed to our external partners in the oligonucleotide space, including Merck with whom we are collaborating on certain undisclosed targets for NASH.”

With this reprioritization of the company’s pipeline, which includes savings from halting two clinical development programs (ALG-010133 and ALG-020572), as well as proceeds resulting from Aligos’ partnership activities and other cost saving measures, Aligos believes its cash, cash equivalents and investments as of December 31, 2021 continue to provide sufficient resources to fund planned operations into the first half of 2024. Aligos plans to use any cost savings from the discontinuation of its ALG-020572 program to further support its aforementioned clinical and small molecule preclinical development programs, all of which target novel mechanisms that have the potential to enhance the care of patients with CHB, NASH and COVID.

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 a small interfering RNA (siRNA) drug candidate, 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-) agonist, ALG-055009, as well as an oligonucleotide program

with undisclosed targets 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 Aligos’ continuing to follow emerging safety and antiviral activity data as the subjects from the ALG-020572-401 study complete their off-treatment follow-up; Aligos’ continuing to focus on advancing its clinical development programs with respect to ALG-000184, ALG-055009, ALG-125755, and its SARVS-CoV-2 protease inhibitor and accelerating its internal oral small molecule pre-clinical development programs with respect to a Class-I CAM for CHB and a PD-L1 inhibitor for CHB; Aligos’ commitment to external partners in the oligonucleotide space; Aligos’ cash, cash equivalents and investments as of December 31, 2021 continuing to provide sufficient resources to fund planned operations into the first half of 2024; Aligos’ plan to use any cost savings from the discontinuation of our ALG-020572 program to further support its aforementioned clinical and small molecule preclinical development programs, all of which target novel mechanisms that have the potential to enhance the care of patients with CHB, NASH and COVID; the properties of Aligos’ CHB portfolio indicating that their use in combination could yield potentially best-in-class treatment regimens that may achieve higher rates of functional cure in CHB than current standard of care; and for each of the CHB drug candidates in Aligos’ portfolio, Aligos’ plans 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 and the developing conflict between Russia and Ukraine. 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 10, 2022, 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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