Aligos Therapeutics Announces Strategic Reprioritization of NASH and COVID-19 Programs and Confirms Key Timelines and Extension of Cash Runway to Year-End 2024

– Pipeline reprioritization emphasizes NASH and COVID-19 assets, ALG-055009 and ALG-097558, plus key ongoing collaborations, including the Merck & Co. (MSD) programs in NASH –

– Overall workforce reduction (attrition and reduction in force) of approximately 25% since beginning of January 2022 –

SOUTH SAN FRANCISCO, Calif., Feb. 08, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in NASH and viral diseases, today announced a portfolio reprioritization. Aligos' highest priorities will be focused on rapid advancement of its clinical NASH (ALG-055009) and COVID-19 (ALG-097558) programs as well as maintaining its ongoing NASH oligonucleotide research collaborations with Merck & Co. (MSD outside the U.S. and Canada). Additionally, the Company plans to complete the ≤48-week (ALG-000184) and single ascending dose (ALG-125755) cohorts for its two chronic hepatitis B programs and continue to invest in selected research programs and collaborations with external research organizations.

This portfolio reprioritization is being accompanied by a reduction of the Company's current workforce of approximately 10% and, combined with careful workforce management, including employee attrition and targeted hiring, has resulted in an overall workforce reduction of approximately 25% since the beginning of January 2022.

As a result of the portfolio reprioritization, realignment of its workforce, and other cost-saving measures, the Company expects to maintain a strong balance sheet and extend its projected cash runway to the end of 2024. The Company expects to report Q4 and 2022 year-end financial results as well as provide guidance regarding the amount of anticipated one-time charges related to the reprioritization, which we expect to record in Q1 2023, in mid-March 2023.

"With such a diverse clinical portfolio, including four drug candidates in or near the clinic, as well as maintaining a strong discovery engine, where we continue to support multiple research collaborations, we determined that Aligos would be best positioned to achieve its business objectives by taking action now to streamline operations, reprioritize its portfolio, and implement certain cost-saving measures, including a reduction in force," said Lawrence Blatt, Ph.D., MBA, CEO and Chairman of the Board at Aligos. "I would like to express my sincere gratitude to the employees who are being affected by this reprioritization. We are grateful for their dedicated service and contributions to Aligos' mission."

Dr. Blatt further noted that, "After taking these steps, we can affirm that we are committed to advancing our THR-β NASH drug candidate, ALG-055009, which appears differentiated vs. frontrunner drugs in its class, as well as our differentiated pan-coronavirus drug candidate, ALG-097558. Based on the early activity and the emerging profile we have observed for these programs, we believe they are well positioned to fulfill our mission to leverage our expertise in liver disease and antiviral agents to develop targeted, potentially best-in-class treatments for NASH and viral diseases."

Selected Pipeline Review

Going forward, Aligos will emphasize its programs in nonalcoholic steatohepatitis (NASH) and COVID-19.

NASH

- ALG-055009 – the Company's THR-β agonist in development for NASH is expected to complete an ongoing Phase 1 study in H1 2023. The Company has already initiated Phase 2-enabling activities, including GLP toxicology studies, and it is planning a Phase 2 filing by the end of 2023.

COVID-19

- ALG-097558 – Aligos' 3-chymotrypsin-like protease (3CLpro) inhibitor, a potent pan-coronavirus protease inhibitor candidate that does not require ritonavir boosting, is expected to complete Phase 1-enabling activities in H1 2023. The company aims to complete a Phase 1 study evaluating single and multiple ascending doses in healthy volunteers in H2 2023 to enable the start of a Phase 2 study by the end of 2023.

Chronic Hepatitis B (CHB)

- ALG-000184 – The Phase 1b study of Aligos' capsid assembly modulator-empty (CAM-E) is expected to complete ongoing cohorts evaluating ≤48 weeks of treatment. Emerging data from these cohorts will be presented at scientific conferences throughout the year. Aligos plans to review next steps based on these data.
- ALG-125755 – As part of the portfolio reprioritization, Aligos will continue to evaluate its siRNA candidate in a Phase 1 single ascending dose (SAD) study in CHB patients and expects to present emerging data at scientific conferences throughout the year. Aligos plans to review next steps for this program based on these expected data.

Discovery Engine and General Corporate Operations

- Aligos plans to continue to support its collaboration agreements, including the agreement with Merck & Co. to develop oligonucleotide candidates to address NASH.

- Collaborations with the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Disease (NIAID)'s Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern program through the Metropolitan AntiViral Drug Accelerator (MAVDA) consortium, KU Leuven, the Rega Institute, and the Leuven Centre for Drug Design and Discovery remain unchanged.

- Aligos' two South San Francisco locations will be consolidated into the Company's headquarters location. The Leuven, Belgium and the Shanghai, China sites are expected to remain in operation.

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 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 and infectious disease, 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' commitment and priorities being focused on rapid advancement of its NASH (ALG-055009) and COVID-19 (ALG-097558) programs as well as maintaining its ongoing NASH oligonucleotide research collaborations with Merck & Co.; the Company's plan to complete the ≤ 48-week (ALG-000184) and single ascending dose (ALG-125755) cohorts for its two chronic hepatitis B programs and to continue to invest in selected research programs and collaborations with external research organizations; the Company's ability to maintain a strong balance sheet and extend its expected cash runway to the end of 2024; the Company's expectation to report Q4 and 2022 year-end financial results in mid-March 2023; the Company's belief its ALG-055009 and ALG-097558 programs are well positioned to fulfill the Company's mission to leverage its expertise in liver disease and anti-viral agents to develop targeted, potentially best-in-class treatments for NASH and viral diseases; with respect to ALG-055009, the completion of an ongoing Phase 1 study in H1 2023 and the Company's plan to complete a Phase 2 filing by the end of 2023; with respect to ALG-097558, the completion of Phase 1-enabling activities in H1 2023 and the aim to complete a Phase 1 study evaluating single and multiple ascending doses in healthy volunteers in H2 2023 to enable the start of a Phase 2 study by the end of 2023; with respect to ALG-000184, the completion of ongoing cohorts evaluating ≤48 weeks of treatment in the Company's Phase 1b study, the Company's plan to present at scientific conferences throughout the year emerging data from its Phase 1b study cohorts evaluating ≤48 weeks of treatment and the Company's plan to review next steps for this program based on these data; with respect to ALG-125755, Aligos' plans to evaluate its siRNA candidate in a Phase 1 SAD study in CHB patients and its expectation to present emerging data at scientific conferences throughout the year; Aligos' plans to support its collaboration agreements including its agreement with Merck & Co.; and the consolidation of Aligos' two South San Francisco locations into the Company's headquarter location and the Leuven, Belgium and Shanghai, China sites remaining in operation. 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 products, 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 ongoing 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 2, 2022 and its future periodic reports to be filed or submitted 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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