Aligos Therapeutics Announces the Initiation of the Phase 2a HERALD Study of ALG-055009 in MASH Subjects

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- *Screening of subjects has begun at clinical study sites*
- *The Phase 2a study is being led by Principal Investigator, Dr. Stephen Harrison*
- *Aligos anticipates dosing the first subject in Q2 2024 with topline safety and efficacy data expected in Q4 2024*

SOUTH SAN FRANCISCO, Calif., March 18, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today announced the initiation of the Phase 2a HERALD study of ALG-055009 in subjects with metabolic dysfunction-associated steatohepatitis (MASH). Screening of subjects has begun at clinical study sites across the U.S.

“ALG-055009 has enhanced potency, greater beta selectivity, and a favorable PK profile. We believe that these optimized pharmacologic properties may result in improved therapeutic outcomes for patients living with MASH. The initiation of the HERALD study is an important next step in achieving our goal to create a best-in-class thyroid hormone receptor beta agonist,” stated Lawrence Blatt, Ph.D., MBA, Chairman, President, and CEO of Aligos Therapeutics. “This is an exciting time in the MASH space with the first drug recently approved, but we believe there is still a need for additional treatment options. We look forward to sharing topline HERALD data in Q4 this year.”

The 12-week randomized, placebo-controlled trial will enroll 100 subjects with presumed MASH and liver fibrosis at stages 1-3 (F1-F3). Subjects will be randomized to receive one of four doses (0.3, 0.5, 0.7, 0.9 mg) of ALG-055009 or placebo (~20 subjects/arm) given orally once daily. In addition to collecting safety and pharmacokinetics (PK) data, this study will also assess multiple non-invasive biomarkers, which include Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF) and other tests previously shown to be impacted by treatment with thyroid hormone receptor beta (THR-ß) agonists. Dosing is anticipated to begin in Q2 2024 and topline safety and efficacy data from this study is expected in Q4 2024.

About ALG-055009
ALG-055009 appears to be a best-in-class thyroid hormone receptor beta (THR-ß) agonist discovered by Aligos for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). ALG-055009 recently completed a Phase 1 first in human study, with preliminary data after single and multiple daily doses showing that ALG-055009 was well tolerated, had dose proportional pharmacokinetics (PK) and low variability, and demonstrated expected thyromimetic effects. Aligos has initiated the Phase 2a HERALD study of ALG-055009 to assess safety, PK, and multiple efficacy biomarkers such as Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF). Dosing is anticipated to begin in Q2 2024 and topline safety and efficacy data from this study is expected in Q4 2024.

About MASH
One of the effects of improper diet and insufficient exercise is the accumulation of fatty deposits in the liver, referred to as metabolic dysfunction-associated steatotic liver disease (MASLD), which was estimated to occur in approximately 30% of the worldwide population as of 2019. An estimated 1.5% to 6.5% of the global population is believed to have an ongoing inflammatory response to these excess fat deposits, which is referred to as metabolic dysfunction-associated steatohepatitis (MASH). In the United States alone, the prevalence of MASH is projected to increase from approximately 16.5 million in 2015 to 27.0 million in 2030. In the absence of changes in diet and exercise, the inflammation inherent in MASH persists and may result in progressive fibrosis of the liver, which may result in cirrhosis. These fibrotic changes are associated with numerous morbidities including recurrent hospitalization for complications of cirrhosis, hepatocellular carcinoma, need for liver transplant, and death. The first drug to treat this growing patient population, a THR-ß agonist, was recently approved for the treatment of MASH.

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 liver and viral diseases. Aligos’ strategy is to harness the deep expertise and decades of drug development experience its team has in liver and viral diseases to discover and develop potentially best-in-class therapeutics for metabolic dysfunction-associated steatohepatitis (MASH) and viruses with high unmet medical need such as chronic hepatitis B (CHB) and coronaviruses.

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, the anticipation that the first subject will be dosed in the HERALD study in Q2 2024 with topline safety and efficacy data expected in Q4 2024 and the company looking forward to sharing such data in Q4 2024; the belief that the enhanced

potency, greater beta selectivity, and favorable PK profile of ALG-055009 may result in improved therapeutic outcomes for patients living with MASH; the initiation of the HERALD study being an important step in achieving the goal of creating a best-in-class thyroid hormone receptor beta agonist; the belief that there is still a need for additional treatment options in the MASH space; and the estimation and projection of the prevalence of the MASH patient population. 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, and the impact of global events and other macroeconomic conditions on the Aligos’ business. 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 12, 2024 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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