Aligos Therapeutics Announces the Completion of Enrollment in the ALG-055009 Phase 2a HERALD Study for the Treatment of MASH

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Topline data now projected in early Q4 2024

Rohit Loomba, MD, MHSc to serve as Principal Investigator

SOUTH SAN FRANCISCO, Calif., May 21, 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 that it has completed enrollment in the ALG-055009 Phase 2a HERALD study for metabolic dysfunction-associated steatohepatitis (MASH) with topline safety and efficacy data anticipated in early Q4 2024. The company also announced that Dr. Rohit Loomba will serve as Principal Investigator for the study.

“Completing enrollment in our first Phase 2a trial is a tremendous accomplishment for the Aligos team,” said Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer at Aligos Therapeutics. “We thank the patients, their families and our investigators for their efforts. In addition, I’d like to welcome Dr. Rohit Loomba as our Principal Investigator for the HERALD study. Dr. Loomba has a broad track record of contributions to the MASH field, having pioneered the use of MRI-PDFF as a noninvasive test to assess liver steatosis. We look forward to his insights and contributions to the HERALD study and beyond.”

Dr. Loomba is the Chief of the Division of Gastroenterology and Hepatology and Professor of Medicine at the University of California, San Diego (UCSD). He is also the Director of the UCSD NAFLD Research Center. Dr. Loomba completed a fellowship in gastroenterology at the UC San Diego School of Medicine and a fellowship in hepatology at the National Institutes of Health (NIH) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr. Loomba earned his medical degree from the Armed Forces Medical College in India and a Master of Health Science in clinical research from Duke University School of Medicine.

“I am pleased to serve as the Principal Investigator for the Phase 2a HERALD study,” stated Rohit Loomba, MD, MHSc, Chief, Division of Gastroenterology and Hepatology, University of California, San Diego. “The excellent potency and PK profile makes ALG-055009 a compelling potential treatment option for MASH patients. I look forward to working with the team to complete this study.”

HERALD (NCT06342947) is a randomized, double-blind, placebo-controlled trial that has enrolled approximately 100 subjects with presumed MASH and stage 1-3 liver fibrosis (F1-F3). Subjects were 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 for 12 weeks. The primary endpoint is relative change in liver fat content by Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF) at week 12. Safety, pharmacokinetics (PK) and other non-invasive biomarkers/tests previously shown to be impacted by treatment with thyroid hormone receptor beta (THR-ß) agonists will also be evaluated.

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 fully enrolled 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). Topline safety and efficacy data from this study are expected in early 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.

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 hepatitis B and coronaviruses.

Forward-Looking Statements
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' research and development activities, including the expected timing of topline data from the Phase 2a HERALD Study. 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, and other matters that could affect the sufficiency of Aligos' capital resources to fund operations. 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 May 7, 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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