



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

Apr 3, 2024

SOUTH SAN FRANCISCO, Calif., April 03, 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 dosing in the Phase 2a HERALD study of ALG-055009 has been initiated in subjects with metabolic dysfunction-associated steatohepatitis (MASH).

"Dosing the first subjects in our Phase 2a HERALD study is an important milestone for Aligos," said Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer at Aligos Therapeutics. "We are pleased by the engagement of the clinicians and subjects, demonstrating the need for additional oral MASH therapies. We look forward to continuing to advance this potent, potential best-in-class drug candidate through the clinic."

HERALD ([NCT06342947](#)) is a randomized, placebo-controlled trial that will enroll ~100 subjects with presumed MASH and stage 1-3 liver fibrosis (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 for 12 weeks. In addition to collecting safety and pharmacokinetic (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- β) agonists. Topline safety and efficacy data from this study are expected in Q4 2024.

About ALG-055009

ALG-055009 appears to be a best-in-class thyroid hormone receptor beta (THR- β) 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 begun dosing in 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 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- β 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 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, with respect to ALG-055009, the company looking forward to continuing to advance it through the clinic, it being a potential best-in-class THR- β agonist drug candidate and the expectation of topline safety and efficacy data from the HERALD study in Q4 2024; and, with respect to MASH, the estimated occurrences of each of MASLD and MASH globally, the projected prevalence of MASH in the United States, and the possibility of cirrhosis resulting from the inflammation inherent in MASH in the absence of changes in diet and exercise. 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.

Contacts

Company

Jordyn Tarazi
Vice President, Investor Relations & Corporate Communications
(650) 910-0427
jtarazi@Aligos.com

Media

Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com