Aligos Therapeutics Announces the Selection of Stephen Harrison, MD as Principal Investigator of Ph2a Study and Key Study Design Elements/Milestones for NASH Drug Candidate, ALG-055009

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- Phase 1 study conduct complete with preliminary data indicating THR-beta agonist ALG-055009 was well-tolerated with a favorable PK profile and dose responsive changes in relevant biomarkers

-Upcoming randomized, double blind, placebo-controlled Ph2a study will evaluate the safety, PK, and efficacy (MRI-PDFF and other biomarkers) of ALG-055009 in NASH subjects after dosing x 12 weeks

-Dr. Stephen Harrison appointed Principal Investigator of Ph2a study

-US IND on track to be filed in Q4 2023

-Anticipated Ph2a topline results in Q4 2024

SOUTH SAN FRANCISCO, Calif., July 19, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today announced the selection of Stephen Harrison, MD as principal investigator of, and key design elements for, its upcoming Ph2a study of NASH drug candidate ALG-055009. The company has now completed Phase 1 testing (NCT05090111), where single oral ≤4 mg doses and 14 daily ≤1.0 mg doses of ALG-055009 were found to be well tolerated with linear PK, low variability and expected effects on biomarkers, including generally dose responsive reductions in various atherogenic lipids and increases in sex hormone binding globulin, a marker of target engagement.

“We have made significant progress over the past several months wrapping up the Ph1 study and defining the upcoming Ph2a study of our oral THR-β drug candidate, ALG-055009,” noted Matthew W. McClure, MD, Chief Medical Officer of Aligos Therapeutics. “Thanks to the expertise of the study’s Principal Investigator, Dr. Stephen Harrison, who is a world-class thought leader in NASH drug development, we have recently been able to define many of the key design elements of this important study. Specifically, the preliminary design is as a US-based, randomized, double blind, placebo-controlled Ph2a study in NASH subjects that will evaluate the safety, PK, and efficacy (as measured by MRI-PDFF and other biomarkers) after dosing for 12 weeks with ALG-055009. The trial will assess a broad range of ALG-055009 dose levels across parallel arms in order to define the optimal risk-benefit profile before initiating longer term, biopsy-based clinical trials. We remain on track to file the Ph2a protocol in Q4 2023 and anticipate having topline data in Q4 2024.”

“The pathogenesis of NASH involves dysregulated thyroid hormone action in the liver and data suggest that working through THR-β in the liver we can improve metabolic and liver related health in the setting of NASH. I am excited to lead the Ph2a study to determine if the pharmacokinetic and pharmacologic differences of ALG-055009 as compared to the frontrunner THR-β drugs will translate into enhanced safety and efficacy,” said Stephen Harrison, MD, Visiting Professor of Hepatology at the Radcliffe Department of Medicine, University of Oxford.

“As a company with a focus on liver diseases, including NASH, it is important to know that our lead NASH drug candidate, ALG-055009, is in good hands as it goes through clinical development,” noted Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. “This is certainly true for ALG-055009 and we are grateful to Dr. Harrison for the wealth of knowledge and experience he has brought in helping us design this important Ph2a study. We look forward to working with Dr. Harrison on this exciting program and study.”

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 nonalcoholic steatohepatitis (NASH) and viruses with high unmet medical need such as coronaviruses and chronic hepatitis B (CHB).

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 with respect to remaining on track to file the US IND/protocol for the Ph2a study of the THR-β drug

candidate, ALG-055009, in Q4 2023 and the anticipation of having topline data in Q4 2024. 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 May 4, 2023 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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