



Aligos Therapeutics Announces IND Clearance for NASH lead, ALG-055009

Sep 21, 2023

- Phase 2a NASH protocol on track to be submitted to the IND in Q4 2023, enrollment expected to begin in Q1 2024

SOUTH SAN FRANCISCO, Calif., Sept. 21, 2023 (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 it has received clearance of its Investigational New Drug (IND) application from the US Food and Drug Administration (FDA) for ALG-055009, its thyroid hormone receptor beta agonist (THR- β), intended for the treatment of nonalcoholic steatohepatitis (NASH).

"This is an important milestone for the development of our potentially best-in-class THR- β agonist, ALG-055009," said Lawrence Blatt, Ph.D., MBA, Chairman & Chief Executive Officer of Aligos Therapeutics. "Equally important, we remain on track to submit the Phase 2a protocol to the IND in Q4 2023 and expect to initiate enrollment in Q1 2024. We look forward to sharing topline proof of concept data from the study in Q4 2024."

Matthew W. McClure, M.D., Chief Medical Officer of Aligos, added, "ALG-055009 is the most potent known THR- β agonist in clinical development and has demonstrated enhanced beta selectivity preclinically and favorable pharmacokinetics in the recently completed Phase 1 first-in-human study. Our focus now is on successfully conducting the Phase 2a study alongside Dr. Stephen Harrison, the trial's Principal Investigator."

The study is designed to evaluate the safety and efficacy of up to 4 dose levels of ALG-055009, compared to placebo, over a 12-week treatment period in presumed NASH patients. As is typical for studies at this phase of development, the study's primary endpoint will be change in MRI-PDFF, which has been shown to correlate with liver histology with other THR- β agonists in development.

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, Aligos' remaining on track to submit the Phase 2a protocol to the IND in Q4 2023 and to initiate enrollment in Q1 2024; Aligos' looking forward to sharing topline proof of concept data in Q4 2024; Aligos' focus on successfully conducting the Phase 2a study alongside Dr. Stephen Harrison; Aligos' plan in the study to compare the safety and efficacy of up to 4 dose levels of ALG-055009 compared to placebo over a 12 week treatment period in presumed NASH patients; and the plan for the study's primary endpoint to be change in MRI-PDFF, which has been shown to correlate with liver histology with other THR- β agonists in development. 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 changes in the competitive landscape. 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 August 3, 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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