# Aligos Therapeutics Presents Clinical and Nonclinical Data at the AASLD Liver Meeting® 2023 Demonstrating that ALG-055009 has a Favorable Risk-Benefit Profile

Nov 13, 2023

*The thyroid hormone receptor-beta (THR-b) drug ALG-055009:*

- *Was well tolerated when oral daily doses up to 1.0 mg were given for 2 weeks in a Phase 1 study in hypercholesterolemic subjects*
- *Demonstrated favorable PK with low variability*
- *Dose responsively lowered lipid levels in study subjects*
- *Was well tolerated in animals following repeated daily dosing in 13 week toxicology studies*
- *Is more b selective and 5-47x more potent than resmetirom and VK-2809 parent*
- *Has a favorable overall risk-benefit profile which supports conducting a 12-week Phase 2a study in NASH subjects*

SOUTH SAN FRANCISCO, Calif., Nov. 13, 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 that clinical and nonclinical data for its thyroid hormone receptor-beta (THR-b) drug, ALG-055009, were presented Saturday, November 11th at The Liver Meeting® of the American Association for the Study of Liver Diseases (AASLD), being held in Boston, Massachusetts, November 10 – 14, 2023. The clinical (#2900-A) and nonclinical (#2461-C) posters for these data can also be found on the "Scientific Presentations & Conferences" section of the Aligos website (www.aligos.com).

The clinical poster describes a Phase 1 study which evaluated 14 oral daily doses of up to 1.0 mg ALG-055009 solution formulation in hypercholesterolemic subjects. Important highlights include:

a. ALG-055009 was well tolerated with no safety signals identified

b. No clinical evidence of hyper- or hypo-thyroidism was observed

c. As expected for a thyromimetic, ALG-055009 dose responsively
    i. Increased sex hormone binding globulin levels
    ii. Lowered lipids levels

d. ALG-055009 exposures increased in a dose proportional manner with low variability (geometric CV <30%) and a ~20 hour half-life that supports QD dosing

e. The planned Phase 2a gelcap formulation delivered exposures ~86% of the solution formulation and did not demonstrate a food effect

The nonclinical poster describes *in vitro* and *in vivo* studies which characterize the properties of ALG-055009. Important highlights include:

a. ALG-055009 is 5-47 times more potent than resmetirom and VK-2809 (parent)

b. ALG-055009 is more beta selective than resmetirom and VK-2809 (parent) in cell based assays

c. Lipid levels decreased in a dose responsive manner in *in vivo* models

d. In 13-week repeat dose toxicology studies, ALG-055009 was well tolerated with safety margins supporting dosing in the planned Phase 2a clinical study

"We are excited to share at AASLD these favorable clinical and nonclinical data, which serve as the basis for advancing ALG-055009 into a Phase 2a study in NASH patients," said Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. "This study, called the **HE**patic fat **R**eduction with **A**LG-055009 in steatotic **L**iver **D**isease (HERALD) study, is on track to initiate dosing in Q1 2024 with topline data, including 12-week MRI-PDFF results, projected in Q4 2024."

**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 advancing ALG-055009 into a Phase 2a study in NASH patients as supported by the aforementioned clinical and nonclinical data shared at AASLD, being on track to initiate dosing in Q1 2024 and the projection of having topline data, including 12-week MRI-PDFF results, 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, the risks and uncertainties associated with market conditions, 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 2, 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.

**Media Contact**

Veronica Eames
LifeSci Communications
veames@lifescicomms.com

**Investor Contact**
Corey Davis, Ph.D.
LifeSci Advisors
+1 212 915 2577
cdavis@lifesciadvisors.com