Aligos Therapeutics Announces Positive Topline Results from the Phase 2a HERALD Study of ALG-055009 for the Treatment of MASH

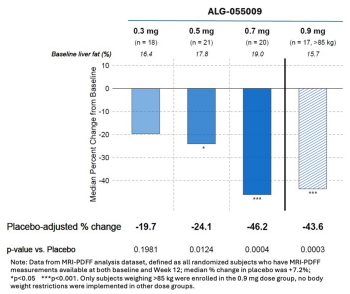
Sep 19, 2024

- ALG-055009 dose groups met the primary endpoint with statistically significant reductions in liver fat at Week 12 as measured by MRI-PDFF
- Placebo-adjusted median relative reductions in liver fat were up to 46.2% with a clear dose response
- ALG-055009 was well-tolerated with no serious adverse events or dose reductions. Importantly, ALG-055009 dose groups had a similar incidence of gastrointestinal-related adverse events with less diarrhea compared to placebo
- Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a), and apolipoprotein B were observed
- Conference call scheduled for 8:30am ET/5:30am PT today

SOUTH SAN FRANCISCO, Calif., Sept. 19, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS) a clinical stage biopharmaceutical company focused on improving patient outcomes through best-in-class therapies for liver and viral diseases, today announced positive topline results from the Phase 2a HERALD study of ALG-055009, a thyroid hormone receptor beta (THR-β) agonist, in metabolic-dysfunction associated steatohepatitis (MASH) subjects.

HERALD (NCT06342947) is a randomized, double-blind, placebo-controlled trial that enrolled 102 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. Only subjects weighing >85 kg were enrolled in the 0.9 mg dose group, with no body weight restrictions implemented in the other dose groups. Key endpoints assessed were safety, tolerability, pharmacokinetics, relative change in liver fat content by Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF), and other non-invasive biomarkers/tests.

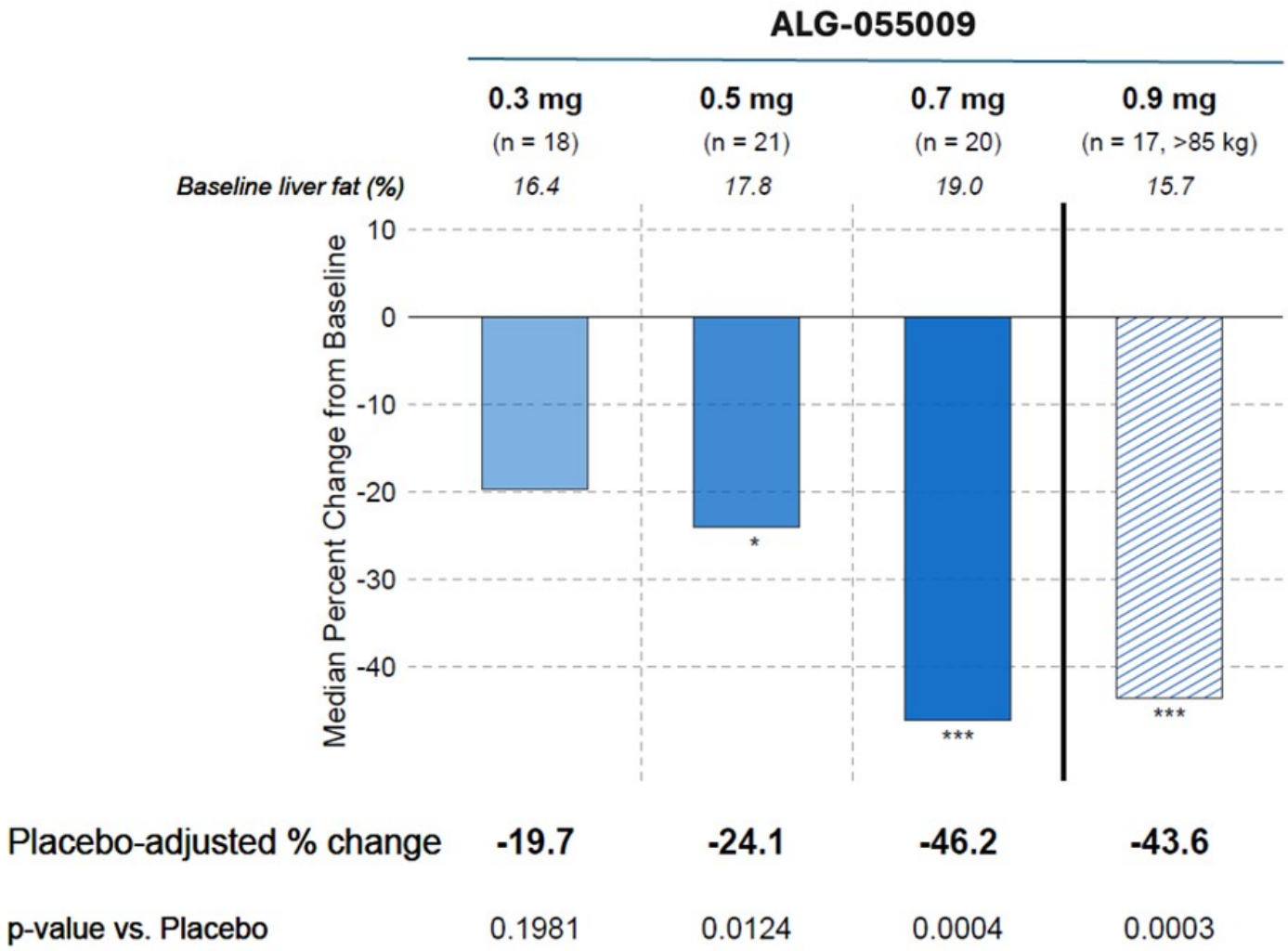
HERALD: Primary Endpoint Achieved



Placebo-adjusted median relative change in liver fat at Week 12

Doses of 0.5 mg to 0.9 mg ALG-055009 demonstrated statistically significant reductions in liver fat at Week 12, with placebo-adjusted median relative reductions up to 46.2% as measured by MRI-PDFF. Up to 70% of subjects achieved ≥30% relative reduction in liver fat compared to baseline.

The MRI-PDFF results are summarized in the figure below.



Note: Data from MRI-PDFF analysis dataset, defined as all randomized subjects who have MRI-PDFF measurements available at both baseline and Week 12; median % change in placebo was +7.2%; *p<0.05 ***p<0.001. Only subjects weighing >85 kg were enrolled in the 0.9 mg dose group, no body weight restrictions were implemented in other dose groups.

“The robust improvements in liver fat and other clinically relevant biomarkers, such as lipoprotein (a), demonstrate why potency and PK are pertinent when designing molecules aimed at improving patient outcomes,” said Rohit Loomba, MD, MHSc, Chief, Division of Gastroenterology and Hepatology, University of California, San Diego. “This has been an exciting year for the MASH space, which continues with this excellent data from Aligos’ ALG-055009, which has the potential for not only improvement in resolution of MASH, but also fibrosis improvement. In addition, it has potential to improve cardiovascular risk if the non-invasive tests (NIT) data are confirmed in future trials. I look forward to continuing to work with the Aligos team to further develop this program.”

ALG-055009 demonstrated a favorable tolerability profile with no serious adverse events (SAEs), or clinical hyper/hypothyroidism. The majority of treatment emergent adverse events (TEAEs) were mild to moderate, with one discontinuation due to worsening insomnia in a subject with pre-existing insomnia. No clinically meaningful findings in laboratory tests, electrocardiograms, vital signs, or physical examinations were observed. Incidence of gastrointestinal-related TEAEs were similar in ALG-055009 dose groups compared to placebo. Specifically, a non-dose-related, lower incidence of diarrhea was observed in ALG-055009 dose groups compared to placebo.

Treatment with ALG-055009 resulted in significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a) (LpA), and apolipoprotein B (ApoB). In addition, dose dependent increases in sex hormone binding globulin (SHBG), a marker of THR-β target engagement in the liver, were observed.

“When designing ALG-055009, our goal was to create a potential best-in-class THR-β agonist through enhanced potency and a superior PK profile,” stated Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer at Aligos Therapeutics. “Today’s data demonstrates that these enhanced pharmacologic properties did indeed translate into robust improvements in liver fat reduction. In addition, ALG-055009 demonstrated a favorable tolerability profile, which is important given that MASH medications will likely be administered for prolonged periods of time. We believe ALG-055009 has the potential to help patients better adhere to MASH treatment. These results indicate that ALG-055009 warrants further development. We are currently in early discussions with potential partners and evaluating a variety of options to fund the continued development. We plan to complete the activities required for a Phase 2b study by the middle of 2025 and are assessing potential Phase 2b clinical trial designs.”

The company plans to present additional results and analyses at a future scientific meeting later this year.

Conference Call & Webcast Details

The company will host a conference call and webcast with a slide presentation today at 8:30am ET/5:30am PT. To access the live webcast with slides, please visit the Presentation & Events page on the Aligos website at www.aligos.com. Please register ten minutes prior to its start. Following the live webcast, a replay will be available on the company’s website for 90 days.

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 the HERALD Study

HERALD (NCT06342947) is a randomized, double-blind, placebo-controlled trial that enrolled 102 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 was 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-β) agonists were also evaluated.

About ALG-055009

ALG-055009 was designed to be a potential best-in-class thyroid hormone receptor beta (THR-β) agonist discovered by Aligos for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). Recent topline data from the Phase 2a HERALD study demonstrated a favorable tolerability profile with significant reductions in liver fat as measured by MRI-PDFF following once a day, low oral dose.

About Aligos

Aligos Therapeutics, Inc. (NASDAQ: ALGS) is a clinical stage biopharmaceutical company founded with the mission to improve patient outcomes by developing best-in-class therapies for the treatment of liver and viral diseases. Aligos applies its science driven approach and deep R&D expertise to advance its purpose-built pipeline of therapeutics for metabolic dysfunction-associated steatohepatitis (MASH) and viruses with high unmet medical need such as hepatitis B and coronaviruses.

For more information, please visit www.aligos.com or follow us on LinkedIn or X.

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 Aligos’ goals in designing ALG-055009, MASH medications being administered for prolonged periods of time, ALG-055009’s potential for greater patient adherence, ALG-055009’s results indicating that ALG-055009 warrants future development, Aligos’ discussions with potential partners and evaluation of options to fund the continued development of ALG-055009, Aligos’ plans to complete the activities required for a Phase 2b study and Aligos’ assessment of potential Phase 2b clinical trial designs. 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 August 6, 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/f305238a-fd16-4b0d-85d9-5bc31c7dacc2