Aligos Therapeutics Presents 28-Day Safety, Efficacy and Pharmacokinetic Clinical Data for CAM Drug Candidate ALG-000184, First Clinical Data for NASH Drug Candidate ALG-055009 and Nonclinical Data in Other Chronic Hepatitis B Programs at the European Association for the Study of the Liver's Digital International Liver Congress™ 2022

-Similar significant reductions of hepatitis B virus (HBV) DNA and HBV RNA observed following 28 days of daily oral ALG-000184 dosing, regardless of HBeAg status, across first four dosing chronic hepatitis B (CHB) patient cohorts
-In the first clinical data presentation from our NASH program, preliminary data on multiple ascending doses of ALG-055009 in subjects with hyperlipidemia demonstrated favorable pharmacokinetics, safety, and anti-lipid activity
-Presentations include nonclinical data from 2 other CHB programs

SOUTH SAN FRANCISCO, Calif., June 22, 2022 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases, today announced that the company is presenting two posters showcasing preliminary Phase 1 data from its capsid assembly modulator (CAM) program in CHB and its thyroid hormone receptor-beta (THR-b) agonist in nonalcoholic steatohepatitis (NASH) at the European Association for the Study of the Liver Digital International Liver Congress™ 2022 (EASL ILC 2022). ILC 2022 is being held on June 22 - 26 at the ExCeL London Exhibition Centre in London, UK.

The company is also presenting nonclinical data from two other drug classes within Aligos' CHB portfolio: small interfering RNA (siRNA) and a small molecule PD-L1 inhibitor. The posters will be available on the "Scientific Presentation and Publications" page in the "Presentations" section of Aligos' website at www.aligos.com.

"We are pleased to continue demonstrating progress from across our chronic hepatitis B portfolio including small-molecule capsid assembly modulators, small interfering RNA molecules and small-molecule PD-L1 inhibitors. Our team is also proud to announce the first clinical data from our THR-b agonist in NASH," said Lawrence Blatt, Ph.D., MBA, Chairman and CEO of Aligos. "In the context of CHB, we believe that a multi-part approach that addresses HBV viral replication, HBsAg reduction and host T cell exhaustion may lead to either functional cure or effective chronic suppression for CHB patients. To date, our CAM program has shown dramatic reductions in viral DNA and RNA in CHB patients following 28 days of dosing in several CHB patient cohorts and dosing in additional cohorts is ongoing. We also plan to soon initiate a longer-term study evaluating ALG-000184 in combination with nucleos(t)ide analog therapy in HBeAg positive CHB. With respect to our siRNA program, ALG-125755, a potential best-in-class HBV siRNA, we remain on track to begin dosing in a Phase 1 study in healthy volunteers in the fourth quarter of this year. Meanwhile, on the NASH front, we are encouraged by initial clinical data for ALG-055009 in subjects with hyperlipidemia; additional data from this trial are expected to be released in the third quarter of this year."

Aligos' ILC 2022 presentations, and their potential implications, are summarized below.

Chronic hepatitis B (CHB)

ALG-000184: Capsid assembly modulator (CAM)
Poster number: SAT365
Title: Safety, Pharmacokinetics, and Antiviral Activity of the Class II Capsid Assembly Modulator ALG-000184 in Subjects with Chronic Hepatitis B
Presenter: Professor Man-Fung Yuen, MBBS, M.D., Ph.D., DSc, University of Hong Kong, Hong Kong
Summary: ALG-000184 is currently being evaluated in the ALG-000184-201 trial, a multi-part, double blind, randomized, placebo-controlled Phase 1 study (NCT04536337). Part 3 is ongoing and evaluating multiple cohorts (N=10/cohort; 8 active: 2 placebo) of currently not treated/treatment-naïve CHB subjects, who receive daily oral doses of ALG-000184 for 28 days, after which they are followed up for 8 weeks.

Here, authors report preliminary safety, pharmacokinetic and antiviral data for CHB subjects enrolled in the following cohorts in Part 3:

- Cohort 1: 100 mg drug/placebo in HBeAg negative CHB
- Cohort 2: 50 mg drug/placebo in HBeAg-negative CHB
- Cohort 3: 10 mg drug/placebo in HBeAg-negative CHB
- Cohort 4: 100 mg drug/placebo in HBeAg-positive CHB

Key findings were as follows:

- Similar rapid declines in HBV DNA and HBV RNA were observed at all dose levels, regardless of HBeAg status.
  - Among HBeAg-negative subjects, high rates of DNA and RNA reductions below the lower limit of quantification (LLOQ) were observed, with 100% of subjects <LLOQ for both DNA and RNA at the 10 mg dose level.
  - The largest DNA (4.2 $\log_{10}$ IU/mL) and RNA (3.1 $\log_{10}$ copies/mL) reductions were observed in HBeAg-positive subjects.
- All dose levels of ALG-000184 were generally well tolerated.

ALG-125755: siRNA

Poster number: SAT386
Title: The HBV siRNA, ALG-125755, demonstrates a favourable nonclinical profile and significant and durable hepatitis B surface antigen reductions in the AAV-HBV mouse efficacy model
Presenter: Megan Fitzgerald, Ph.D.

Summary: In AAV-HBV mice, dose-dependent inhibition of plasma HBsAg was observed with ALG-125755. Reductions in HBsAg levels were sustained for at least 70 days following the final dose of ALG-125755. Following single or repeated doses in rats and monkeys, ALG-125755 was well tolerated with no toxicologically relevant findings up to 300 and 100 mg/kg/dose, respectively.

Next-Generation HBV siRNAs

Poster number: SAT402
Title: Incorporation of novel siRNA chemistries significantly improves the potency and durability of HBV siRNAs in the AAV-HBV mouse model
Presenter: Jin Hong, Ph.D.
Summary: Authors applied proprietary 5' phosphate-mimetic end cap and 2'fluoro mimic nucleotides, both proprietary nucleotide stabilization chemistries, to siRNA molecules designed to knock down hepatitis B S antigen (HBsAg), with the objective of determining the added moieties' effects on the extent and duration of HBsAg knockdown. Adding both in combination to two existing siRNA molecules yielded compounds ALG-126081 and ALG-126101, which demonstrated significant improvements in the potency and duration of HBsAg knockdown in mouse models of HBV infection (AAV-HBV mice).

PD-L1 small molecule inhibitors

Poster number: SAT401
Title: Discovery of oral PDL1 small molecule inhibitors specifically designed for the treatment of chronic hepatitis B
Presenters: Francois Gonzalvez, Ph.D. and Tongfei Wu, Ph.D.
Summary: In CHB, upregulation of both PD-1 on hepatitis B virus (HBV)-specific T cells and PD-L1 on liver cells causes T cell exhaustion and thus persistent HBV infection. Inhibiting the PD-1/PD-L1 pathway may be an effective therapeutic strategy in CHB, but the PD-1/PD-L1 antibodies approved in cancer are limited by systemic immune-related adverse effects.

- With the objective of developing better tolerated therapeutic compounds, authors rationally designed two oral, liver-targeted PDL1 small molecule inhibitors, ALG-093453 and ALG-093578, which demonstrated similar potency to FDA-approved antibodies and higher liver specificity.
- Both molecules activate HBV-specific T cell cultures to a similar extent as the approved antibodies nivolumab and durvalumab.

Nonalcoholic steatohepatitis (NASH)

ALG-055009: Thyroid hormone receptor beta (THR-b) agonist

Poster number: SAT145
Title: Safety and Pharmacokinetics (PK) of Single and Multiple Ascending Oral Doses of ALG-055009, a Thyroid Hormone Receptor Beta Agonist, for the Treatment of Non-Alcoholic Steatohepatitis (NASH), in Healthy Volunteers and Subjects with Hyperlipidaemia
Presenter: Hakim Charfi, M.D.
Summary: The small molecule THR-□ agonist ALG-055009, designed for the treatment of NASH, is being evaluated in the ALG-055009-301 multi-part, double-blind, randomized, placebo-controlled first-in-human Phase 1 study (NCT05090111). Here, authors report preliminary study results regarding the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of the study's completed Part 1 (single ascending doses (SAD) of the compound in healthy volunteers (HV)) and of the study's ongoing Part 2 (multiple ascending doses (MAD) of the compound in subjects with mild hyperlipidemia).

- Single ascending oral doses of ALG-055009 up to 4 mg in HV and multiple doses of 0.3 mg for 14 days in subjects with hyperlipidemia were well tolerated.
    - Across the SAD and MAD, there were no serious adverse events, dose-limiting toxicities, or Grade ≥ 3 treatment emergent AEs (TEAEs)
    - In the MAD, there were no TEAEs leading to study drug discontinuation.
- ALG-055009 showed favorable PK with dose-proportional and linear plasma exposures, low variability, and a ~1.7 accumulation ratio after multiple doses.
- Evidence of liver target engagement and anti-lipid activity was observed. The effect on lipids, although highly variable, was generally dose-dependent after single doses.

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 viral infections and liver diseases. Aligos is focused on the discovery and development of targeted antiviral therapies for chronic hepatitis B (CHB) and coronaviruses as well as leveraging its expertise in liver diseases to create targeted therapeutics for nonalcoholic steatohepatitis (NASH). Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver disease, particularly viral hepatitis, to rapidly advance its pipeline of potentially best-in-class molecules.

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 regarding the continued demonstration of progress from across Aligos' CHB portfolio including small-molecule capsid assembly modulators, small interfering RNA molecules and small-molecule PD-L1 inhibitors; the company's belief that a multi-part approach that addresses HBV viral replication, HBsAg reduction and host T cell exhaustion may lead to either functional cure or effective chronic suppression for CHB patients; its plan to soon initiate a longer-term study evaluating ALG-000184 in combination with nucleos(t)ide analog therapy in HBeAg positive CHB; the potential of ALG-125755, its siRNA program, being a best-in-class HBV siRNA and the company remaining on track to begin dosing in a Phase 1 study in healthy volunteers in the fourth quarter of 2022; and the expectation that additional data from the clinical trial for its NASH program, ALG-055009, will be released in the third quarter of this 2022. 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’s 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’s ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos’s 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 developing 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’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 4, 2022 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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