



Aligos Therapeutics Presents Data from its Liver Disease Programs at the European Association for the Study of the Liver (EASL) Congress 2023

Jun 21, 2023

-Presentations include a late breaking poster from an ongoing Phase 1b study of ALG-000184 demonstrating multi-log reductions in HBsAg, DNA, and RNA levels in subjects dosed for up to 36 weeks-

-Data collectively highlight company's progress advancing new potentially best-in-class compounds for liver disease-

SOUTH SAN FRANCISCO, Calif., June 21, 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 the company is presenting several posters collectively highlighting data from its liver disease programs at the European Association for the Study of the Liver (EASL) Congress 2023, taking place in Vienna, Austria, June 21 – 24, 2023.

Notably, the Company's late breaking poster (LBP-18) highlights promising emerging data from its ongoing Phase 1b study evaluating the oral capsid assembly modulator (CAM-E), ALG-000184. Specifically, a majority of HBeAg positive subjects dosed with 300 mg ALG-000184 + entecavir (ETV) for up to 36 weeks demonstrated time-dependent HBsAg reductions, with a maximum reduction of 2.0 log₁₀ IU/mL observed in week 36. Importantly, ALG-000184 continues to demonstrate a favorable safety and pharmacokinetic (PK) profile over these extended dosing durations.

Additionally, the Company is presenting results from its ongoing Phase 1 study evaluating single ascending doses of ALG-125755, a GalNAc-conjugated small interfering RNA, in virologically suppressed subjects with chronic hepatitis B (CHB). Specifically, subjects from cohorts 1 (50 mg, n=6) and cohort 2 (120 mg, n=6) demonstrated a sustained dose dependent reduction in HBsAg levels over 90 days. Evaluation of a third, higher dose cohort is ongoing. To date, all single ascending dose levels of ALG-125755 have been well tolerated in CHB subjects.

"We are excited to present emerging clinical data from our CHB portfolio of drug candidates at EASL," said Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. "The data presented highlights the progress we have made advancing new targeted therapies for multiple liver diseases. We look forward to presenting additional data from our robust pipeline of programs later this year."

The presentations will be available on the [Scientific Presentations and Conferences](#) page on Aligos' corporate website following the meeting. Presentation details are described below.

Presentation Details

Chronic Hepatitis B

CAM-E ALG-000184

Title: ALG-000184, a capsid assembly modulator, dosed with entecavir for up to 28 weeks is well tolerated and resulted in substantial declines in surface antigen levels in untreated hepatitis B e antigen positive subjects with chronic hepatitis

Presentation: Late Breaking Poster (LBP-18)

Presenter: Jinlin Hou, M.D.

Summary: Oral dosing with 300 mg ALG-000184 + ETV for up to 36 weeks in untreated HBeAg positive CHB subjects resulted in a favorable safety and PK profile and significant reductions in HBV DNA and RNA, superior to those seen with ETV alone. These data additionally showed that a majority of subjects dosed for 12 weeks achieved HBsAg reductions of ≥ 0.4 log₁₀ IU/mL (7 of 12 subjects) and those dosed for 24 weeks demonstrated ≥ 1.0 log₁₀ IU/mL reductions (4 of 7 subjects). The maximum reduction observed to date was at week 36: 2.0 log₁₀ IU/mL.

siRNA ALG-125755

Title: Safety, pharmacokinetics, and antiviral activity of single ascending doses of ALG-125755, a GalNAc-conjugated small interfering RNA, in subjects with chronic hepatitis B

Presentation: Poster

Presenter: Alina Jucov, M.D., Ph.D.

Summary: Single subcutaneous doses of 50 mg and 120 mg ALG-125755, an siRNA designed to reduce hepatitis B surface antigen (HBsAg) in subjects with chronic hepatitis B (CHB), resulted in dose-dependent reductions in HBsAg levels through 90 days. Importantly, the safety and PK profile of these dose levels also support further evaluation of higher dose levels.

Title: Pharmacodynamic durability of ALG-125755, a GalNAc-conjugated siRNA, correlated with total and RNA induced complex

(RISC) bound siRNA in mouse liver

Presentation: Poster

Presenter: Kusum Gupta

Summary: In AAV-HBV mice, ALG-125755 was shown to bind to argonaute-2 (AGO-2), confirming its mechanism of action is consistent with that of an siRNA. Additionally, the pharmacodynamic response of HBsAg reduction and durability correlated with total siRNA and RISC-bound siRNA in mouse liver.

Small molecule PD-L1 inhibitor ALG-093702

Title: Preclinical pharmacokinetic, pharmacodynamic and efficacy relationships of ALG-093702, a liver targeted PD-L1 small molecule inhibitor, in different in vivo models

Presentation: Poster

Presenter: Tongfei Wu, Ph.D.

Summary: ALG-093702, a liver-targeted PD-L1 small molecule inhibitor, demonstrated similar in vitro potency and in vivo PD-L1 target occupancy and tumor growth inhibition as the PD-L1 antibody drug, durvalumab. Preclinical pharmacokinetic, pharmacodynamic and efficacy data provided guidance for the efficacious human dose prediction and dosing strategy for clinical studies of oral liver targeted PD-L1 small molecule inhibitors.

siRNA PD-L1 inhibitor

Title: A potent human PD-L1 siRNA leads to significant reduction of AAV-HBV infected hepatocytes via immune activation in human PD-1/PD-L1 double knock in mice

Presentation: Poster

Presenter: Jin Hong, Ph.D.

Summary: ALG-072571, a liver targeted PD-L1 siRNA therapy, demonstrated significant reduction of AAV-hepatitis B virus (HBV) infected hepatocytes through immune activation in human PD-1/PD-L1 double knock in mice. Therefore, ALG-072571 may lead to restoration of immune responses against HBV and consequent clearance of HBV infection.

Hepatitis B virus model system

Title: An in vivo duck hepatitis B virus model recapitulates key aspects of nucleic acid polymer treatment outcomes in chronic hepatitis B patients

Presentation: Poster

Presenter: Yannick Debing, Ph.D.

Summary: Nucleic acid polymer (NAP) efficacy in patients with chronic hepatitis B has been difficult to recapitulate in animal models. However, Pekin ducks have demonstrated some potential as a model. A preclinical investigation found that subcutaneous administration of NAPs in Pekin ducks injected with duck hepatitis B virus (DHBV)-containing serum recapitulated the efficacy of several established NAPs and suggest this model may be useful for the future evaluation of other NAPs.

Hepatocellular carcinoma

Title: Selective inhibition of human β -catenin DNA transactivation activity using splice switching oligonucleotides for an improved therapeutic window in treating hepatocellular carcinoma

Presentation: Poster

Presenter: Jin Hong, Ph.D.

Summary: ALG-135041, a human β -catenin SSO, demonstrated selective inhibition against DNA transactivation activity in the nucleus and showed a better therapeutic window than either siRNAs or ASOs. There is the potential for a significantly improved therapeutic window by precision targeting of only the DNA transactivating region of the multifunctional β -catenin protein.

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 ALG-000184 continuing to demonstrate a favorable safety and PK profile over the extended dosing durations; the ongoing evaluation of a third, higher dose cohort with respect to ALG-125755 and the Company looking forward to presenting additional data from its robust pipeline of programs later this year. 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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