Aligos Therapeutics Announces U.S. FDA Clearance of IND Application for ALG-000184

Oct 22, 2024

- Company to conduct a Phase 1 Drug-Drug Interaction Study
- Phase 2 filing on track for Q1 2025

SOUTH SAN FRANCISCO, Calif., Oct. 22, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biopharmaceutical company focused on improving patient outcomes through best-in-class therapies for liver and viral diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company’s Investigational New Drug (IND) for a Phase 1 Drug-Drug Interaction (DDI) study of ALG-000184, a capsid assembly modulator (CAM-E) for the treatment of Chronic Hepatitis B (CHB).

“The acceptance of our third U.S. IND is an important milestone for Aligos,” said Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer of Aligos Therapeutics. “This IND clearance allows us to begin the next stages of our clinical development for ALG-000184, including the advancement of the compound into Phase 2 clinical trials. ALG-000184 is the first novel, oral drug candidate for the treatment of HBV infection that can inhibit multiple components of the viral lifecycle, leading to more complete suppression of the virus compared to other therapeutic modalities.”

The DDI study is designed to evaluate the effect of a cytochrome P450 inhibitor and inducer on ALG-000184 pharmacokinetics. In addition, Phase 2 enabling activities are ongoing, with a planned filing in Q1 2025 for the Phase 2 study. This clinical trial will be a randomized, double-blind, active controlled study of ALG-000184 vs. standard of care in HBeAg-positive and HBeAg-negative CHB subjects.

“ALG-000184 has demonstrated impressive data to date with broad antiviral activity,” stated Hardean Achneck, MD, Chief Medical Officer at Aligos Therapeutics. “ALG-000184 has the potential to improve outcomes compared to the current standard of care. We look forward to finalizing the Phase 2 study design in conjunction with KOLs and the FDA and anticipate enrolling patients next year.”

Data from ≤72 weeks following an oral daily dose of 300 mg ALG-000184 has demonstrated the ability to disrupt the entire HBV lifecycle through best-in-class reductions of the relevant viral markers: HBV DNA, RNA, HBsAg, HBeAg, and HBcrAg. Dosing through 96 weeks is ongoing, with interim data readouts expected at upcoming scientific conferences. ALG-000184 has a clear regulatory path endorsed by the FDA and CDE (China) for chronic suppressive therapy with a potential superiority label compared to standard of care.

About ALG-000184

ALG-000184 was derived from initial IP licensed from the laboratory of Dr. Raymond Schinazi at Emory University, which was further optimized by Aligos. ALG-000184 is a potent potential best/first-in-class oral small molecule capsid assembly modulator (CAM-E) being developed for chronic hepatitis B (CHB). Phase 1a studies have demonstrated after single and multiple daily doses that ALG-000184 was well-tolerated, with no safety signals observed, and demonstrated linear PK and excellent antiviral activity. In longer term Phase 1b studies of ALG-000184 300mg QD x ≤96 weeks ± Entecavir (ETV) and ALG-000184 monotherapy have demonstrated best-in-class sustained reductions in HBV DNA, RNA, HBsAg, HBeAg, and HBcrAg. Dosing is ongoing through 2025 with interim data readouts expected at upcoming scientific conferences. Phase 2 enabling activities are ongoing, with a planned Phase 2 IND filing in Q1 2025. ALG-000184 has a clear regulatory path endorsed by the FDA and CDE (China) for chronic suppressive therapy with a potential superiority label compared to standard of care.

About Chronic Hepatitis B

There were more than 290 million chronic carriers of Chronic Hepatitis B (CHB) worldwide as of July 2020 and approximately 30 million individuals become newly infected every year despite the availability of a prophylactic vaccine. In 2015, there were more than 90 million cases of CHB in China alone, while the European Union, United States and Japan accounted for nearly 8 million cases. Complications from CHB include cirrhosis, end-stage liver disease, and hepatocellular carcinoma, which collectively resulted in approximately 900,000 deaths in 2015, according to the World Health Organization. CHB is the primary cause of liver cancer worldwide, and the mortality associated with HBV-related liver cancer continues to increase.

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’ financial results and performance as well as research and development activities, including regulatory status and the timing of announcements and updates relating to our regulatory filings and clinical trials. 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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