



Aligos Therapeutics Announces Clinical Collaboration with Xiamen Amoytop Biotech Co., Ltd.

Amoytop to sponsor a Phase 1b exploratory clinical study evaluating the efficacy and safety of ALG-000184 in combination with PEGBING® (Mipегinterferon alfa-2b) in CHB patients

SOUTH SAN FRANCISCO, Calif., July 22, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, "Aligos"), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today announced that it has entered into a clinical trial collaboration agreement with Xiamen Amoytop Biotech Co., Ltd. ("Amoytop").

Under the terms of the agreement, Amoytop will sponsor and perform a Phase 1b exploratory clinical study evaluating the efficacy and safety of ALG-000184 in combination with PEGBING® (Mipегinterferon alfa-2b) in chronic hepatitis B (CHB) patients in China. The clinical study is expected to begin after approval by the National Medical Products Administration in China.

"We are pleased to build on our existing relationship with Amoytop, as they have proven to be a valuable partner," stated Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer at Aligos Therapeutics. "We look forward to initiating this exploratory study to evaluate the combination of ALG-000184 with PEGBING®, one of the approved drugs for CHB patients in China, to assess the potential benefits of a combinatory approach."

ALG-000184 is a potent best/first-in-class oral small molecule capsid assembly modulator (CAM-E) being developed for CHB. It is designed to exploit the dual role of CAMs by disrupting hepatitis B cccDNA levels and its derived transcripts by reducing expression of viral markers such as DNA, RNA, and the relevant antigens (HBsAg, HBeAg, HBcrAg). 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 pharmacokinetics (PK) and excellent antiviral activity. In longer term Phase 1b studies of ALG-000184 300mg x ≤96 weeks ± entecavir (ETV), ALG-000184 monotherapy has demonstrated best-in-class reductions in HBV DNA, RNA, HBsAg, HBeAg, and HBcrAg without viral breakthrough to date.

PEGBING®, independently developed by Amoytop, is the world's first 40kD pegylated interferon α-2b injection. With dual effects of inhibiting viral replication and enhancing immunity, PEGBING® is mainly used in the clinical treatment of viral hepatitis and is the first-line drug for the antiviral treatment of chronic hepatitis B, which plays an important role in improving the clinical cure rate of hepatitis B and reducing the risk of liver cancer.

"We are pleased to deepen our cooperation in the field of liver disease treatment and look forward to working together to provide a new treatment solution for patients in need," said Sun Li, Chairman and Chief Executive Officer at Amoytop. "Amoytop is committed to further optimizing the chronic hepatitis B combination treatment pathway and hopes that the cooperation will lead to better clinical value drugs and drug combinations."

The Phase 1b study will be a randomized, double blinded, active controlled study to evaluate the safety, pharmacokinetics, and antiviral activity of oral once daily doses of 300 mg ALG-000184 + PEGBING® + entecavir (ETV) compared with 300 mg ALG-000184 + ETV or PEGBING® + ETV in treatment naïve or currently-not-treated HBeAg-positive and nucleos(t)ide analog (NA) suppressed HBeAg-negative subjects with CHB for 48 weeks.

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 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.

About Xiamen Amoytop Biotech Co., Ltd.

Xiamen Amoytop Biotech Co., Ltd. is an innovative biopharmaceutical company and a listed company on the Science and Technology Innovation Board (SSE STAR Market) in China, specializing in R&D, manufacturing and marketing of regular and long-acting recombinant protein drugs. Focusing on the R&D of immune-related cytokine medicines, Amoytop is committed to becoming a leader in solving cytokine medicine-based systemic immune problems, providing better solutions for major diseases (such as viral hepatitis, malignant tumors) and immunotherapy.

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 May 7, 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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