ALX Oncology Announces First Patient Dosed in ASPEN-06, a Phase 2/3 Study of Evorpacept for the Treatment of Patients with Advanced Gastric or Gastroesophageal Junction Cancer

March 2, 2022

Phase 2/3 study initiated in collaboration with Eli Lilly and Company

SOUTH SAN FRANCISCO, Calif., March 02, 2022 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or the "Company"), a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, today announced the first patient has been dosed in the Phase 2/3 ASPEN-06 study evaluating the combination of evorpacept, a next generation CD47 blocker, and CYRAMZA® (ramucirumab), Eli Lilly and Company's anti-VEGFR2 antibody, added to trastuzumab and paclitaxel for the treatment of patients with HER2-positive gastric cancer or gastroesophageal junction ("GEJ") cancer.

ASPEN-06 (NCT05002127) is a randomized phase 2 (open-label) / phase 3 (double-blind), international, multi-center study to evaluate the efficacy of evorpacept in combination with ramucirumab, trastuzumab, and paclitaxel for the treatment of patients whose tumors have progressed following treatment with HER2-targeted therapy and chemotherapy. Approximately 450 adult patients will be enrolled in the study across both phases.

This study follows the ongoing ASPEN-01 Phase 1b trial in patients with HER2-positive gastric/GEJ cancer who have progressed following treatment with HER2-targeted therapy and chemotherapy (NCT03013218). As presented at the Society for Immunotherapy of Cancer's 36 th Annual Meeting in 2021, evorpacept used in combination with ramucirumab, trastuzumab, and paclitaxel demonstrated an initial confirmed objective response rate of 72.2% with a median duration of response of 14.8 months, a 12-month overall survival rate of 79%, and a median overall survival of 17.1 months in patients who historically have low response rates and poor outcomes in this clinical setting [SITC 2021 poster].

"Patients with HER2-positive gastric/GEJ cancer are in need of tolerable and effective treatments, particularly in the 2nd line and later settings where resistance to HER2-directed therapy may have developed," said Keun-Wook Lee, M.D., Ph.D., Professor of Seoul National University College of Medicine and Director of Clinical Trials Center, Seoul National University Bundang Hospital, Seoul, Korea. "Evorpacept's favorable tolerability coupled with its novel approach of enhancing antibody dependent cellular phagocytosis engages the individual's own innate anti-cancer immune response distinguishing it from other HER2-targeted approaches."

"We are greatly encouraged by the exciting data that continue to emerge from ASPEN-01 and are pleased to announce the first patient dosed in ASPEN-06," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "This milestone is an important step towards establishing evorpacept as a unique CD47 blocker that may be used in combination with other anti-cancer drugs for difficult-to-treat solid tumors, such as gastric/GEJ cancer, where more treatment options are desperately needed to improve disease outcomes."

About Gastric Cancer and Gastroesophageal Junction Cancer

Gastric cancer begins in the cells lining the inner wall of the stomach and spreads through the outer layers and eventually the body as it grows. It is estimated that there will be over 26,000 newly diagnosed cases of gastric/GEJ cancer at all stages in the U.S. in 2021, and approximately 17 percent of all gastric/GEJ cancer patients have HER2-positive disease. The five-year survival rate is only 5.5 percent for those patients diagnosed with metastatic disease. Gastric/GEJ cancer is even much more common in East Asian countries, with incidence rates 4 to 10 times higher than in the U.S.

About ALX Oncology

ALX Oncology is a publicly traded, clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpacept has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies, including acute myeloid leukemia and myelodysplastic syndromes.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. Such forward-looking statements are based on ALX Oncology's beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission ("SEC"), including ALX Oncology's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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