ALX Oncology Receives U.S. FDA Orphan Drug Designation for Evorpacept for the Treatment of Patients with Gastric Cancer and Gastroesophageal Junction Cancer

January 27, 2022

SOUTH SAN FRANCISCO, Calif., Jan. 27, 2022 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., (“ALX Oncology”) (Nasdaq: ALXO) a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced that the U.S. Food and Drug Administration (“FDA”) granted orphan drug designation (“ODD”) to evorpacept, a next-generation CD47 blocker, for the treatment of patients with gastric cancer and gastroesophageal junction cancer (collectively “GC”).

“Receiving orphan drug designation from the FDA is an important regulatory milestone for ALX Oncology and reinforces the FDA’s recognition of evorpacept’s potential to improve clinical outcomes in patients with GC,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. “In ASPEN-01, patients with ≥2L HER2 positive GC (n=18) treated with evorpacept in combination with trastuzumab plus ramucirumab and paclitaxel demonstrated an initial objective response rate of 72.2% with a median duration of response of 14.8 months and a median overall survival of 17.1 months [SITC 2021 poster]. These results compare favorably with the clinical experience with both ramucirumab plus paclitaxel and trastuzumab-deruxtecan in similar populations. With promising and consistent anti-cancer activity demonstrated in the solid tumor setting, we are focused on advancing the clinical development of evorpacept and enrolling ASPEN-06 (NCT05002127), a Phase 2/3 study of evorpacept for the treatment of patients with advanced HER2 positive GC.”

The FDA’s Office of Orphan Products Development grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for qualified clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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 GC at all stages in the U.S. in 2021, and approximately 17 percent of all GC patients have HER2-positive disease. The five-year survival rate is only 5.5 percent for those patients diagnosed with metastatic disease. GC 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.

Investor Contact: Peter Garcia Chief Financial Officer, ALX Oncology (650) 466-7125 Ext. 113 peter@alxoncology.com Argot Partners (212)-600-1902 alx@argotpartners.com Media Contact: Karen Sharma MacDougall (781) 235-3060 alx@macdougall.bio