ALX Oncology Receives Orphan Drug Designation from the European Commission for Evorpacept for the Treatment of Patients with Gastric Cancer

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SOUTH SAN FRANCISCO, Calif., June 26, 2023 (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 evorpacept, a next-generation CD47 blocker, has received orphan drug designation ("ODD") from the European Commission ("EC") for the treatment of patients with gastric cancer. This ODD indication includes both gastric cancer and gastroesophageal junction adenocarcinoma (collectively "GC"). The U.S. Food and Drug Administration ("FDA") also granted ODD to evorpacept for the treatment of patients with GC as previously announced in January 2022.

"Receiving orphan drug designation from both the EC and the FDA represents a significant regulatory achievement for ALX Oncology and signifies the growing recognition of evorpacept as a potential new drug to improve clinical outcomes in patients with GC," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "Evorpacept has demonstrated promising and consistent anti-cancer activity in the solid tumor setting, and we look forward to presenting data in the second half of 2023 for ASPEN-06, a randomized Phase 2 trial of evorpacept in combination with trastuzumab, paclitaxel and CYRAMZA® (ramucirumab) for the treatment of patients with HER2-positive GC."

Orphan drug designation is granted by the EC for medicines in development to treat rare conditions affecting no more than five in 10,000 people in the European Union, provided there is no other satisfactory treatment option or the medicine can be of significant benefit to those affected by the condition. Medicines that are granted orphan drug designation by the EC qualify for financial and regulatory incentives including protocol assistance, possible exemptions or reductions in certain regulatory fees, and, if approved for marketing, ten years of market exclusivity in the European Union.

About Gastric Cancer and Gastroesophageal Junction Cancer (section to be updated)

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. Approximately 17 percent of all GC patients have HER2-positive disease, and the five-year survival rate is only 5.5 percent for those patients diagnosed with metastatic disease (SEER). The National Cancer Institute estimates there will be over 26,000 newly diagnosed cases of GC and 11,000 deaths in the U.S. in 2023. In comparison, GC is significantly more common in Europe with over 130,000 newly diagnosed cases and 96,000 deaths in 2020 (Globocan).

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.

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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