



ALX Oncology Announces First Patient Dosed in ASPEN-07, a Phase 1 Study of Evorpaccept for the Treatment of Patients with Urothelial Cancer

February 16, 2023

SOUTH SAN FRANCISCO, Calif., Feb. 16, 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 the first patient has been dosed in the ASPEN-07 study evaluating evorpaccept, a next generation CD47 blocker, in combination with PADCEV® (enfortumab vedotin-ejfv), an antibody drug conjugate ("ADC"), in patients with urothelial cancer ("UC").

ASPEN-07 is a phase 1, open-label, multi-center study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of evorpaccept in combination with enfortumab vedotin-ejfv in subjects with unresectable locally advanced or metastatic UC (NCT05524545).

"Outcomes for patients diagnosed with locally advanced or metastatic UC remain poor, and treatment options after initial chemotherapy and immunotherapy are limited," said Sophia Randolph, M.D., Ph.D., ALX Oncology's Chief Medical Officer. "We are excited to initiate ASPEN-07 to investigate this novel combination therapy that has the potential to change the treatment course of advanced UC. We are encouraged that PADCEV is the first ADC therapy to demonstrate meaningful clinical activity in these difficult-to-treat patients, and the addition of a CD47 blocker is expected to act through different but complementary mechanisms to positively impact efficacy without increasing toxicity."

About Bladder and Urothelial Cancer

As estimated by the National Cancer Institute, bladder cancer is the sixth most common cancer type in the United States. Urothelial cancer is the most common type of bladder cancer and accounts for approximately 90% of all bladder cancer cases. 81,000 new cases of bladder cancer will be diagnosed in the United States in 2022 with over 17,000 deaths. The five-year survival for patients with metastatic bladder cancer is less than 8%. Worldwide, over 573,000 new cases of bladder cancer and over 212,000 deaths occurred in 2020 according to The Global Cancer Observatory.

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, evorpaccept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpaccept 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 evorpaccept 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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