ALX Oncology Announces First Patient Dosed in ASPEN-05, a Phase 1/2 Study of Evorpacept in Combination with Venetoclax and Azacitidine in Patients with Acute Myeloid Leukemia

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Second study of evorpacept in patients with myeloid malignancies

SOUTH SAN FRANCISCO, Calif., Oct. 21, 2021 (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 Phase 1/2 ASPEN-05 study evaluating the combination of evorpacept, a next-generation CD47 blocker, with venetoclax and azacitidine for the treatment of patients with acute myeloid leukemia ("AML").

The Phase 1 portion of the ASPEN-05 study will characterize the safety and confirm the dose of evorpacept in combination with venetoclax and azacitidine in patients with relapsed/refractory AML and previously untreated AML who are not candidates for intensive induction therapy. The Phase 2 portion of the study will evaluate the efficacy of the combination in patients with previously untreated AML who are not candidates for intensive induction therapy.

ASPEN-05 is based on promising preclinical data with evorpacept in combination with venetoclax and azacitidine in non-clinical models of leukemia, as well as clinical data from an ongoing phase 1 study (NCT03013218) evaluating evorpacept in combination with multiple anti-cancer agents in both solid and hematologic malignancies.

"Patients with either relapsed/refractory AML or previously untreated AML who are not considered eligible for intensive induction regimens remain in urgent need of tolerable and effective new therapies," said Harry Erba, M.D., Ph.D., Director of the Leukemia Program at the Duke Cancer Institute. "We are looking forward to evaluating the addition of evorpacept to venetoclax and azacitidine. ALX148 was specifically designed for use in combination to maximize phagocytosis of tumor cells while minimizing the toxicities commonly associated with other CD47-targeted approaches."

"ASPEN-05 builds upon compelling evorpacept combination activity observed in non-clinical models of leukemia. With demonstrated tolerability of evorpacept in multi-agent chemotherapy regimens, we are excited to characterize evorpacept with this standard backbone of AML therapy," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. "Through blockade of the CD47 myeloid checkpoint, evorpacept in combination with venetoclax and azacitidine may potentially transform treatment options for patients with AML."

The ASPEN-05 trial is registered under NCT04755244. ALX Oncology owns worldwide commercial rights to evorpacept.

About Acute Myeloid Leukemia

AML is an aggressive blood cell cancer that can rapidly progress and lead to death if not treated promptly. AML is the most common form of acute leukemia in adults, with an estimated 19,940 new cases and 11,180 deaths from AML in the United States. Due to advanced age and comorbidities at the time of diagnosis, a significant number of patients are not considered eligible for intensive and potentially curative therapies. Despite advances in available care, the estimated 5-year survival for patients in the United States with AML remains only 29%.

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 (also known as ALX148), 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 malignances, 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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