# ALX Oncology Announces Initial Data from ASPEN-05 Study of Evorpacept in Combination with Azacitidine and Venetoclax, Demonstrating Tolerability and Preliminary Activity in Patients with Acute Myeloid Leukemia

December 12, 2022

**-- Antileukemic activity demonstrated in patients with both relapsed/refractory and newly diagnosed AML**

**-- No evorpacept-related cytopenias observed and no maximum tolerated dose identified in combination with azacitidine and venetoclax**

**-- ALX Oncology to Host Conference Call on December 13th at 7:30 a.m. EST**

SOUTH SAN FRANCISCO, Calif., Dec. 12, 2022 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint pathway, today announced the presentation of clinical data from the Phase 1a dose escalation part of the ASPEN-05 trial evaluating evorpacept in combination with azacitidine and venetoclax for the treatment of patients with relapsed or refractory ("r/r") or newly diagnosed ("ND") acute myeloid leukemia ("AML"). The new results, shared in a poster at the 64th American Society of Hematology ("ASH") Annual Meeting [Abstract #4076], show that the combination of evorpacept with azacitidine and venetoclax is active and generally well tolerated. As of October 3, 2022, 14 patients with either r/r or ND AML have been treated with evorpacept in the Phase 1 dose escalation part of the study, administered at 20 mg/kg or 30 mg/kg once every 2 weeks ("Q2W") or 60 mg/kg once every 4 weeks ("Q4W") together with standard dosing of azacitidine and venetoclax.

- Evorpacept in combination with azacitidine and venetoclax was generally well tolerated (N=14) with no maximum tolerated dose identified and a maximum administered dose of 60 mg/kg Q4W.
- In 10 relapsed or refractory AML response-evaluable patients, including 8 that had progressed after prior venetoclax treatment, all experienced a reduction in bone marrow blasts, and 4 achieved a response.
- In 3 newly diagnosed AML response-evaluable patients, all 3 achieved a response, including 1 complete response ("CR"), 1 CR with incomplete hematologic recovery ("CRi"), and 1 morphologic leukemia free state ("MLFS").

"It is extremely encouraging to observe evorpacept's preliminary clinical activity in a population of difficult to treat AML patients with primarily relapsed or refractory disease after prior venetoclax therapy, as well as TP53 mutation and adverse risk genetics," said Harry Erba M.D., Director of the Leukemia Program in the Division of Hematologic Malignancies and Cellular Therapy at Duke University, Durham, NC. "Additionally, evorpacept's favorable initial tolerability profile in combination with azacitidine and venetoclax suggests it may be safely added to this AML backbone therapy without worsening cytopenias, which is particularly important for this patient population."

"The initial data from this early part of the ASPEN-05 study support the tolerability and activity of evorpacept in patients with AML, and provide further validation for adding our CD47 myeloid checkpoint blocker to established backbone regimens in patients with cancer," said Sophia Randolph M.D., Ph.D., Chief Medical Officer, ALX Oncology. "We are pleased to see this initial data as part of our ongoing studies of evorpacept in both solid tumor indications and hematologic malignancies, which support the emerging role of CD47-blockade in enhancing the innate immune anti-cancer response."

**Conference Call on December 13th at 7:30 a.m. EST**

ALX Oncology will host a conference call on Tuesday, December 13, 2022 at 7:30 a.m. EST to further discuss the initial AML data from ASPEN-05. In addition to ALX Oncology's executive management team, Harry Erba M.D., Director of the Leukemia Program in the Division of Hematologic Malignancies and Cellular Therapy at Duke University, Durham, NC will be featured on the call to discuss the results.

To access the conference call, please dial (800) 715-9871 (U.S./Canada) or (646) 307-1963 (international) at least 10 minutes prior to the start time and refer to conference ID 1300143. Presentation slides will be available to download under "News & Events (see "Events") in the Investors section of the ALX Oncology website at www.alxoncology.com.

**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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