ALX Oncology Announces Evorpacept Clinical Program Updates

June 3, 2022

– Expansion of solid tumor clinical program
– ASPEN-02 dose optimization data to inform dosing for ASPEN-05

SOUTH SAN FRANCISCO, Calif., June 03, 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 clinical program updates for its lead program, evorpacept, a next generation CD47 blocker.

Introducing ASPEN-07, a Phase 1 Trial of Evorpacept for the Treatment of Patients with Urothelial Carcinoma ("UC")

- ALX Oncology will initiate a new clinical study, ASPEN-07, to investigate evorpacept in combination with an antibody-drug conjugate ("ADC"), PADCEV® (enfortumab vedotin-ejfv), for the treatment of patients with urothelial carcinoma ("UC") in the fourth quarter of 2022.
- Enfortumab vedotin-ejfv is an ADC directed to Nectin-4, a protein located on the surface of cells that is highly expressed in UC.
- In April 2022, ALX Oncology successfully completed a pre-IND consultation with the U.S. Food and Drug Administration ("FDA") for a Phase 1 study of evorpacept in combination with enfortumab vedotin-ejfv in patients with previously treated locally advanced or metastatic UC.
- The IND application for ASPEN-07 was submitted to the FDA in May 2022.

"We continue to pursue strategies to expand the potential value of evorpacept as a cornerstone therapy for the treatment of patients with cancer," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "ASPEN-07 further expands our solid tumor investigations and will be the first combination study of evorpacept with an ADC. The addition of evorpacept is expected to enhance the antibody-dependent cellular phagocytosis mediated by enfortumab vedotin-ejfv to improve efficacy in patients with UC without increasing toxicity. Our currently enrolling randomized Phase 2 studies remain a key priority for us in order to maintain ALX Oncology's leadership position in solid tumors in the CD47 space."

Update of ASPEN-05, a Phase 1 / 2 Clinical Trial of Evorpacept in Combination with Venetoclax and Azacitidine in Acute Myeloid Leukemia ("AML"), and ASPEN-02, a Phase 1/2 Study of Evorpacept in Combination with Azacitidine in Myelodysplastic Syndrome ("MDS")

- The Phase 1 dose escalation portion of ASPEN-05 has successfully completed enrollment with no safety concerns to date up to the highest protocol defined dose level of 60 mg/kg evorpacept once every four weeks. This portion of the study is designed to characterize the initial safety of evorpacept in combination with venetoclax and azacitidine for the treatment of patients with relapsed/refractory AML and previously untreated AML who are not candidates for intensive induction therapy.
- Patient enrollment will be paused before proceeding into the Phase 1 dose optimization portion of ASPEN-05 pending completion of the Phase 1 portion of ASPEN-02, a Phase 1/2 study of evorpacept in combination with azacitidine in patients with MDS. Data from ASPEN-02 will be used to inform the optimal dose(s) of evorpacept to be studied in the ASPEN-05 study in combination with venetoclax and azacitidine. Ongoing patients in ASPEN-05 will continue to be treated and followed per protocol.

"The decision to pause ASPEN-05 is based on the desire to leverage upcoming dose optimization data from the ASPEN-02 MDS study to effectively inform dose optimization in ASPEN-05," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. "MDS and AML are indications where evorpacept possesses a similar mechanism of action, and this strategy allows us to evaluate evorpacept in a cost-efficient manner in patients with AML while maintaining our focus in our solid tumor programs. We anticipate preliminary dose escalation data from ASPEN-05 to be presented at a scientific conference in 2022, and initial dose optimization data from ASPEN-02 to be presented at a scientific conference in mid-2023."

Update of ASPEN-03 and ASPEN-04, which are two distinct randomized Phase 2 studies for the treatment of patients with advanced head and neck squamous cell carcinoma ("HNSCC")

- ALX Oncology continues to advance evorpacept in two randomized Phase 2 studies in patients with HNSCC in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, with or without chemotherapy. Both studies are being conducted in collaboration with Merck, known as MSD outside the United States and Canada. The first study, ASPEN-03, is evaluating the efficacy of evorpacept in combination with pembrolizumab for the first-line ("1L") treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC with a Combined Positive Score ("CPS") ≥ 1. The second study, ASPEN-04, is investigating evorpacept in combination with pembrolizumab and standard chemotherapy

for the 1L treatment of patients with metastatic or unresectable, recurrent HNSCC (any CPS value).

- Patient enrollment for ASPEN-03 and ASPEN-04 continues as planned with results expected to be presented by mid-2024.

Update of ASPEN-06, a Phase 2/3 Study of Evorpacept for the Treatment of Patients with Advanced Gastric or Gastroesophageal Junction ("GEJ") Cancer

- ASPEN-06 is a randomized Phase 2 (open-label) / Phase 3 (double-blind), international, multi-center study to evaluate the efficacy of evorpacept and CYRAMZA® (ramucirumab) added to trastuzumab and paclitaxel for the treatment of patients with HER-positive gastric/GEJ cancer whose tumors have progressed following treatment with HER2-targeted therapy and chemotherapy. ASPEN-06 is being conducted in collaboration with Eli Lilly and Company.
- In March 2022, the first patient was dosed in the Phase 2/3 ASPEN-06 study.
- Patient enrollment continues to progress and results from the Phase 2 portion of ASPEN-06 are expected to be presented in 2023.

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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