ALX Oncology Announces Update on ASPEN-03 and ASPEN-04, the ALX148 Phase 2 Head and Neck Cancer Studies

June 14, 2021

--Interim report completed by ALX for a standard ongoing non-clinical safety study

--Based on the safety study results, the FDA has lifted a previously set partial clinical hold and cap on patient enrollment in ASPEN-03 and ASPEN-04

--The first of two distinct randomized Phase 2 head and neck cancer studies in collaboration with Merck has been initiated; enrollment in ASPEN-03 is ongoing

BURLINGAME, Calif., June 14, 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 updates on its ALX148 Phase 2 studies in patients with advanced head and neck squamous cell carcinoma ("HNSCC"). The U.S. Food and Drug Administration ("FDA") informed ALX Oncology that it reviewed its standard non-clinical safety study and has lifted the previously set partial clinical hold and cap on patient enrollment. The two randomized Phase 2 studies, ASPEN-03 and ASPEN-04, are potentially registrational with patient enrollment unimpacted in either study. ASPEN-03 has initiated with enrollment ongoing.

ALX Oncology is advancing ALX148 into two randomized Phase 2 studies in subjects with HNSCC in combination with pembrolizumab, marketed as KEYTRUDA®, the market leading anti-programmed cell death protein-1, or PD-1, checkpoint inhibitor, with or without chemotherapy. Both studies are being conducted in collaboration with Merck. The first study, ASPEN-03, is evaluating the efficacy of ALX148 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 evaluating ALX148 in combination with pembrolizumab and standard chemotherapy for the 1L treatment of patients with metastatic or unresectable, recurrent HNSCC (any CPS value). Further details can be found here.

"We are very pleased that the FDA has reviewed our standard non-clinical safety study and has removed the partial clinical hold and patient cap on our two Phase 2 studies of ALX148 in patients with HNSCC," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "Patients with advanced HNSCC are in need of novel therapeutic options, and we look forward to expediting the global enrollment of patients into ASPEN-03 and ASPEN-04 in the coming months and evaluating ALX148's contribution to standard pembrolizumab-based therapy."

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, ALX148, is a next-generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. ALX148 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 ALX148 for the treatment of multiple solid tumor indications and hematologic malignances, including AML and myelodysplastic syndromes (MDS).

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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