ALX Oncology Announces Updates on Planned ALX148 Phase 2 Head and Neck Cancer Studies

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-- Due to the registration potential of two planned Phase 2 head and neck cancer studies, FDA has requested completion of a standard ongoing non-clinical safety study

-- Initiation of planned Phase 2 studies is allowed with enrollment of up to 50 total ALX148 treated subjects with full accrual proceeding upon non-clinical report acceptance by FDA

-- Cap on patient enrollment is defined as partial clinical hold and no delays in the clinical program are anticipated

-- FDA request is not in response to any adverse event from ALX148 clinical studies

BURLINGAME, Calif., Dec. 07, 2020 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or "Company") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint pathway, today announced updates on its planned ALX148 Phase 2 studies in patients with advanced head and neck squamous cell carcinoma ("HNSCC"). The U.S. Food and Drug Administration ("FDA") verbally informed the Company that given its planned initiation of two Phase 2 HNSCC studies that could be potentially registrational, they require completion of a routine non-clinical safety study that the Company currently has in process. The FDA noted that for any drug development program moving swiftly through development, this non-clinical study is still required prior to the initiation of a clinical trial that could be considered pivotal. ALX Oncology is allowed to initiate both Phase 2 HNSCC studies with the enrollment capped at a total of 50 subjects treated with ALX148 across both studies (excluding safety lead-in cohorts) pending acceptance of the non-clinical safety study report. The Company expects to provide the required report to the FDA prior to reaching the 50-patient enrollment cap. While this cap on enrollment is defined as a partial clinical hold, no delays are anticipated in the Company's current clinical study timelines.

ALX Oncology plans to advance ALX148 into two 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, in the first half of 2021. Both studies will be conducted in collaboration with Merck. The first study will evaluate 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") $\geq$ 1. The second study will evaluate ALX148 in combination with pembrolizumab and standard chemotherapy for the 1L treatment of patients with metastatic or unresectable, recurrent HNSCC (any CPS value).

"We are pleased that the FDA is allowing us to initiate our two planned Phase 2 studies of ALX148 in patients with HNSCC and we are on track to complete the standard ongoing non-clinical safety study. We do not anticipate any delays in our planned clinical study timelines," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "Importantly, this recent FDA communication is not in response to any adverse events seen in ALX Oncology's ongoing clinical studies of ALX148. We are excited to have demonstrated encouraging anti-tumor activity with ALX148 in combination treatment in patients with HNSCC as well as HER2-positive gastric and gastroesophageal junction cancer. We believe these indications, in addition to our myelodysplastic syndromes ("MDS") program (ASPEN-02), offer potential registration pathways in combination with existing approved therapies and we intend to accelerate ALX148 development in solid and hematological indications in 2021."

ALX Oncology recently announced that ALX148 in combination with pembrolizumab, 5-fluoropyrimidine and platinum achieved a 75.0% (n=4) overall response rate ("ORR"), including a complete response, in the Company's Phase 1b expansion cohort (ASPEN-01) for the 1L treatment of patients with metastatic or unresectable, recurrent HNSCC who have not received prior treatment for their advanced disease. The Company also reported recent ASPEN-01 data that ALX148 in combination with pembrolizumab achieved a 40.0% ORR (n=10) in patients with 2L HNSCC who had never received a checkpoint inhibitor for their advanced disease. ALX Oncology intends to pursue a strategy that will leverage the data generated from its planned Phase 2 randomized studies of ALX148 and pembrolizumab with and without chemotherapy to request from the FDA that ALX148 be a candidate for accelerated approval in the 1L treatment of HNSCC.

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 a range of solid tumor indications as well as MDS and acute myeloid

leukemia. For more information, please visit ALX Oncology's website at www.alxoncology.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. 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 statements include but are not limited to statements regarding ALX Oncology's clinical pipeline and timeline, strategy, the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of ALX148, and the statements made by ALX Oncology's Chief Medical Officer. These and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission ("SEC"), including ALX Oncology's Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2020, and other documents ALX Oncology subsequently 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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