



ALX Oncology Announces First Patient Dosed in ASPEN-04, a Phase 2 Study of ALX148 in Combination with KEYTRUDA® (pembrolizumab) and Chemotherapy for the Treatment of Patients with Advanced Head and Neck Squamous Cell Carcinoma

July 28, 2021

The second of two distinct randomized Phase 2 studies in collaboration with Merck has been initiated

BURLINGAME, Calif., July 28, 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, in partnership with Merck, known as MSD outside the United States and Canada, today announced the first patient has been dosed in the Phase 2 ASPEN-04 study evaluating the combination of ALX148, a next generation CD47 blocker, with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, and standard chemotherapy for the treatment of patients with advanced head and neck squamous cell carcinoma ("HNSCC").

ASPEN-04 (NCT04675333) is an open-label, randomized phase 2 multi-center study of the anti-tumor efficacy of ALX148 in combination with pembrolizumab and standard chemotherapy in patients with first line metastatic or unresectable, recurrent HNSCC who have not received prior systemic therapy for their advanced disease. This study will enroll patients regardless of PD-L1 expression status. The study is being conducted in collaboration with Merck and is based on promising clinical data reported from the ASPEN-01 Phase 1 study (NCT03013218), which provided the basis for ALX148's Fast Track Approval in HNSCC granted by the U.S. Food and Drug Administration.

"We are excited to expand the ALX148 clinical program with the initiation of a second Phase 2 trial, that has the potential to integrate ALX148 into current standard-of-care therapies for patients with PD-L1-unselected, treatment naive HNSCC," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "The demonstrated tolerability of ALX148 with chemotherapy agents, when both myeloid and T cell checkpoints are inhibited, maximizes the potential anti-cancer immune response to novel tumor antigens. ASPEN-04 builds upon the promising combination activity we have already observed in patients with HNSCC, and provides an opportunity for more optimized anti-cancer activity."

About Head and Neck Cancers

Cancers that are known collectively as head and neck cancers usually begin in the squamous cells. These cells line the moist, mucosal surfaces inside head and neck structures like the mouth, the nose, and the throat. These squamous cell cancers are often referred to as squamous cell carcinomas of the head and neck. It is estimated that there are over 50,000 newly diagnosed cases of HNSCC at all stages in the U.S. each year. The 5-year survival is only 40% for those patients diagnosed with metastatic disease.

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 malignancies, including AML 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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