



ALX Oncology Announces First Patient Dosed in ASPEN-03, a Phase 2 Study of ALX148 in Combination with KEYTRUDA® (pembrolizumab) for the Treatment of Patients with Advanced Head and Neck Squamous Cell Carcinoma

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

BURLINGAME, Calif., May 10, 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-03 study evaluating the combination of ALX148, a next generation CD47 blocker, with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for the treatment of patients with advanced head and neck squamous cell carcinoma ("HNSCC").

ASPEN-03 (NCT04675294) is an open-label, randomized phase 2 multi-center study of the anti-tumor efficacy of ALX148 plus pembrolizumab in patients with first line metastatic or unresectable, recurrent PD-L1 positive HNSCC. This study is being conducted in collaboration with Merck and is based upon promising clinical data reported from the ASPEN-01 Phase 1 study (NCT03013218), which provided the basis for ALX148's Fast Track designation in HNSCC granted by the U.S. Food and Drug Administration.

"We are excited to have achieved this latest milestone of initiating the first Phase 2 trial in the ALX148 clinical program. We believe the combination of ALX148 and pembrolizumab exemplifies the broad therapeutic potential of inhibiting both myeloid and T cell checkpoints across a wide range of solid tumor cancers including HNSCC," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "ASPEN-03 builds upon the promising combination activity already observed in patients with HNSCC, and our team intends to continue to accelerate ALX148 development in both this and additional solid and hematological indications this year."

About Head and Neck Cancers

Cancers that are known collectively as head and neck cancers usually begin in squamous cells. These cells line the moist, mucosal surfaces in head and neck structures such as the mouth, nose, and 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 a range of solid tumor indications as well as MDS and AML. 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 and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission ("SEC"), including ALX Oncology's Annual Report on Form 10-K, filed with the SEC on March 18, 2021, 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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