ALX Oncology's Evorpacept Receives Fast Track Designation from FDA as First-Line Treatment for Head and Neck Squamous Cell Carcinoma

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SOUTH SAN FRANCISCO, Calif., Aug. 01, 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 that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to evorpacept, a next generation CD47 blocker, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for the first-line treatment of adult patients with PD-L1 positive advanced head and neck squamous cell carcinoma ("HNSCC").

The FDA's decision is informed by the results of ALX Oncology's phase 1 clinical trial, ASPEN-01, that showed preliminary antitumor activity and a favorable safety profile in checkpoint inhibitor-naïve patients with second-line or greater advanced HNSCC treated with evorpacept and pembrolizumab (n=10). The preliminary objective response rate of 40% in this limited population represents an improvement over historical anti-PD-1 monotherapy activity in a similar population and supported the initiation of the ASPEN-03 (NCT04675294) study in May 2021 in collaboration with Merck (known as MSD outside the US and Canada). ASPEN-03 is a randomized phase 2 multi-center study to investigate the anti-tumor efficacy of evorpacept plus pembrolizumab in patients with first-line metastatic or unresectable, recurrent PD-L1 positive HNSCC.

"The FDA's Fast Track designation for the first-line treatment of HNSCC with evorpacept in combination with pembrolizumab builds upon evorpacept's prior Fast Track designation in the first-line HNSCC population in combination with pembrolizumab and standard chemotherapy highlighting the potential clinical utility of evorpacept in this difficult-to-treat disease," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "We are pleased by the patient enrollment progress being made across our HNSCC phase 2 program (NCT04675294; NCT04675333) as we seek to advance evorpacept to help patients living with this disease."

About FDA Fast Track Designation
The FDA's Fast Track program is designed to facilitate the development and expedite the review of medicines that may treat serious or life-threatening conditions and address significant unmet medical needs. The designation provides the opportunity for more frequent meetings with the FDA over the course of drug development. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review if relevant criteria are met, as well as for Rolling Review, which enables a drug company to submit portions of the Biologic License Application to the FDA as they are completed.

About HNSCC
HNSCC is a serious and life-threatening disease with poor prognosis despite current available standard of care therapies. According to the Global Cancer Observatory, HNSCC was the 6th most common cancer globally in 2018 and the incidence of HNSCC is expected to increase 30% by 2030. For 2022, the National Cancer Institute estimates about 54,000 new cases of HNSCC will be diagnosed and nearly 11,230 of men and women will die from HNSCC in the United States.

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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