ALX Oncology to Collaborate with Merck on Phase 2 Immuno-Oncology Studies Evaluating ALX148, Targeting CD47, in Combination with KEYTRUDA® (pembrolizumab) in Patients with Head & Neck Cancer

September 22, 2020

Phase 2 Program Planned Based on Promising Phase 1b Data Shown with ALX148 Plus Pembrolizumab in Patients with HNSCC at American Society for Clinical Oncology (ASCO), Virtual Scientific Program, May 29-31, 2020

BURLINGAME, Calif., Sept. 22, 2020 (GLOBE NEWSWIRE) -- ALX Oncology (NASDAQ:ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced it has entered into a clinical trial collaboration with Merck, known as MSD outside the United States and Canada, to evaluate the combination of ALX148, an investigational next generation CD47 blocker, and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for the treatment of patients with Head & Neck Squamous Cell Carcinoma (HNSCC).

Under the terms of the agreement, ALX Oncology will conduct a Phase 2 program comprising two separate Phase 2 studies. The first study will evaluate the efficacy of ALX148 in combination with KEYTRUDA for the first line treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC. The second study will evaluate ALX148 in combination with KEYTRUDA and standard chemotherapy for the first line treatment of patients with metastatic or unresectable, recurrent HNSCC.

These new studies will be initiated based on promising data from ALX148 in combination with pembrolizumab generated by ALX Oncology in a Phase 1b trial evaluating patients with HNSCC that was the basis for ALX148's Fast Track Approval granted by the U.S. Food and Drug Administration. Phase 1b trial results presented at ASCO 2020 showed that patients with HNSCC who had progressed on prior platinum therapy and who had never received a checkpoint inhibitor treated with ALX148 in combination with pembrolizumab demonstrated a 40% objective response rate (ORR), a median progression-free survival (PFS) of 4.6 months with a median overall survival (OS) that was not reached.

"ALX148 was designed for use in combination to maximize clinical activity with a range of anti-cancer agents. We believe that blocking the CD47 myeloid checkpoint pathway bridges the innate and adaptive immune response against cancer to enhance efficacy. This collaboration builds upon the compelling combination activity observed in patients with ALX148 and KEYTRUDA," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "Our goal is to transform treatment options for patients with cancer by developing ALX148 as a foundational checkpoint immunotherapy."

ALX Oncology owns worldwide commercial rights to ALX148.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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 advance ALX148 into clinical development for the treatment of myelodysplastic syndromes and to continue clinical development for the treatment of a range of solid tumor indications.

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 Holdings Inc.'s (the "Company") 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 the Company'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 the Company's continued reliance on third parties to conduct clinical trials of ALX148, the Company's expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of ALX148, the design, progress and timing of clinical trials for ALX148, including enrollment and its regulatory plans, and the ability of the Company's clinical trials to demonstrate the safety and efficacy of ALX148. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 27, 2020, and other documents the Company subsequently files with the SEC from time to time. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact: Peter Garcia CFO, ALX Oncology (650) 466-7125 Ext. 113 peter@alxoncology.com Argot Partners (212) 600-1902 alxoncology@argotpartners.com Media Contact: Karen Sharma MacDougall (781) 235-3060 alx@macbiocom.com