ALX Oncology and Quantum Leap Healthcare Collaborative™ Announce the Selection of Evorpacept in the I-SPY-P1 TRIAL in Combination with Enhertu® in Breast Cancer

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SOUTH SAN FRANCISCO, Calif., Aug. 15, 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, and Quantum Leap Healthcare Collaborative™ (“Quantum Leap”) today announced that ALX Oncology’s next generation CD47 blocker, evorpacept, has been selected for a new investigational treatment arm in the I-SPY-P1 TRIAL for the treatment of patients with unresectable or metastatic HER2-positive and HER2-low breast cancer. Sponsored by Quantum Leap, this Phase 1 (open-label), multi-center study arm will investigate evorpacept in combination with ENHERTU® (fam-trastuzumab deruxtecan-nxki), a HER2 directed antibody-drug conjugate (“ADC”), to determine the safety, tolerability and efficacy of this drug combination.

“Patients with advanced breast cancer who develop resistance to therapies are in need of novel and tolerable treatment options,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. “We are thrilled to partner with Quantum Leap, recognized as a leader in the development of research initiatives supporting new therapies, to accelerate the advancement of evorpacept in breast cancer. Moreover, this collaboration expands our solid tumor investigations with evorpacept in combination with an ADC. We believe the addition of evorpacept can improve ENHERTU’s anti-cancer activity without increasing toxicity.”

The I-SPY-P1 TRIAL will be led by Paula Pohlmann, Associate Professor of Breast Medical Oncology at The University of Texas MD Anderson Cancer Center. ALX Oncology will provide funding and supply evorpacept. As the study sponsor, Quantum Leap will be responsible for managing the trial.

About the I-SPY TRIALs

The I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The trial is a unique collaborative effort by a consortium that includes the Food and Drug Administration (FDA), industry, patient advocates, philanthropic sponsors, and clinicians from 16 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit www.ispytrials.org.

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate care and research, and to foster high-impact trials with embedded clinical processes and systems technology and improved data management, greater access to clinical trial matching, and greater benefit to patients, providers, and researchers. Our goal is to improve and save lives. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit https://www.quantumleaphealth.org/.

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.

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