ALX Oncology Receives IND Clearance from U.S. FDA for ALX2004, a Novel EGFR-targeted Antibody-drug Conjugate

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- ALX2004 is a potential best- and first-in-class antibody-drug conjugate (ADC) for the treatment of EGFR-expressing solid tumors that was created from ALX Oncology's proprietary linker-payload platform
- ALX2004, the company's first ADC, was fully designed and developed in-house by ALX Oncology scientists
- Company expects to initiate Phase 1 clinical trials of ALX2004 in mid-2025, with initial safety data available in 1H 2026

SOUTH SAN FRANCISCO, Calif., April 07, 2025 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or the "Company") (Nasdaq: ALXO), a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer and extend patients' lives, today announced receipt of U.S. Food and Drug Administration (FDA) clearance for the Investigational New Drug (IND) application for ALX2004, the company's potential best- and first-in-class antibody-drug conjugate (ADC) for the treatment of epidermal growth factor receptor (EGFR)-expressing solid tumors. Based on this clearance, ALX Oncology will initiate a single-agent dose-escalation and expansion Phase 1 clinical trial for ALX2004 in mid-2025.

"Clinical advancement of our first ADC and the first drug candidate developed on our proprietary linker-payload platform is an important milestone in our mission to deliver breakthrough therapies that will help transform the future of cancer treatment," said Jason Lettmann, Chief Executive Officer at ALX Oncology. "We meticulously designed all aspects of ALX2004 – the antibody backbone, linker and payload – to optimize the targeted delivery of a powerful chemotherapy payload to tumor cells while minimizing systemic toxicity. The resulting, highly differentiated molecule has demonstrated potent anti-tumor activity in preclinical models and is a strategic addition to our clinical pipeline, which also includes multiple trials evaluating our lead therapeutic candidate, evorpacept."

EGFR is a transmembrane protein located on the surface of cells that regulates cell growth; overexpression occurs across various tumor types, including breast cancer, colorectal carcinoma, head and neck squamous cell carcinoma and non-small cell lung cancer. EGFR is clinically validated as a therapeutic target with several FDA-approved targeted antibodies and small molecules. However, there are currently no approved EGFR-targeted ADCs. Early-generation attempts to develop EGFR-targeted ADCs were limited by drug design, on-target off-tumor toxicities and toxicity of older generation payloads.

Utilizing the company's proprietary, highly differentiated topoisomerase I inhibitor payload platform, ALX Oncology scientists designed ALX2004 to optimize ADC-based mechanisms of anti-tumor activity and improve outcomes in patients with EGFR-expressing tumors. The ALX2004 molecule, created entirely in ALX Oncology labs, comprises an antibody backbone engineered to optimize anti-EGFR activity, a linker with enhanced stability and a proprietary topoisomerase I payload that can generate an enhanced bystander effect.

ALX Oncology plans to conduct an R&D call focused on ALX2004 in Q2 2025 and to initiate a Phase 1 clinical trial of the investigational therapy in mid-2025.

About ALX Oncology
ALX Oncology (Nasdaq: ALXO) is a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer and extend patients' lives. ALX Oncology's lead therapeutic candidate, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpacept is currently being evaluated across multiple ongoing clinical trials in a wide range of cancer indications. More information is available at www.alxoncology.com and on LinkedIn @ALX Oncology.

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 objectives 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.

Investor Relations Contact:
Elhan Webb, CFA, IR Consultant
ewebb@alxoncology.com

Media Contact:
Audra Friis, Sam Brown, Inc.
audrafriis@sambrown.com
(917) 519-9577