ALX Oncology Doses First Patient in Phase 1 Dose Escalation Trial Evaluating ADC ALX2004 for the Treatment of EGFR-Expressing Solid Tumors

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- A potential best- and first-in-class antibody-drug conjugate (ADC) for the treatment of EGFR-expressing solid tumors, ALX2004 is uniquely designed with every component optimized to maximize the therapeutic window

-First-in-human trial of ALX2004 builds upon body of positive preclinical data demonstrating dose dependent anti-tumor activity and favorable safety profile

-Initial safety data anticipated in first half 2026

SOUTH SAN FRANCISCO, Calif., Aug. 19, 2025 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or the"Company") (Nasdaq: ALXO), a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives, today announced that the first patient has been dosed in the Company's Phase 1 clinical trial for ALX2004, a potential best- and first-in-class, epidermal growth factor receptor (EGFR) ADC that is being studied for the treatment of EGFR-expressing solid tumors.

"Dosing of the first patient in the Phase 1 trial is an important milestone in ALX Oncology's mission to develop a pipeline of best-in-class drugs; ALX2004 is our first ADC and treating our first patient with this drug is a significant step forward in fulfilling the potential of EGFR-targeted ADCs," said Jason Lettmann, Chief Executive Officer at ALX Oncology. "Our preclinical data supports our conviction that ALX2004, with its optimized antibody, linker and payload, has the potential to overcome the toxicity challenges that have limited earlier generation EGFR-targeted ADCs. We look forward to enrolling this trial and expect to report initial safety data in the first half of 2026."

The Phase 1 clinical trial (NCT07085091) is a first-in-human, open-label multicenter study evaluating ALX2004 in participants with advanced or metastatic select EGFR-expressing solid tumors. The study consists of a Phase 1a dose escalation portion followed by dose exploration, and a Phase 1b dose expansion. The dose escalation portion of the trial will enroll patients with previously treated advanced or metastatic non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), esophageal squamous cell carcinoma (ESCC) and colorectal cancer (CRC). All or a subset of these tumor types may be included in the dose exploration and expansion portions of the trial.

ALX2004: Optimized for Success Based on Rigorous Drug Design Process

Developed by ALX Oncology's protein engineers utilizing the Company's proprietary topoisomerase I inhibitor (Top1i) payload and linker payload platform, ALX2004 is a uniquely designed EGFR-targeted ADC where every component is optimized to maximize the therapeutic window by reducing toxicity. This includes an affinity-tuned EGFR antibody with a binding epitope distinct from approved EGFR antibodies. ALX2004 also has a proprietary Top1i payload engineered to offer enhanced bystander effect with improved linker stability for on-target delivery of payload.

Robust Preclinical Data: Supporting Differentiation in EGFR-ADC Class

Preclinical data supports ALX2004's differentiated linker-payload construct, which has demonstrated superior stability versus other ADCs in its class, with dose-dependent activity and a favorable safety profile. In addition, ALX2004 has shown dose-dependent activity across a range of tumors, EGFR expression levels and mutations. Potent activity in tumor models supports its potential for treating patients with EGFR-expressing tumors. Preclinical model findings did not demonstrate EGFR-related skin toxicity at clinically relevant doses or payload-related interstitial lung disease, supportive of a potentially differentiated safety profile.

About ALX Oncology
ALX Oncology (Nasdaq: ALXO) is a clinical-stage biotechnology company advancing a pipeline of novel therapies designed 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. ALX Oncology's second pipeline candidate, ALX2004, is a novel EGFR-targeted antibody-drug conjugate with a differentiated mechanism of action and entered the clinic in a Phase 1 trial in August 2025. 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 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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