ALX Oncology Highlights Differentiated Design, Preclinical Data and Development Plans for EGFR-Targeted ADC, ALX2004, in R&D Webcast Event

May 20, 2025

- 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 by reducing toxicity

- Following recent IND clearance from U.S. FDA, ALX2004 will enter clinical studies mid-year 2025 with initial safety data anticipated in 1H 2026

- Trials evaluating the Company's lead investigational therapy, CD47-blocker evorpacept, in breast and colorectal cancers planned to initiate in mid-2025 with multiple key inflection points from evorpacept and ALX2004 development programs anticipated in 2026

SOUTH SAN FRANCISCO, Calif., May 20, 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, provides an overview of the clinical development program for its highly-differentiated antibody-drug conjugate (ADC), ALX2004, at the Company's R&D webcast event today. ALX Oncology leadership will discuss the unique design profile, preclinical data and clinical development plans for ALX2004, a potential best- and first-in-class ADC for the treatment of epidermal growth factor receptor (EGFR)-expressing solid tumors, that is planned to enter Phase 1 studies in mid-year 2025.

"ALX Oncology is driving a new, highly differentiated approach to the treatment of EGFR-expressing tumors, harnessing our proprietary linker-payload platform to bring forward an ADC candidate that we believe may be able to overcome challenges seen with EGFR-ADCs in the past and drive a best-in-class molecule forward," said Jason Lettmann, Chief Executive Officer at ALX Oncology. "As we advance ALX2004 into the clinic, we are excited to share the development program and highlight how we rigorously designed all components of this ADC with an optimized, validated payload and antibody to maximize its potential for success across a variety of tumor types."

The Company's ALX2004 R&D webcast event will include presentations on:

ALX2004 Unique Design: Optimized for Anti-Tumor Activity and Improved Outcomes

Developed by ALX Oncology's protein engineers utilizing the Company's proprietary topoisomerase I inhibitor payload and linker-payload platform, ALX2004 has been rigorously designed to maximize the therapeutic window and overcome toxicity challenges observed in this class.

This includes an affinity-tuned EGFR antibody with a binding epitope distinct from approved EGFR antibodies. ALX2004 also has a proprietary linker-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.

Initiation of Phase 1 Clinical Development Program

The U.S. Food and Drug Administration (FDA) cleared ALX Oncology's Investigational New Drug (IND) application for ALX2004 in April 2025. ALX Oncology will provide an overview of its Phase 1 clinical trial design for ALX2004 planned to initiate mid-2025. The Company anticipates initiating a Phase 1 dose escalation trial in EGFR-expressing solid tumors, including non-small cell lung cancer, colorectal cancer, head and neck squamous cell carcinoma and esophageal squamous cell carcinoma, targeting patients with relapsed/refractory cancers. The Company anticipates initial safety data in the first half of 2026.

ALX2004 Webcast Information
The virtual event will be webcast live and a replay will be available after the event by visiting the "Investors" section of ALX Oncology's website and selecting "Events and Presentations."

Date & Time: Tuesday, May 20, 2025, 8:00 a.m. PT/11:00 a.m. ET
Webcast Access: https://edge.media-server.com/mmc/p/ohnn53h5

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 is anticipated to enter Phase 1 trials mid-2025. More information is available at www.alxoncology.com and on LinkedIn @ALX Oncology.

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