



## **ALX Oncology Advances Separate Clinical Trials Evaluating Investigational CD47-Inhibitor Evorpaccept and Novel EGFR-Targeted Antibody-Drug Conjugate ALX2004**

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***- First patient dosed in Phase 2 ASPEN-09-Breast trial evaluating evorpaccept in combination with trastuzumab and physician's choice of chemotherapy in HER2-positive metastatic breast cancer; interim analysis anticipated Q3 2026 –***

***- Third dose cohort initiated in Phase 1 trial of ALX 2004; study remains on track to provide initial safety data in 1H 2026***

SOUTH SAN FRANCISCO, Calif., Jan. 08, 2026 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc. ("ALX Oncology," Nasdaq: ALXO), a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives, announced that the first patient has been dosed in the Company's Phase 2 ASPEN-09-Breast trial evaluating its investigational CD47-inhibitor evorpaccept. This trial will evaluate the combination of evorpaccept with trastuzumab and physicians' choice of chemotherapy in patients with HER2-positive metastatic breast cancer whose disease has progressed after ENHERTU® (T-DXd).

Additionally, after successfully clearing the second dose cohort, the Phase 1 trial evaluating the Company's epidermal growth factor receptor (EGFR)-targeted antibody-drug conjugate (ADC) ALX2004 for the treatment of EGFR-expressing solid tumors has begun enrolling patients in the third dose cohort at 4mg/kg. No dose-limiting toxicities were observed in the prior two dose cohorts.

"We are extremely pleased with the progress we are making on these clinical trials," said Jason Lettmann, Chief Executive Officer at ALX Oncology. "We believe both evorpaccept and ALX2004 have the potential to fill significant gaps in the standard of care for many types of cancer."

Evorpaccept is the first CD47 inhibitor to show substantial tumor response and a well-tolerated safety profile in a randomized trial. Data from this prior gastric cancer trial, ASPEN-06, show that evorpaccept demonstrated benefit across all efficacy parameters in patients with HER2-positive disease and high CD47 expression levels. Research has demonstrated that increased CD47 expression is correlated with poor patient outcomes in many tumor types, including breast cancer.

The Phase 2 ASPEN-09-Breast clinical trial ([NCT07007559](#)) is a single-arm, open-label, multicenter study evaluating evorpaccept plus trastuzumab and physicians' choice of chemotherapy in 80 patients with HER2-positive breast cancer previously treated with ENHERTU® (fam-trastuzumab deruxtecan-nxki), which was recently approved as first-line therapy. The trial will utilize participants' CD47 expression levels as a biomarker to assess responses.

The primary endpoint of the trial is overall response rate (ORR) in patients who are confirmed HER2 positive by circulating tumor DNA (ctDNA). Key secondary endpoints are ORR in the HER2 ctDNA+ subpopulation by level of CD47 expression, clinical benefit rate (CBR), duration of response (DOR), progression-free survival (PFS) and overall survival (OS), and safety. ORR in the HER2 ctDNA-negative subpopulation is an exploratory endpoint. ALX Oncology anticipates sharing interim data from the trial in Q3 2026.

The ALX2004 Phase 1 clinical trial ([NCT07085091](#)) is a first-in-human, open-label, multicenter trial 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 optional dose exploration, and a Phase 1b dose expansion. The dose escalation portion of the trial is enrolling 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).

"Preclinical data suggest that ALX2004 has the potential to overcome the toxicity challenges associated with earlier generation EGFR-targeted ADCs," said Lettmann. "It is encouraging that, after clearing the second dose cohort in our Phase 1 trial at 2mg/kg, we are able to double the dosage to 4mg/kg in the third cohort."

ALX Oncology expects to provide an initial safety update from the Phase 1 ALX2004 trial during 1H 2026.

### **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, evorpaccept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpaccept 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. A Phase 1, dose-escalation trial of

ALX2004 is ongoing in patients with EGFR-expressing solid tumors.

**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.

More information is available at [www.alxoncology.com](http://www.alxoncology.com) and on LinkedIn [@ALX Oncology](https://www.linkedin.com/company/alxoncology).

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