ALX Oncology's Evorpacept in Combination with Zanidatamab Generates Promising, Durable Response in Patients with Advanced HER2-Positive Breast Cancer and High CD47 Expression

May 7, 2026

- Data from Phase 1b/2 trial presented at ESMO Breast Cancer 2026 further validate a biomarker-driven development strategy for evorpacept -

- Findings are consistent with previous results from the randomized ASPEN-06 trial in HER2-positive gastric cancer, which indicated CD47 expression could potentially serve as an important predictive biomarker of evorpacept activity -

- ALX Oncology will host a webcast on May 8 to report first quarter 2026 financial results; breast cancer expert will discuss the evorpacept + zanidatamab trial results in detail -

SOUTH SAN FRANCISCO, Calif., May 07, 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 data from exploratory analyses in the Phase 1b/2 clinical trial evaluating the company's investigational CD47-inhibitor evorpacept in combination with Jazz Pharmaceuticals' zanidatamab (ZIIHERA ®) in patients with heavily pre-treated HER2-positive metastatic breast cancer (mBC) were presented for the first time today in a poster session at the ESMO Breast Cancer 2026 congress. The findings show that patients with centrally confirmed HER2-positive (ccHER2-positive) mBC and high CD47 expression experienced a promising, durable response.

Specifically, patients in the trial with ccHER2-positive disease and high CD47 expression (defined as total membrane staining of ≥20%) had a confirmed objective response rate (cORR) of 100% (n=5/5), while the cORR was 25% (n=1/4) among those with lower CD47 expression (<20%). Those patients whose tumors expressed higher levels of CD47 also had longer median progression-free survival (mPFS): 22.1 months as compared to 3.4 months in the low-CD47 expression group. The median duration of response (mDOR) among patients whose tumors expressed high levels of CD47 was also notable at 20.2 months.

"There is a large and growing population of patients with advanced breast cancer who need novel treatment options once their disease has progressed following treatment with currently available therapies, including trastuzumab deruxtecan," said Funda Meric-Bernstam, M.D., Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center, who presented the findings today. "Our data suggest that adding evorpacept to HER2-targeted agents may provide one such option, and we may be able to optimize patient selection for these regimens by using a biomarker-driven approach that incorporates CD47."

The Phase 1b/2 open-label, multi-center clinical trial (NCT05027139) evaluating evorpacept plus zanidatamab included patients with heavily pre-treated HER2-positive mBC (median of five prior HER2-targeted therapies), all of whom had received prior ENHERTU therapy. The primary trial results, presented at the 2024 San Antonio Breast Cancer Symposium (SABCS), demonstrated that the investigational combination generated promising anti-tumor activity and a manageable safety profile.

The exploratory analyses comprised 24 patients, including 10 with ccHER2-positive disease. Seventeen of 24 samples were evaluable for CD47 expression, including samples from nine of the 10 ccHER2-positive patients. Patients received zanidatamab plus evorpacept at dosages of 20 mg/kg (n=3) or 30 mg/kg (n=21). As of the August 1, 2024 data cut-off, key findings from the analyses include:

- The cORR among all 24 patients was 33% and the mPFS was 3.6 months.
- Patients with ccHER2-positive disease (n=10) had higher response rates, with a cORR of 60% and mPFS of 8.3 months.
- All of the patients (n=5/5) with ccHER2-positive disease and high CD47 expression (defined as total membrane staining of ≥20%) responded (including one complete response and four partial responses), with an mDOR of 20.2 months and mPFS of 22.1 months. In comparison, among the patients with ccHER2-positive disease and low CD47 expression (defined as total membrane staining of <20%), cORR was 25% (n=1/4) and mPFS was 3.4 months.

"The findings from these exploratory analyses provide additional evidence that adding evorpacept to HER2-targeted therapies may generate durable responses in heavily pretreated HER2-positive breast cancers, including in patients in the post-ENHERTU setting," said Barbara Klencke, M.D., Chief Medical Officer at ALX Oncology. "They also further support the use of a biomarker-driven approach to predict treatment response, as we previously observed in the HER2-positive gastric cancer setting. We designed the ongoing ASPEN-09-Breast Phase 2 trial of evorpacept plus trastuzumab and chemotherapy to provide additional insight into this approach and, we hope, move closer to delivering a new therapeutic option for this group of patients."

Q1 2026 Results Conference Call and Webcast Details

ALX Oncology management will host a webcast tomorrow (Friday, May 8), to provide an overview of Q1 2026 financial results. Sara Hurvitz, M.D., will join the call to discuss and provide perspective on the Phase 1b/2 trial data shared at the ESMO Breast Cancer congress.

Date & Time: Friday, May 8, 2026, 8:30 a.m. ET
Guest Speaker: Sara Hurvitz, M.D., Professor, Senior Vice President and Director, Clinical Research Division and Smith Family Endowed Chair in Women's Health at Fred Hutchinson Cancer Center; Professor and Head, Division of Hematology and Oncology, Department of Medicine, University of Washington
Webcast Access: https://viavid.webcasts.com/starthere.jsp?ei=1758590&tp_key=2800839c82
Participant Listening Options by Phone: To access the conference call, please dial 1-877-407-0752 or +1-201-389-0912 and ask to be joined into the ALX Oncology First Quarter 2026 Financial Results Conference Call.

Another option for instant telephone access to the event is to use the Call Me™ link below:
https://callme.viavid.com/viavid/?callme=true&passcode=13755276&h=true&info=company&r=true&B=6

A live audio webcast of the call, along with the ALX Oncology corporate presentation, will be available under "Events & Presentations" in the Investor section of the Company's website, www.alxoncology.com. An archived webcast will be available on the Company's website after the event.

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. A Phase 1, dose-escalation trial of ALX2004 is ongoing in patients with EGFR-expressing solid tumors. More information is available at www.alxoncology.com and on LinkedIn.

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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