# ALX Oncology Reports Topline Data From ASPEN-06 Phase 2 Trial Demonstrating Evorpacept Improves Tumor Response in Patients With HER2-Positive Gastric Cancer

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- **Evorpacept is the first CD47 blocker to show durable clinical benefit and a well-tolerated safety profile in a prospective randomized trial**
- **Evorpacept combination achieved a confirmed overall response rate (ORR) of 40.3% compared to 26.6% for the control arm and demonstrated a median duration of response of 15.7 months compared to 7.6 months in the full trial population**
- **In the pre-specified population of patients with fresh HER2-positive biopsies, evorpacept combination showed the greatest benefit with ORR of 54.8% vs. 23.1% in the control, suggesting HER2-expression strongly correlates with evorpacept efficacy and validating its mechanism of action**
- **Company to host conference call and webcast today at 4:30 PM EDT**

SOUTH SAN FRANCISCO, Calif., July 31, 2024 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., (“ALX Oncology” or the “Company”) (Nasdaq: ALXO), an immuno-oncology company developing therapies that block the CD47 immune checkpoint pathway, today announced topline data from its Phase 2 ASPEN-06 clinical trial. The trial demonstrated clinically meaningful improvements in overall response rate and duration of response among patients with previously treated HER2-positive advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.

“The topline results from the ASPEN-06 clinical trial confirm the robust response that evorpacept can deliver, generating a clinically meaningful impact on key measures of anti-cancer activity for patients with gastric cancers and continuing to surpass benchmarks in the field,” said Jason Lettmann, chief executive officer at ALX Oncology. “Additionally, they provide valuable insight beyond the interim data previously reported, offering a more conclusive look at the impact of evorpacept and identifying the most responsive patient population. Importantly, the level of clinical benefit seen in this trial provides support for developing evorpacept in combination with anti-cancer antibodies in additional tumor types and drives ALX’s development strategy.”

ASPEN-06 is a randomized, multi-center, international trial evaluating evorpacept, ALX Oncology’s investigational CD47-blocking therapeutic that uniquely combines a high-affinity CD47-binding domain with an inactivated proprietary Fc domain, in combination with trastuzumab, CYRAMZA® (ramucirumab) and paclitaxel (collectively, TRP) against TRP alone for the treatment of patients with HER2-positive gastric/GEJ cancer, where all patients had received an anti-HER2 agent in prior lines of therapy. Patients in the trial (N=127) were generally well-balanced across arms based on pre-specified stratification factors including line of therapy, prior ENHERTU® (fam-trastuzumab deruxtecan-nxki) use, Asia region, tumor location (GC or GEJ), HER2 expression level (IHC3+ or IHC2+/ISH+) and HER2-positive biopsy (fresh or archival).

The trial’s primary endpoint is overall response rate (ORR). Key secondary endpoints are safety, median duration of response (mDOR), progression-free survival (PFS) and overall survival (OS).

**Key Phase 2 ASPEN-06 Clinical Trial Topline Results:**

- In the full intent-to-treat population (N=127), the addition of evorpacept to TRP demonstrated an ORR of 40.3% compared to the TRP control ORR of 26.6%
- In patients with fresh HER2-positive biopsies (n=48), evorpacept plus TRP demonstrated an ORR of 54.8% compared to 23.1% for the TRP control
- Median duration of response (DOR) in the evorpacept arm was 15.7 months [95% CI: 11.0; NE] compared to the TRP control of 7.6 months [95% CI: 6.3; NE] in the full intent-to-treat population
- Secondary endpoints of PFS and OS were immature at the time of analysis
- Evorpacept in combination with TRP was generally well tolerated and consistent with TRP control

“By meeting our clinically meaningful and pre-specified threshold of greater than 10% difference in response between the evorpacept treatment and control arms, these new data validate the mechanism of action and potential clinical utility of evorpacept for patients. Notably, this is now the first CD47 blocker to demonstrate clinical benefit and a well-tolerated safety profile in a

randomized trial," said Sophia Randolph, M.D., Ph.D., chief medical officer at ALX Oncology. "ASPEN-06 also provides valuable insights into responding patient populations and the importance of HER2 target expression that will inform our clinical program. These data represent a significant advancement for immuno-oncology."

The ASPEN-06 full data set will be submitted for presentation at an upcoming medical conference.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to evorpacept for the second-line treatment of patients with HER2-positive gastric or GEJ carcinoma. Additionally, both the FDA and European Commission have granted Orphan Drug Designation for this indication.

**Conference Call and Webcast on July 31 at 4:30 PM EDT**
The Company will host a conference call and webcast today at 4:30 PM EDT. To access the live conference call, please dial (800) 715-9871 (U.S./Canada) or +44.800.260.6466 (internationally) at least 10 minutes prior to the start time and refer to conference ID 9637001. The link to the live webcast of the conference call will be posted in the News & Events section (see "Events") of the Company's website at www.alxoncology.com. An archived replay will be accessible for 90 days following the event.

**About the ASPEN-06 Phase 2 Clinical Trial**
ASPEN-06 is a randomized Phase 2 (open-label) / Phase 3 (double-blinded), multi-center, international trial of patients with second- or third-line metastatic HER2-overexpressing gastric/GEJ adenocarcinoma that progressed on or after prior HER2-directed therapy and fluoropyrimidine- or platinum-containing chemotherapy (NCT05002127). HER2 status was determined by an FDA-approved test in the most recent gastric/GEJ cancer tissue sample. The primary analysis of the full intent-to-treat population included all randomized patients whose HER2 status was based on a tissue sample obtained at any time. An additional primary analysis was conducted on patients who had a recent HER2-positive tissue sample after prior anti-HER2 therapy ("fresh biopsy"). While trastuzumab is currently approved in combination with cisplatin and capecitabine/5-FU for HER2-positive gastric/GEJ cancers, it is not approved in combination with standard-of-care CYRAMZA + paclitaxel. The Phase 2 portion of the ASPEN-06 trial enrolled 127 patients. To determine the activity of evorpacept + trastuzumab + CYRAMZA + paclitaxel, in the Phase 2 portion of ASPEN-06, patients were randomized to receive either a four-drug combination regimen (evorpacept + trastuzumab + CYRAMZA + paclitaxel) or a three-drug combination regimen (trastuzumab + CYRAMZA + paclitaxel). This design enabled the assessment of evorpacept's contribution to the standard of care plus trastuzumab and to global standard of care, CYRAMZA + paclitaxel.

**About ALX Oncology**
ALX Oncology is a publicly traded, clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 immune checkpoint inhibitor and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, is a CD47 blocking therapeutic that combines a high-affinity CD47-binding domain with an inactivated, proprietary Fc domain. To date, evorpacept has been dosed in over 500 subjects and has demonstrated promising activity and favorable tolerability profile across a range of hematologic and solid malignancies in combination with various leading anti-cancer antibodies. ALX Oncology is currently focusing on combining evorpacept with anti-cancer antibodies, antibody-drug conjugates and PD-1/PD-L1 immune checkpoint inhibitors.

**Evorpacept's Unique Profile: Anchored by a Rational Design and Triple Development Pillars**
Rationally engineered with an inactive Fc effector function, evorpacept's clinical data to date have demonstrated a substantially improved safety profile over other anti-CD47 molecules in the clinic with an active Fc (i.e., binding the Fc gamma receptor on macrophages). This best-in-class safety profile allows for higher dosage with minimal overlapping toxicity in the combination treatment setting. CD47 expressed on cancer cells binds to its receptor SIRP alpha, which is predominantly expressed on two cell types: macrophages and dendritic cells. The Company's pipeline of therapeutic candidates with standard-of-care agents include:

- **Anti-cancer antibodies and ADCs (the "*don't eat me*" signal):** evorpacept enables Fc-mediated antibody-dependent phagocytosis by macrophages in combination with anti-cancer antibodies (e.g., Herceptin®) and ADCs (e.g., PADCEV and ENHERTU®) with an active Fc domain, which is otherwise impaired by CD47 expression on cancer cells binding to SIRP alpha on macrophages. Additionally, ADCs target the delivery of a chemotherapeutic payload to tumor cells to exert cytotoxic effects.
- **PD-1/PD-L1 immune checkpoint inhibitors (the "*don't activate T-cells*" signal)**: evorpacept enables T-cell activation by dendritic cells that are constitutively inhibited by CD47 expression on cancer cells binding to SIRP alpha on dendritic cells. Activated dendritic cells present neoantigens to T cells that once activated will kill cancer cells when the PD-1/PD-L1 inhibitory interaction is blocked by T-cell checkpoint inhibitors.

**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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