ALX Oncology Presents Positive Updated Data from ASPEN-06 Phase 2 Trial Demonstrating Evorpacept Generates Strong Response and Durable Clinical Benefit in Patients with HER2-Positive Gastric Cancer

January 23, 2025

- **Oral presentation at 2025 ASCO Gastrointestinal Cancers Symposium today highlights evorpacept as the first CD47 blocker to show substantial tumor response and a well-tolerated safety profile in a prospective randomized trial**
- **Greatest benefit observed among patients with confirmed HER2-positive cancer, as demonstrated by either fresh biopsy or ctDNA HER2-expression, with confirmed ORR of 48.9% and mDOR of 15.7 months vs. 24.5% ORR and mDOR of 9.1 months in the control group, and a PFS Hazard Ratio of 0.64**
- **Company to host conference call and investor webcast today at 1:00 PM PT/4:00 PM ET**

SOUTH SAN FRANCISCO, Calif., Jan. 23, 2025 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., (“ALX Oncology” or the “Company”) (Nasdaq: ALXO), a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer and extend patients’ lives, announced positive updated data from the ASPEN-06 Phase 2 clinical trial demonstrating that the company’s investigational CD47-blocker evorpacept generates a durable clinical response with a well-tolerated safety profile among patients with previously treated HER2-positive advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer. The updated results, which build upon previously announced topline results, will be shared today in an oral presentation (Abstract #332) at the 2025 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in San Francisco.

“The updated data from the ASPEN-06 trial highlight the potential clinical utility of CD47 inhibition from evorpacept in combination with trastuzumab, ramucirumab and paclitaxel in patients with previously treated HER2-positive gastric cancer,” said Kohei Shitara, M.D., Director of the Department of Gastrointestinal Oncology, National Cancer Center Hospital East, Kashiwa, Japan and the study’s presenter. “Overall, the findings suggest that evorpacept generates durable and clinically meaningful anti-tumor activity in this population of patients who had previously received a HER2-targeted agent, with the largest benefit among those patients with confirmed HER2-positive disease.”

ASPEN-06 is a randomized, multi-center, international trial (NCT05002127) 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, ETRP) against trastuzumab, ramucirumab and paclitaxel (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 were enrolled with either archival or fresh HER2-positive biopsies.

The trial’s primary endpoints were investigator-assessed overall response rate (ORR) in the intent-to-treat (ITT) population and in the population of patients with fresh HER2-positive biopsies, compared to both internal control (TRP) and historical control (ramucirumab and paclitaxel, or RP). Key secondary endpoints were safety, duration of response (DOR), progression-free survival (PFS) and overall survival (OS). The updated dataset being presented today includes results from a December 2, 2024 data cut, including an analysis that assessed patients with HER2-positive tumors via circulating tumor DNA (ctDNA) at baseline. Overall survival data were not yet mature at the time of data cut.

Updated trial results to be shared today at 2025 ASCO GI include:

- **Primary endpoints** (December data cut):
  - **ITT patient population ORR (N=127)**: Evorpacept plus TRP (ETRP) demonstrated an ORR of 41.3% compared to 30% for RP historical control and 26.6% for TRP control.
  - **Fresh HER2-positive biopsy patient population ORR (n=48)**: ETRP demonstrated an ORR of 59.1% compared to 30% for RP historical control and 23.1% for TRP control.
- In the ITT population, ETRP demonstrated a median DOR (mDOR) of 15.7 months and a median PFS (mPFS) of 7.5 months compared to an mDOR of 9.1 months and mPFS of 7.4 months in the TRP control group, with a PFS Hazard Ratio (HR) in this population of 0.77.
- In patients with fresh HER2-positive biopsies, ETRP demonstrated an mDOR of 15.7 months and mPFS of 9.5 months compared to an mDOR of 14.5 months and 7.1 months in the TRP control group, with a PFS HR of 0.62.
- In patients with confirmed HER2-positive expression as determined by either fresh biopsy or ctDNA HER2-positivity (n=96), the addition of evorpacept to TRP resulted in a 48.9% ORR, an mDOR of 15.7 months and mPFS of 7.5 months, compared to 24.5% ORR, an mDOR of 9.1 months and mPFS of 6.7 months in the TRP control group, with a PFS HR of

0.64.
- Evorpacept plus TRP was generally well tolerated, with the incidence of adverse events in the evorpacept population consistent with those in TRP control.

“The results from this trial tell a clear story that when a cancer cell is expressing HER2, evorpacept can combine with a regimen containing an anti-HER2 antibody such as trastuzumab to improve upon the activity you would expect from that regimen alone,” said Alan Sandler, M.D., Chief Medical Officer at ALX Oncology. “This is evidenced by the near doubling of PFS at one year among the patients with HER2-positivity confirmed via either fresh biopsy or ctDNA who received ETRP vs control. Additionally, the analysis of this patient population affirms HER2-expression is a key biomarker for evorpacept efficacy and validates the strategy behind evorpacept’s novel design.”

The updated ASPEN-06 data add to positive findings from a Phase 1b/2 trial recently presented at the 2024 San Antonio Breast Cancer Symposium (SABCS). These findings suggested that patients with heavily pretreated HER2-positive advanced breast cancer had anti-tumor activity from CD47 inhibition with evorpacept when it is combined with a HER2-targeted agent.

“The dataset shared today from the ASPEN-06 randomized clinical trial suggests durable clinical benefit driven by evorpacept and a differentiated safety profile – a first for any CD47 blocker,” said Jason Lettmann, Chief Executive Officer at ALX Oncology. “Based on the collective clinical data we’ve now seen across patients with HER2-positive gastric and breast cancers, we believe evorpacept is working as designed in combination with antibodies when there is HER2 expression, even when patients had been previously treated with other HER2-directed therapies. We look forward to sharing the updated ASPEN-06 data with the FDA and are confident in our path to pursue evorpacept as a therapeutic option for patients.”

A copy of the 2025 ASCO GI presentation will be available in the “Publications” section of the ALX Oncology website following the presentation.

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.

Company Conference Call and Webcast on January 23 at 1:00 PM PT/4:00 PM ET
ALX Oncology will host a conference call and webcast today at 1:00 PM PT/4:00 PM ET to review the updated ASPEN-06 data. The event will be webcast live and a replay will be available after the call by visiting the “Investors” section of ALX Oncology’s website and selecting “Events and Presentations”.

Date & Time: Thursday, January 23, 1:00 PM PT/4:00 PM ET
Webcast Access: https://edge.media-server.com/mmc/p/ipy66o44

About ALX Oncology
ALX Oncology (Nasdaq: ALXO) is a clinical-stage biotechnology company advancing therapies that boost the immune system 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. 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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