ALX Oncology Announces Nature Medicine Publication of ASPEN-06 Phase 2 Clinical Data Demonstrating Strong Responses and Durable Clinical Benefit with Evorpacept in HER2-Positive Gastric Cancer

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Achieved 40.3% ORR with evorpacept plus trastuzumab, ramucirumab and paclitaxel versus 26.6% for control, with response rates increasing to 63.6% versus 23.1% among patients with high CD47 expression and retained HER2-positive disease

Subgroup analyses support CD47 expression as a predictive biomarker

ASPEN-06 clinical findings further validate Company's biomarker-driven development strategy and reinforce its continued advancement in the ongoing Phase 2 ASPEN-09-Breast clinical trial

On track for mid-2027 topline data readout from 80 patients in Phase 2 ASPEN-09-Breast clinical trial evaluating evorpacept in combination with trastuzumab and chemotherapy in HER2-positive metastatic breast cancer

SOUTH SAN FRANCISCO, Calif., Sept. 28, 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, today announced the publication of clinical data from its ASPEN-06 randomized Phase 2 clinical trial in *Nature Medicine*.

The *Nature Medicine* publication, titled "Evorpacept plus trastuzumab, ramucirumab and paclitaxel in HER2-positive gastric cancer: a randomized phase 2 trial" can be accessed here. The data demonstrated that the Company's investigational CD47-blocker, evorpacept, generated encouraging efficacy with manageable safety among patients with previously treated HER2-positive advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.

"Publication of our ASPEN-06 data in *Nature Medicine,* a prestigious peer-reviewed scientific journal, further validates the clinical potential of evorpacept and reinforces our biomarker-driven development strategy," said Barbara Klencke, M.D., Chief Medical Officer of ALX Oncology. "Data from ASPEN-06 demonstrated that patients whose tumors retained HER2 expression and had high CD47 expression experienced the greatest benefit from evorpacept-based therapy, supporting our hypothesis that evorpacept can enhance the activity of HER2-directed treatment regimens and highlights CD47 expression as a potential predictive biomarker. These findings further strengthen our conviction in the ongoing Phase 2 ASPEN-09-Breast clinical trial in HER2-positive metastatic breast cancer, which remains on track for a topline data readout from 80 patients in mid-2027."

The ASPEN-06 clinical trial (NCT05002127) was a randomized Phase 2 (open-label)/3 (blinded), international, multi-center study, that evaluated evorpacept in combination with HERCEPTIN® (trastuzumab), CYRAMZA® (ramucirumab) and paclitaxel (TRP) compared with TRP alone (control), for patients with metastatic second- or third-line HER2 overexpressing GC/GEJ adenocarcinoma who have progressed on or after prior HER2-directed therapy and fluoropyrimidine- or platinum-containing chemotherapy, and who were suitable for chemotherapy. One hundred twenty-seven adult patients were enrolled in the Phase 2 portion of the study.

Results demonstrated that evorpacept plus TRP achieved an objective response rate (ORR) of 40.3% compared with 26.6% for TRP alone in the intent-to-treat (ITT) population. Among patients with retained HER2-positive disease, based either on a fresh tumor biopsy or *ERBB2* gene amplification detected in circulating tumor DNA (ctDNA), ORR increased to 48.9% versus 25.0% for the control arm.

Post-hoc biomarker analyses demonstrated CD47 expression as a potential predictive biomarker for evorpacept. Among patients with retained HER2-positive disease and elevated CD47 expression (≥5% CD47 IHC3+ staining), evorpacept plus TRP achieved an ORR of 63.6% compared with 23.1% for TRP alone, with improvements in median progression-free survival (PFS) to 19.5 months versus 7.0 months and median duration of response (DOR) of 25.5 versus 8.4 months, supporting further evaluation of CD47-guided patient selection in future studies.

In conclusion, findings from the randomized Phase 2 portion of the ASPEN-06 study suggest that evorpacept in combination with TRP may provide meaningful clinical benefit as a second- or third-line treatment for patients with GC or GEJ cancer with retained HER2 expression. Post-hoc analyses further suggest that this benefit may be enhanced in patients with high CD47 expression, supporting the proposed mechanism that both retained HER2 expression and elevated CD47 levels may be important drivers of efficacy through enhanced antibody-dependent cellular phagocytosis. Given the Company's disciplined focus and resource allocation priorities, ALX Oncology elected to not pursue a U.S. registrational path with a Phase 3 trial in GC and will consider exploring development partnerships to advance this program in gastric cancer. Importantly, findings from the ASPEN-06 study

further validate the Company's biomarker-driven development approach and support the ongoing Phase 2 ASPEN-09-Breast trial (NCT07007559) evaluating evorpacept in combination with trastuzumab and chemotherapy in patients with HER2-positive metastatic breast cancer, with topline data from 80 patients expected in mid-2027.

HERCEPTIN® and CYRAMZA® are the registered trademarks of their respective owners.

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 and X.

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, such as the ongoing Phase 2 ASPEN-09-Breast clinical trial in HER2-positive metastatic breast cancer, 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.

Investor Relations Contact:
Kevin Lui
Director, Investor Relations
kevin.lui@precisionaq.com

Media Contact:
Genevieve Britton
Senior Director, Public Relations
genevieve.britton@precisionaq.com