



ALX Oncology Announces Updated Data from Ongoing Clinical Trial (ASPEN-01) of Evorpaccept Showing Emerging Clinical Benefit in Survival-Based Endpoints in Patients with Advanced Solid Tumors

November 9, 2021

-- ORR of 72.2%, mDOR of 14.8 months, 12-month OS rate of 79%, and mOS of 17.1 months in Patients with \geq 2L HER2 Positive Gastric/Gastroesophageal Junction Cancer --

-- 12-month OS rate of 87.5% and mOS not reached in Patients with 1L Head and Neck Cancer --

-- 12-month OS rate of 80% and mOS of 24.5 months in Patients with Checkpoint Naïve \geq 2L Head and Neck Cancer --

-- ALX Oncology to Host Conference Call on November 9 at 8:00 a.m. EST --

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc. ("ALX Oncology") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, today announced updated results from ASPEN-01, an ongoing evorpaccept phase 1b study, evaluating patients with solid tumor malignancies at the Society for Immunotherapy of Cancer's ("SITC") 36th Anniversary Annual Meeting [abstract 498].

ALX Oncology reports updated results from both cohorts: the gastric/gastroesophageal junction cancer ("GC") patient cohort receiving evorpaccept plus trastuzumab plus chemotherapy, and from the head and neck squamous cell carcinoma ("HNSCC") patient cohort receiving evorpaccept plus pembrolizumab with and without chemotherapy. All data reflect response evaluable patients as of September 1, 2021. The SITC 36th Anniversary Annual Meeting poster is available to download under "Publications" in the Science section of the ALX Oncology website at www.alxoncology.com.

- In patients with \geq 2L HER2 positive GC (n=18), evorpaccept in combination with trastuzumab plus ramucirumab and paclitaxel demonstrated an initial objective response rate ("ORR") of 72.2% with a median duration of response ("mDOR") of 14.8 months, a 12-month overall survival ("OS") rate of 79%, and a median overall survival ("mOS") of 17.1 months. These results compare favorably with the clinical experience of both ramucirumab + paclitaxel and trastuzumab-deruxtecan in similar populations.
- In patients with 1L HNSCC who have not received prior treatment for their advanced disease (n=13), evorpaccept demonstrates an initial ORR of 38.5% with a 12-month OS rate of 87.5% and mOS not reached in combination with pembrolizumab + 5FU + platinum. These results compare favorably with benchmark survival data from standard pembrolizumab + chemotherapy in the 1L HNSCC setting where ORR is a less reliable predictor for clinical benefit compared to longer-term metrics such as 12-month OS rate and mOS (the gold standard of clinical benefit) in patients with aggressive disease.
- In patients with \geq 2L HNSCC who have not received a prior checkpoint inhibitor ("CPI") (n=10), long-term follow-up data shows that evorpaccept + pembrolizumab demonstrates a 12-month OS rate of 80% with a mOS of 24.5 months, which compares favorably with standard pembrolizumab therapy in patients with 2L CPI naïve HNSCC.
- Preliminary data suggest that evorpaccept is well tolerated when combined with the multi-agent chemotherapy regimens studied with no maximum tolerated dose reached.

"These updated data provide growing support that evorpaccept in combination with the standard regimens studied may translate into a meaningful survival benefit in patients with advanced HNSCC and GC who historically have poor outcomes," said Keun-Wook Lee, M.D., Ph.D., Professor of Seoul National University College of Medicine and Director of Clinical Trials Center, Seoul National University Bundang Hospital, Seoul, Korea.

"The consistency and predictive value of evorpaccept's emerging survival-based data in aggressive solid tumor diseases is highly encouraging," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "We are excited to investigate the impact of evorpaccept on these longer-term measures of clinical benefit in our randomized phase 2 programs in patients with HNSCC (ASPEN-03 and ASPEN-04) and GC (ASPEN-06)."

Conference Call on November 9th at 8:00 a.m. EST

ALX Oncology will host a conference call on Tuesday, November 9, 2021 at 8:00 a.m. EST to further discuss the recent GC and

HNSCC data from ASPEN-01, the Phase 1b study of evorpacept that was presented at the SITC 36th Anniversary Annual Meeting. In addition to ALX Oncology's executive management team, Dr. Kevin Harrington, Professor of Biological Cancer Therapies and Head of the Division of Radiotherapy and Imaging at the Institute of Cancer Research, London, UK will be featured on the call to discuss the latest evorpacept clinical data in HNSCC patients.

To access the conference call, please dial (844) 467-7655 (U.S./Canada) or (409) 983-9840 (international) at least 10 minutes prior to the start time and refer to conference ID 1291278. Presentation slides will be available to download under "News & Events" (see "Events") in the Investors section of the ALX Oncology website at www.alxoncology.com.

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 checkpoint pathway and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpacept has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies, including acute myeloid leukemia and myelodysplastic syndromes.

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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