ALX Oncology Provides Corporate Update and Highlights Key Milestones in 2023

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SOUTH SAN FRANCISCO, Calif., Jan. 05, 2023 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today provided a corporate update and highlighted key milestones anticipated in 2023.

"2022 marked a successful year of continued clinical and corporate accomplishments for ALX Oncology. Marked by steady progress in the clinical development of our lead program, evorpacept, for the treatment of multiple solid tumor indications and hematological malignancies, we expanded clinical development of evorpacept in new indications and combinations. These included a Phase 1 trial in urothelial cancer ("UC") in combination with PADCEV ®, an investigator-sponsored Phase 2 trial in refractory microsatellite stable metastatic colorectal cancer in combination with ERBITUX® and KEYTRUDA®, and a new investigational treatment arm in the I-SPY-P1 trial for the treatment of patients with unresectable or metastatic HER2-positive and HER2-low breast cancer in combination with ENHERTU® and in partnership with Quantum Leap Healthcare Collaborative. 2023 is expected to be an exciting year for ALX Oncology as we look forward to the presentation of data from ASPEN-06, a randomized Phase 2 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-positive gastric/gastroesophageal junction ("GEJ") cancer and presentation of dose optimization results from ASPEN-02, a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with myelodysplastic syndromes ("MDS"). We are also on track to file an Investigational New Drug ("IND"), in collaboration with Tallac Therapeutics, for ALTA-002 that will further expand our clinical pipeline beyond evorpacept," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology.

Key Clinical Accomplishments in 2022

- Presented initial clinical data from the Phase 1a dose escalation portion of the ASPEN-05 trial evaluating evorpacept in combination with azacitidine and venetoclax for the treatment of patients with relapsed or refractory ("r/r") or new diagnosed ("ND") acute myeloid leukemia ("AML") at the American Society of Hematology ("ASH") annual meeting.
- Presented trial in progress poster from ASPEN-03 and ASPEN-04, the Company's Phase 2 head and neck squamous cell carcinoma ("HNSCC") studies, at the Society for Immunotherapy of Cancer ("SITC") annual meeting. ALX Oncology continues to advance ASPEN-03 and ASPEN-04, which are two distinct randomized Phase 2 studies for the treatment of patients with advanced HNSCC in combination with KEYTRUDA (pembrolizumab) with or without chemotherapy. Patient enrollment for ASPEN-03 and ASPEN-04 continues as planned.
- Announced a new investigational treatment arm in the I-SPY-P1 TRIAL in collaboration with Quantum Leap Healthcare Collaborative, for the treatment of patients with unresectable or metastatic HER2-positive and HER2-low breast cancer. A Phase 1 (open-label), multi-center study arm will investigate evorpacept in combination with ENHERTU (fam-trastuzumab deruxtecan-nxki), a HER2 directed antibody-drug conjugate ("ADC"), to determine the safety, tolerability and efficacy of this drug combination.
- Dosed first patient in a Phase 2 investigator-sponsored trial of evorpacept in combination with ERBITUX (cetuximab) and pembrolizumab in patients with mCRC who have progressed on at least two lines of systemic therapy.
- The Food and Drug Administration ("FDA") granted Fast Track designation to evorpacept in combination with pembrolizumab for the first-line treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC, which is the second Fast Track designation granted in HNSCC. Previously the FDA granted Fast Track designation for evorpacept in combination with pembrolizumab, platinum, and fluorouracil for the first-line treatment of adult patients with metastatic or unresectable, recurrent HNSCC.
- FDA granted Orphan Drug Designation ("ODD") to evorpacept for the treatment of patients with AML.
- Initiated ASPEN-07, a Phase 1 trial of evorpacept for the treatment of patients with UC. ASPEN-07 will investigate evorpacept in combination with an antibody-drug conjugate ("ADC"), PADCEV ® (enfortumab vedotin-ejfv).
- Began enrolling patients in ASPEN-06, a Phase 2/3 study evaluating the combination of evorpacept and CYRAMZA® (ramucirumab), Eli Lilly and Company's anti-VEGFR2 antibody, added to HERCEPTIN ® (trastuzumab) and paclitaxel for the treatment of patients with HER2-positive gastric/GEJ cancer.

- FDA granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer.

Key Corporate Accomplishments in 2022

- Entered into a loan facility with Oxford Finance LLC and Silicon Valley Bank for up to $100 million of non-dilutive financing. Under the terms of the loan agreement, ALX Oncology drew $10 million of an initial $50 million tranche at closing, with the remaining $40 million available at its discretion through the end of 2023. ALX Oncology also has access up to an additional $50 million with $12.5 million available in each of two tranches based upon the achievement of milestones related to the development of evorpacept and one pre-clinical product candidate, and $25 million available at the Lenders' discretion.
- Strengthened board of directors by adding two independent board members with significant operational and commercial leadership experience in the biopharmaceutical industry:
    - Itziar Canamasas, Ph.D., most recently the Head of Oncology EMEA and Commercial Lead for Oncology for Bayer Consumer Care AG and has more than 20 years of biopharmaceutical experience with Bayer and brings expertise in driving business growth and operational excellence.
    - Scott Garland, currently CEO of Pact Pharma and previously CEO of Portola Pharmaceuticals, has more than 30 years of biopharmaceutical industry knowledge and brings deep commercial and executive leadership experience.

Anticipated Milestones in 2023

- Presentation of data from a randomized Phase 2 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-positive gastric/GEJ cancer (ASPEN-06) in the second half of 2023.
- Presentation of dose optimization results of a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with MDS (ASPEN-02) in the second half of 2023.
- Initiation of a Phase 1b dose optimization clinical trial of evorpacept in combination with azacitidine and venetoclax for the treatment of patients with r/r or ND AML (ASPEN-05) in the second half of 2023.
- Initiation of a Phase 1 trial of evorpacept in combination with antibody drug conjugate, PADCEV® (enfortumab vedotin-ejfv), for the treatment of patients with UC (ASPEN-07) in the first half of 2023.
- Filing an IND for ALTA-002, a SIRPα Toll-like receptor agonist antibody conjugate ("TRAAC") in collaboration with Tallac Therapeutics in the first half of 2023.
- Expansion of the ADC platform acquired from ScalmiBio to identify clinical development candidates by the second half of 2023.

Cash Position and Financial Guidance

- ALX Oncology ended the third quarter 2022 with approximately $293.1 million in cash and cash equivalents. The Company expects that its cash, and cash equivalents, investments and the $50 million to which it has access under its term loan are sufficient to fund planned operations through mid-2025.

Upcoming Presentation at 41st Annual J.P. Morgan Healthcare Conference

ALX Oncology will present at the 41st Annual J.P. Morgan Healthcare Conference on Tuesday, January 10, 2023 at 10:30 am PT at the Westin St. Francis in San Francisco. A live webcast of the presentation will be available here and can be accessed by visiting the Investors section of ALX Oncology's website at www.alxoncology.com and selecting Events under the News and Events tab. A replay of the webcast will be archived for up to 30 days following the presentation date.

About ALX Oncology

ALX Oncology is a 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 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 commercial anti-cancer agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies.

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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