ALX Oncology Reports Third Quarter 2022 Financial Results and Provides Clinical Development and Operational Highlights

November 8, 2022

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2022 (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 reported financial results for the third quarter ended September 30, 2022 and provided clinical development and operational highlights.

“We continued to expand the clinical development of our lead program, evorpacept, during the third quarter of 2022, with the announcement of 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 partnership with Quantum Leap Healthcare Collaborative,” said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. “With our recently announced non-dilutive term loan facility expected to extend our cash runway to mid-2025, we are focused on the advancement of evorpacept through multiple clinical milestones over the next two years.”

Recent Clinical Developments for Evorpacept

- **Abstract Data for Phase 1 Dose Escalation Portion of ASPEN-05 Study in acute myeloid leukemia (“AML”) Released as Part of the 64th American Society of Hematology (“ASH”) Annual Meeting**
  - In November 2022, ALX Oncology’s ASH abstract was released online with initial results of the Phase 1 dose escalation portion of ASPEN-05, a Phase 1/2 clinical trial of evorpacept in combination with venetoclax and azacitidine for the treatment of patients with AML. Session 616: Poster III; Publication Number: 4076.
  - The results presented were as of July 8, 2022. 14 subjects were treated at evorpacept doses of 20 mg/kg Q2W (N=4), 30 mg/kg Q2W (N=4), and 60 mg/kg Q4W (N=6). The addition of evorpacept to standard dose venetoclax and azacitidine for AML was well tolerated with no maximum tolerated dose reached. Preliminary dose-proportional pharmacokinetics was seen along with full CD47 target occupancy in both peripheral blood and bone marrow across all dose levels evaluated. Initial anti-leukemic activity was observed in subjects with both newly diagnosed and relapse refractory AML. These initial results support further evaluation of evorpacept in myeloid malignancies, including AML.
  - A poster presentation from the dose escalation portion of ASPEN-05 with updated results will be presented at the ASH Annual Meeting on Monday, December 12, 2022, 6:00pm to 8:00pm CT, at the Ernest N. Morial Convention Center, Hall D, New Orleans, LA.
- **Trials in Progress Abstracts Related to Data from ASPEN-03 and ASPEN-04 Clinical Trials Accepted for Poster Presentation at the Society for Immunotherapy of Cancer (“SITC”) 37th Annual Meeting**
  - In October 2022, ALX Oncology announced the acceptance of two Trials in Progress abstracts related to ASPEN-03 and ASPEN-04, the Company’s Phase 2 head and neck squamous cell carcinoma (“HNSCC”) studies which will be presented at SITC in Boston, MA, from November 10–11, 2022 (abstracts 678 and 676).
  - 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 with results expected to be presented by the middle of 2024.
- **Clinical Trial Agreement in Combination with ENHERTU® (Fam-trastuzumab deruxtecan-nxki) Entered with Quantum Leap**
  - In August 2022, ALX Oncology entered into a collaboration and supply agreement with Quantum Leap Healthcare Collaborative™ (“Quantum Leap”) to evaluate evorpacept for 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.
  - Sponsored by Quantum Leap, this 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, to determine the safety, tolerability and efficacy of this drug combination.
- **First Patient Dosed in Phase 2 Investigator-sponsored Trial of Evorpacept in Combination with ERBITUX® (Cetuximab) and KEYTRUDA (Pembrolizumab) in Patients with Advanced Colorectal Cancer**
  - In August 2022, ALX Oncology announced the initiation of a Phase 2 investigator-sponsored study of evorpacept in combination with ERBITUX (cetuximab) and KEYTRUDA (pembrolizumab), Merck’s anti-PD-1 therapy, in patients with refractory microsatellite stable metastatic colorectal cancer who have progressed on at least two lines of

systemic therapy. This trial, managed by Criterium, Inc., is led by the Academic GI Cancer Consortium.

- **Additional Clinical Program Updates for Evorpacept**
  - In June 2022, ALX Oncology announced the initiation of ASPEN-07, a Phase 1 trial of evorpacept for the treatment of patients with urothelial cancer ("UC"), with the first patient expected to be dosed in the fourth quarter of 2022. ASPEN-07 will investigate evorpacept in combination with an antibody drug conjugate, PADCEV® (enfortumab vedotin-ejfv), for the treatment of patients with UC.
  - ALX Oncology continues to advance ASPEN-06, a randomized Phase 2 (open-label) / Phase 3 (double-blind), international, multi-center study to evaluate the efficacy of evorpacept and ramucirumab added to trastuzumab and paclitaxel for the treatment of patients with HER-positive gastric cancer or gastroesophageal junction cancer whose tumors have progressed following treatment with HER2-targeted therapy and chemotherapy. ASPEN-06 is being conducted in collaboration with Eli Lilly and Company. Patient enrollment continues to progress and results from the Phase 2 portion of ASPEN-06 are expected to be presented in 2023.

Recent Corporate Updates

- **Loan Facility Agreement with Oxford Finance LLC and Silicon Valley Bank of up to $100 Million of Non-dilutive Financing**
  - In October 2022, 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.

Third Quarter 2022 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments were $293.1 million as of September 30, 2022. ALX Oncology believes its cash, cash equivalents, investments and the ability to draw down up to $50 million of its term loan are sufficient to fund planned operations through mid-2025.
- **Research and Development ("R&D") Expenses:** These expenses for the three months ended September 30, 2022 were $29.4 million, compared to $18.2 million for the prior-year period. Research and development expenses increased by $11.2 million during the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily attributable to an increase of $6.0 million in clinical and development costs primarily due to clinical costs from an increase in the number of active trials and patient enrollment as well as manufacturing of clinical trial materials to support a higher number of active clinical trials and future expected patient enrollment related to the advancement of our lead product candidate, as well as expenses related to the Tallac Collaboration for costs related to the IND filing planned for 2023, an increase of $0.9 million in preclinical costs primarily related to development of new targets, an increase of $2.0 million in personnel and related costs primarily due to an increase driven by headcount growth and a portion of a retention bonus payable to ScalmiBio stockholders, an increase of $1.4 million in stock-based compensation expense due to additional awards granted since September 30, 2021 and an increase of $0.9 million in other research costs due primarily to an increase in facility costs related to the expansion of our new laboratory space.
- **General and Administrative ("G&A") Expenses:** These expenses for the three months ended September 30, 2022 were $7.3 million, compared to $6.4 million for the prior-year period. General and administrative expenses increased by $0.9 million during the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily attributable to an increase of $0.6 million in stock-based compensation expense due to additional stock option awards granted since September 30, 2021 and an increase in facility and information technology costs.
- **Net loss:** GAAP net loss was $35.3 million for the third quarter ended September 30, 2022, or $0.87 per basic and diluted share, as compared to a net loss of $24.6 million for the third quarter ended September 30, 2021, or $0.61 per basic and diluted share. Non-GAAP net loss was $29.1 million for the third quarter ended September 30, 2022, as compared to a net loss of $20.4 million for the third quarter ended September 30, 2021. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.

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.

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.

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 29,382	$ 18,214	$ 73,203	$ 39,276
General and administrative	7,299	6,362	22,014	15,807
Total operating expenses	36,681	24,576	95,217	55,083
Loss from operations	(36,681)	(24,576)	(95,217)	(55,083)
Interest income	1,370	22	2,471	70
Other expense, net	(9)	(12)	(27)	(12)
Net loss	$ (35,320)	$ (24,566)	$ (92,773)	$ (55,025)
Net loss per share, basic and diluted	$ (0.87)	$ (0.61)	$ (2.28)	$ (1.37)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	40,747,026	40,396,188	40,684,172	40,234,159

Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 293,126	$ 363,667
Total assets	$ 317,689	$ 380,183
Total liabilities	$ 30,726	$ 17,134
Accumulated deficit	$ (294,758)	$ (201,985)
Total stockholders' equity	$ 286,963	$ 363,049

GAAP to Non-GAAP Reconciliation
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net loss, as reported	$ (35,320)	$ (24,566)	$ (92,773)	$ (55,025)
Adjustments:				
Stock-based compensation expense	6,207	4,191	17,544	8,228
Non-GAAP net loss	$ (29,113)	$ (20,375)	$ (75,229)	$ (46,797)

Use of Non-GAAP Financial Measures

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered "non-GAAP" financial measures under applicable SEC rules. We believe that the disclosure of these non-GAAP financial measures provides our investors with additional information that reflects the amounts and financial basis upon which our management assesses and operates our business.

These non-GAAP financial measures are not in accordance with generally accepted accounting principles and should not be viewed in isolation or as a substitute for reported, or GAAP, net loss, and are not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

“Non-GAAP net loss attributable to common stockholders” is not based on any standardized methodology prescribed by GAAP and represent GAAP net loss adjusted to exclude stock-based compensation expense. Non-GAAP financial measures used by ALX Oncology may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

Investor Contact: Peter Garcia Chief Financial Officer, ALX Oncology (650) 466-7125 Ext. 113 peter@alxoncology.com Argot Partners (212) 600-1902 alxoncology@argotpartners.com Media Contact: Karen Sharma MacDougall (781) 235-3060 alx@macbiocom.com