ALX Oncology Reports Third Quarter 2021 Financial Results and Provides Clinical Development and Operational Highlights

November 11, 2021

SOUTH SAN FRANCISCO, Calif., Nov. 11, 2021 (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, 2021 and provided clinical development and operational highlights.

"The third quarter was marked by substantial progress advancing our lead program, evorpacept (ALX148) through multiple clinical trials," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "Highlights include reporting new data at the ESMO conference from ASPEN-01, our Phase 1b trial testing evorpacept with trastuzumab, ramucirumab and paclitaxel in ≥2nd line HER2-positive gastric or gastroesophageal junction cancer. We also dosed the first patient in ASPEN-04, our Phase 2 trial testing evorpacept in combination with pembrolizumab and chemotherapy for 1st line patients with unresectable or metastatic squamous cell carcinoma of the head and neck. Subsequent to the quarter end, we dosed the first patients in our ASPEN-05 Phase 1/2 study in acute myeloid leukemia and in our Phase 1/2 collaboration with Zymeworks, which is evaluating the combination of evorpacept and zanidatamab in patients with HER2-positive breast cancer and other solid tumors. On the business development front, in October, we acquired privately-held ScalmiBio, giving us full access to their proprietary SHIELD platform for conditional activation of antibodies in the tumor microenvironment and proprietary cytotoxic payloads for antibody-drug conjugates."

"Looking ahead, we expect a data-filled fourth quarter, which will include four poster presentations at the upcoming SITC conference, including data from ASPEN-01, which we presented on November 9, the trial designs from both our Phase 2 head and neck cancer studies in collaboration with Merck (ASPEN-03 and ASPEN-04) and preclinical data for ALTA-002, a first in class SIRPa-directed TLR9 agonist antibody conjugate being developed in collaboration with Tallac Therapeutics," Dr. Pons continued. "Later this quarter, we expect to report additional Phase 1b data from ASPEN-02 in myelodysplastic syndromes, and the initiation of ASPEN-06, our randomized Phase 2 trial in second line gastric cancer," Dr. Pons continued.

Recent Clinical Developments for Evorpacept (ALX148)

- **Data for Phase 1b ASPEN-01 Study Presented at Society for Immunotherapy of Cancer's 36 th Anniversary Annual Meeting**
  - In November 2021, announced updated results from ASPEN-01, the evorpacept phase 1b study, evaluating patients with solid tumor malignancies at the Society for Immunotherapy of Cancer's 36 th Anniversary Annual Meeting (abstract 498). ALX Oncology reported updated results from the gastric/gastroesophageal junction cancer patient cohort receiving evorpacept plus trastuzumab plus chemotherapy, and from the head and neck squamous cell carcinoma patient cohort receiving evorpacept plus pembrolizumab with and without chemotherapy. Data showed robust and durable responses with emerging signs of clinical benefit in survival-based endpoints in patients with advanced solid tumors. All data reflected response evaluable patients as of September 1, 2021.

- **Abstract Data for Phase 1/2 ASPEN-02 Study in Myelodysplastic Syndromes Released as part of the 63rd American Society of Hematology ("ASH") Annual Meeting**
  - In November 2021, presented an ASH abstract and updated data evaluating evorpacept in combination with azacitidine for the treatment of myelodysplastic syndromes ("MDS"). Among the 5 newly diagnosed subjects evaluable for response (all with TP53 mutation), there were 2 subjects with cytogenetic response who met criteria for complete response subsequent to the date of this abstract, 1 subject with a best response of marrow complete response with hematologic improvement, and 1 subject each with stable disease and progressive disease. No dose-limiting toxicities were observed in any cohort and no maximum tolerated dose was reached. Additional results will be presented in a poster at the ASH meeting to be held December 11-14 conference (Session 637: Poster II).

- **First Patient Dosed in Phase 1/2 ASPEN-05 Study**
  - In October 2021, dosed first patient in the Phase 1/2 ASPEN-05 study evaluating the combination of evorpacept with venetoclax and azacitidine for the treatment of patients with AML. The Phase 1 portion will characterize the dose of evorpacept in combination with venetoclax and azacitidine for the treatment of patients with

relapsed/refractory AML and previously untreated AML who are not candidates for intensive induction therapy.

- **First Patient Dosed in Phase 1b/2 Clinical Trial of Zanidatamab and Evorpacept in Patients with Advanced HER2-Expressing Breast Cancer and Other Solid Tumors**

    - In October 2021, Zymeworks and ALX Oncology dosed the first patient in an open-label, multi-center Phase 1b/2 clinical trial to evaluate the safety and efficacy of zanidatamab, Zymeworks' lead HER2-targeted bispecific antibody, in combination with evorpacept in patients with advanced HER2-positive breast cancer, HER2-low breast cancer and additional non-breast HER2-expressing solid tumors.

- **Initiation of a Phase 1/2 Investigator-Sponsored Trial of Evorpacept in Patients with Indolent and Aggressive Non-Hodgkin Lymphoma ("NHL")**

    - In September 2021, initiated a Phase 1/2 investigator-sponsored trial of evorpacept in combination with rituximab and lenalidomide for the treatment of patients with indolent and aggressive NHL. The study is being led by Dr. Paolo Strati at the University of Texas M.D. Anderson Cancer Center, one of the largest multidisciplinary programs in the U.S. for treating NHL.

Recent Corporate Updates

- **Acquisition of ScalmiBio Expands ALX Oncology's Immuno-Oncology Pipeline**

    - In October 2021, ALX Oncology acquired ScalmiBio thus further expanding its pipeline with plans to develop novel antibody-drug conjugates ("ADCs") based on ScalmiBio's SHIELD platform. These new molecules will be designed to address unmet cancer patient needs as stand-alone therapeutics and in combination with evorpacept. ScalmiBio's SHIELD technology is designed to minimize interaction of an antibody therapeutic with normal tissue and maximize its target binding capability within the tumor microenvironment. ScalmiBio's conditional activation technology aims to increase the therapeutic index by minimizing dose-limiting toxicities of existing checkpoint inhibitors and other targeted anti-cancer biologics as well as enabling the design of ADCs with higher drug-to-antibody ratios for improved anti-cancer activity.

    - Under the terms of the share purchase agreement, ALX Oncology made an initial payment to the stockholders of ScalmiBio at closing on October 4, 2021 of approximately $4.5 million in cash, net of certain expenses and adjustments, and will make an additional payment of $2.0 million in cash at the one-year anniversary of the transaction subject to certain conditions. In addition, ALX Oncology has agreed to pay certain milestones based on the clinical development of the acquired ScalmiBio technology and a low single digit royalty on net sales of any products developed from the ScalmiBio acquired technology for a defined term.

Third Quarter 2021 Financial Results:

- **Cash and Cash Equivalents:** Cash and cash equivalents as of September 30, 2021 were $385.1 million. ALX Oncology believes its cash and cash equivalents is sufficient to fund planned operations through 2024.

- **Net Loss:** Generally accepted accounting principles (GAAP) net loss attributable to common stockholders was $24.6 million, or $0.61 per basic and diluted share and $10.8 million, or $0.36 per basic and diluted share for the three months ended September 30, 2021, and 2020, respectively. Non-GAAP net loss attributable to common stockholders was $20.4 million for the three months ended September 30, 2021, as compared to $9.7 million for the three months ended September 30, 2020. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.

- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of our current lead product candidate, evorpacept. These expenses for the three months ended September 30, 2021, were $18.2 million compared to $5.3 million for the prior-year period. The increase of $12.9 million was primarily attributable to an increase of $10.0 million in clinical and development costs due to $8.7 million higher expenses associated with increased clinical costs mainly associated with higher number of active clinical trials and increased patient enrollment and other research costs in advancement of our current lead product candidate, evorpacept, $0.8 million related to collaborations, of which $0.6 million was related to the Tallac Collaboration, and $0.3 million related regulatory consulting expenses; an increase of $1.9 million in stock-based compensation expense mainly due to additional stock option awards granted in 2021 at higher fair values and negative stock-based compensation expense due to a reduction recorded in corresponding prior period; and an increase of $0.9 million in personnel expense driven by headcount growth.

- **General and Administrative ("G&A") Expenses:** G&A expenses consist primarily of administrative employee-related expenses, legal and other professional fees, patent filing and maintenance fees, and insurance. These expenses for the three months ended September 30, 2021, were $6.4 million compared to $4.5 million for the prior-year period. The increase of $1.9 million was primarily attributable to an increase of $1.6 million in stock-based compensation driven by additional stock option awards granted in 2021 at higher fair values, with the remaining increase due to other general and administrative costs including corporate legal fees, general business insurance fees, and SOX 404 compliance expenses.

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 (also known as ALX148), 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 malignances, including acute myeloid leukemia and myelodysplastic syndromes.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. 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 statements include, but are not limited to, statements regarding ALX Oncology's financial condition, results of operations and sufficiency of its cash and cash equivalents to fund its planned operations as well as statements about ALX Oncology's clinical pipeline, including the timing of clinical trial initiations and data releases, and the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of evorpacept. 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 Report on Form 10-K, filed with the SEC on March 18, 2021, and other documents ALX Oncology subsequently 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 and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Related-party revenue	$ —	$ —	$ —	$ 1,182
Operating expenses:				
Research and development	18,214	5,328	39,276	16,819
General and administrative	6,362	4,481	15,807	9,126
Cost of services for related-party revenue	—	—	—	1,075
Total operating expenses	24,576	9,809	55,083	27,020
Loss from operations	(24,576)	(9,809)	(55,083)	(25,838)
Interest expense	(4)	(226)	(10)	(660)
Other income (expense), net	14	(111)	68	(409)
Loss before income taxes	(24,566)	(10,146)	(55,025)	(26,907)
Income tax provision	—	(35)	—	(59)
Net loss and comprehensive loss	(24,566)	(10,181)	(55,025)	(26,966)
Cumulative dividends allocated to preferred stockholders	—	(578)	—	(5,202)
Net loss attributable to common stockholders	$ (24,566)	$ (10,759)	$ (55,025)	$ (32,168)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (0.36)	$ (1.37)	$ (2.67)
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	40,396,188	29,664,122	40,234,159	12,052,876

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 385,149	$ 434,219
Total assets	$ 399,728	$ 436,054
Total liabilities	$ 14,556	$ 6,209

Total stockholders' equity	$ 385,172	$ 429,845

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, as reported	$ (24,566)	$ (10,759)	$ (55,025)	$ (32,168)
Adjustments:				
Stock-based compensation expense	4,191	689	8,228	3,693
Accretion of term loan	—	118	—	339
Mark-to-market adjustment on financial instruments	—	242	—	650
Total adjustments	4,191	1,049	8,228	4,682
Non-GAAP net loss attributable to common stockholders	$ (20,375)	$ (9,710)	$ (46,797)	$ (27,486)

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 Securities and Exchange Commission 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 (1) stock-based compensation expense, (2) accretion of term loan (interest expense related to ALX Oncology's amortization of debt discount) and (3) mark-to-market adjustment on financial instruments (which include preferred stock warrants and derivatives). 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.

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