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

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SOUTH SAN FRANCISCO, Calif., Aug. 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 second quarter ended June 30, 2022 and provided clinical development and operational highlights.

"The second quarter of 2022 was marked by substantial progress advancing our lead program, evorpacept, through multiple clinical trials," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "Notable accomplishments included the U.S. Food and Drug Administration ("FDA") granting Fast Track designation to evorpacept for the first-line treatment of adult patients with PD-L1 positive advanced head and neck squamous cell carcinoma ("HNSCC") in combination with KEYTRUDA ® (pembrolizumab), Merck's anti-PD-1 therapy, and Orphan Drug Designation ("ODD") to evorpacept for the treatment of patients with acute myeloid leukemia ("AML")."

"We continue to expand our clinical development efforts with the introduction of a new clinical study, ASPEN-07, a Phase 1 trial of evorpacept for the treatment of patients with urothelial carcinoma ("UC") and anticipate initiation in the fourth quarter of 2022. We are continuing enrollment in ASPEN-03 and ASPEN-04, two distinct Phase 2 studies for the treatment of patients with advanced HNSCC. In addition, we continue to advance ASPEN-06, our Phase 2/3 study testing evorpacept and CYRAMZA® (ramucirumab), Eli Lilly and Company's anti-VEGFR2 antibody, added to trastuzumab and paclitaxel for the treatment of patients with HER2-positive gastric cancer or gastroesophageal junction ("GEJ") cancer," Dr. Pons continued.

Recent Clinical Developments for Evorpacept

- **FDA Granted Fast Track Designation as First-Line Treatment for HNSCC**
  - In August 2022, ALX Oncology announced that the FDA granted Fast Track designation to evorpacept, a next-generation CD47 blocker, in combination with KEYTRUDA (pembrolizumab) for the first-line treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC.
  - 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 mid-2024.
- **FDA Granted ODD for Evorpacept for the Treatment of Patients with AML**
  - In June 2022, ALX Oncology announced that the FDA granted ODD to evorpacept for the treatment of patients with AML.
  - 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, has successfully completed enrollment with no safety concerns to date up to the highest protocol defined dose level of 60 mg/kg evorpacept once every four weeks.
  - Patient enrollment was paused before proceeding into the Phase 1 dose optimization portion of ASPEN-05 pending completion of the Phase 1 portion of ASPEN-02, a Phase 1/2 study of evorpacept in combination with azacitidine in patients with myelodysplastic syndrome ("MDS"). Data from ASPEN-02 will be used to inform the optimal dose(s) of evorpacept to be studied in the ASPEN-05 study in combination with venetoclax and azacitidine. Ongoing patients in ASPEN-05 will continue to be treated and followed per protocol.
- **Additional Evorpacept Clinical Program Updates**
  - In June 2022, ALX Oncology announced expected initiation of 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), for the treatment of patients with UC in the fourth quarter of 2022.
  - 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 CYRAMZA (ramucirumab) added to trastuzumab and paclitaxel for the treatment of patients with HER-positive gastric/GEJ 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.

Second Quarter 2022 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2022 were $324.2 million. ALX Oncology recently updated its cash forecast and believes its cash, cash equivalents and investments are sufficient to fund planned operations through the fourth quarter of 2024.
- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of ALX Oncology's current lead product candidate, evorpacept, and R&D employee-related expenses. These expenses for the three months ended June 30, 2022, were $26.7 million, compared to $11.2 million for the prior-year period. The increase in expenses during the three months ended June 30, 2022 compared to the three months ended June 30, 2021 were primarily attributable to an increase of $10.3 million in clinical and development costs primarily due to 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 an increase of $1.6 million related to the Tallac Collaboration for work related to the IND filing planned for 2023; an increase of $0.4 million in preclinical costs primarily related to development of new targets; an increase of $1.8 million in personnel and related costs due primarily to an increase driven by headcount growth and a portion of a retention bonus payable to ScalmiBio stockholders; an increase of $2.0 million in stock-based compensation expense due to additional awards granted since June 30, 2021; and an increase of $1.1 million in other research costs.
- **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 June 30, 2022, were $7.0 million, compared to $5.1 million for the prior-year period. The expense increases during the three months ended June 30, 2022 compared to the three months ended June 30, 2021 were primarily attributable to an increase of $1.6 million in stock-based compensation expense due to additional stock option awards granted since June 30, 2021 and an increase of $0.3 million in personnel and related costs primarily driven by headcount growth.
- **Net loss:** GAAP net loss was $32.9 million for the second quarter ended June 30, 2022, or $0.81 per basic and diluted share, as compared to a net loss of $16.3 million for the second quarter ended June 30, 2021, or $0.40 per basic and diluted share. Non-GAAP net loss was $27.1 million for the second quarter ended June 30, 2022, as compared to a net loss of $14.0 million for the second quarter ended June 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 26,748	$ 11,213	$ 43,821	$ 21,062
General and administrative	7,041	5,086	14,715	9,445
Total operating expenses	33,789	16,299	58,536	30,507
Loss from operations	(33,789)	(16,299)	(58,536)	(30,507)

Interest income	876	23	1,101	48
Other income (expense), net	(7)	2	(18)	—
Net loss	$ (32,920)	$ (16,274)	$ (57,453)	$ (30,459)
Net loss per share, basic and diluted	$ (0.81)	$ (0.40)	$ (1.41)	$ (0.76)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	40,687,751	40,247,110	40,652,224	40,151,802

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 324,226	$ 363,667
Total assets	$ 346,018	$ 380,183
Total liabilities	$ 29,699	$ 17,134
Accumulated deficit	$ (259,438)	$ (201,985)
Total stockholders' equity	$ 316,319	$ 363,049

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net loss, as reported	$ (32,920)	$ (16,274)	$ (57,453)	$ (30,459)
Adjustments:				
Stock-based compensation expense	5,836	2,237	11,337	4,037
Non-GAAP net loss	$ (27,084)	$ (14,037)	$ (46,116)	$ (26,422)

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.

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