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

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SOUTH SAN FRANCISCO, Calif., May 09, 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 first quarter ended March 31, 2022 and provided clinical development and operational highlights.

"Throughout the first quarter, we continued to realize significant progress advancing our lead program, evorpacept, through multiple clinical trials," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "Our highlights include dosing the first patient in ASPEN-06, our Phase 2/3 study testing evorpacept in combination with ramucirumab, trastuzumab, and paclitaxel for the treatment of patients with HER2-positive gastric cancer or gastroesophageal junction ("GEJ") cancer and the U.S. Food and Drug Administration ("FDA") granting Orphan Drug Designation ("ODD") to evorpacept for the treatment of patients with gastric/GEJ cancer."

"Looking ahead, we are excited for clinical milestones by year-end including the expected dose optimization readout of a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with myelodysplastic syndromes ("MDS") (ASPEN-02) and updates on our Phase 1/2 collaboration with Zymeworks in evaluating the combination of evorpacept and zanidatamab in patients with HER2-positive breast cancer and other solid tumors," Dr. Pons continued.

Recent Clinical Developments for Evorpacept

- **Initiation of a Phase 2/3 Study of Evorpacept for the Treatment of Patients with Advanced Gastric or Gastroesophageal Junction Cancer (ASPEN-06)**
    - In March 2022, the first patient was dosed in the Phase 2/3 ASPEN-06 study evaluating the combination of evorpacept, a next generation CD47 blocker, 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/GEJ cancer.
    - ASPEN-06 (NCT05002127) is a randomized Phase 2 (open-label) / Phase 3 (double-blind), international, multi-center study to evaluate the efficacy of evorpacept in combination with ramucirumab, trastuzumab, and paclitaxel for the treatment of patients whose tumors have progressed following treatment with HER2-targeted therapy and chemotherapy. Approximately 450 adult patients will be enrolled in the study across both phases.
- **FDA Granted ODD for Evorpacept for the Treatment of Patients with Gastric/GEJ Cancer**
    - In January 2022, ALX Oncology announced that the FDA granted ODD to evorpacept, a next-generation CD47 blocker, for the treatment of patients with gastric/GEJ cancer.

Recent Corporate Updates

- **Appointed Itziar Canamasas, Ph.D., to its Board of Directors**
    - In April 2022, ALX Oncology announced the appointment of Itziar Canamasas, Ph.D., to its Board of Directors (the "Board"). With more than 20 years of biopharmaceutical industry experience, Dr. Canamasas brings expertise in driving business growth and operational excellence.

First Quarter 2022 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2022 were $341.7 million. ALX Oncology believes its cash, cash equivalents and investments are sufficient to fund planned operations through mid-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 March 31, 2022, were $17.1 million,

compared to $9.8 million for the prior-year period. The increase in expenses during the three months ended March 31, 2022 compared to the three months ended March 31, 2021 were primarily attributable to an increase of $2.6 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 evorpacept, as well as an increase of $0.9 million related to the collaboration with Tallac Therapeutics, Inc., an increase of $2.1 million in personnel related costs driven by headcount growth, an increase of $1.5 million in stock-based compensation expense due to additional awards granted since March 31, 2021 and an increase of $0.6 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:** 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 March 31, 2022, were $7.7 million, compared to $4.4 million for the prior-year period. The expense increases during the three months ended March 31, 2022 compared to the three months ended March 31, 2021 were primarily attributable to an increase of $2.2 million in stock-based compensation expense due to additional awards granted since March 31, 2021 and an increase of $0.8 million in other costs primarily driven by an increase in corporate legal fees, regulatory related filing fees and facility and information technology costs.

- **Net loss:** GAAP net loss was $24.5 million for the first quarter ended March 31, 2022, or $0.60 per basic and diluted share, as compared to a net loss of $14.2 million for the first quarter ended March 31, 2021, or $0.35 per basic and diluted share. Non-GAAP net loss was $19.0 million for the first quarter ended March 31, 2022, as compared to a net loss of $12.4 million for the first quarter ended March 31, 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, 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.

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 17,073	$ 9,849
General and administrative	7,674	4,359
Total operating expenses	24,747	14,208
Loss from operations	(24,747)	(14,208)
Interest income	225	25
Other income (expense), net	(11)	(2)

Net loss	$ (24,533)	$ (14,185)
Net loss per share, basic and diluted	$ (0.60)	$ (0.35)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	40,616,302	40,055,435

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 341,705	$ 363,667
Total assets	$ 363,676	$ 380,183
Total liabilities	$ 20,080	$ 17,134
Accumulated deficit	$ (226,518)	$ (201,985)
Total stockholders' equity	$ 343,596	$ 363,049

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

	Three Months Ended March 31,	
	2022	2021
GAAP net loss, as reported	$ (24,533)	$ (14,185)
Adjustments:		
Stock-based compensation expense	5,501	1,800
Non-GAAP net loss	$ (19,032)	$ (12,385)

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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