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

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BURLINGAME, Calif., Aug. 12, 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 second quarter ended June 30, 2021 and provided clinical development and operational highlights.

"We are pleased to report on the substantial progress we made since the prior quarter with our lead product candidate, ALX148, and that the United States Adopted Names (USAN) Council has approved 'evorpacept' as the nonproprietary (generic) name for ALX148," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "Our highlights include the presentation of additional positive Phase 1b data in second-line or greater HER2 positive gastric or gastroesophageal junction cancer from our ASPEN-01 trial during an oral session at the ESMO World Congress on Gastrointestinal Cancer; these results provide the basis for initiating a randomized Phase 2/3 trial in the same setting (ASPEN-06) scheduled to start in the second half of this year."

"We recently dosed the first patient in our Phase 2 ASPEN-04 trial in first line metastatic or unresectable recurrent head and neck squamous cell carcinoma in combination with KEYTRUDA® and chemotherapy, are continuing enrollment in our Phase 2 ASPEN-03 trial in first line metastatic or unresectable, PD-L1 positive recurrent head and neck cancer in combination with KEYTRUDA, and plan to present full results of the Phase 1b study (ASPEN-01) in the fourth quarter of this year. In addition, we plan to present results from our Phase 1 study in myelodysplastic syndromes, to initiate a Phase 2 study in the same setting (ASPEN-02), as well as to initiate a Phase 1 study in acute myeloid leukemia (ASPEN-05)," Dr. Pons continued.

Recent Clinical Developments for Evorpacept (Also known as ALX148)

- **First Patient Dosed in Phase 2 ASPEN-04 Study**
    - In July 2021, dosed first patient in the Phase 2 ASPEN-04 study evaluating the combination of evorpacept, a next generation CD47 blocker, with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, and standard 5-fluorouracil and platinum chemotherapy for the first line ("1L") treatment of patients with metastatic or unresectable, recurrent head and neck squamous cell carcinoma ("HNSCC"). In June 2021, the U.S. Food and Drug Administration ("FDA") informed ALX Oncology that it reviewed its standard non-clinical safety study and has lifted the previously set partial clinical hold and cap on patient enrollment.
- **First Patient Dosed in Phase 2 ASPEN-03 Study**
    - In May 2021, dosed first patient in the Phase 2 ASPEN-03 study, which is also evaluating the efficacy of evorpacept in combination with KEYTRUDA (pembrolizumab) for the 1L treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC with a combined positive score ("CPS") ≥ 1. In June 2021, the FDA informed ALX Oncology that it reviewed its standard non-clinical safety study and has lifted the previously set partial clinical hold and cap on patient enrollment.
- **Data for Phase 1b ASPEN-01 Study Presented at 23rd ESMO World Congress on Gastrointestinal Cancer**
    - In July 2021, updated clinical data from the Phase 1b ASPEN-01 trial evaluating evorpacept in combination with trastuzumab and CYRAMZA® (ramucirumab) for the treatment of gastric or gastroesophageal junction cancer ("G/GEJ") were shared in an oral presentation at the 23 rd ESMO World Congress on Gastrointestinal Cancer. Data showed that evorpacept in combination with trastuzumab and ramucirumab is highly active and well-tolerated in patients with second line ("≥2L") or greater HER2 positive G/GEJ cancer.
- **Collaboration and Supply Agreement Entered with Eli Lilly**
    - In June 2021, ALX Oncology entered into a clinical trial collaboration and supply agreement with Eli Lilly and Company to evaluate the combination of evorpacept with CYRAMZA (ramucirumab), Lilly's anti-VEGFR2 antibody, for the treatment of patients with HER2 positive G/GEJ. Under the terms of the agreement, ALX Oncology will conduct a Phase 2/3 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 of HER2 targeted therapy and chemotherapy. Lilly will supply ramucirumab for this trial.

Anticipated Key Milestones for Remainder of 2021

- Full results of a Phase 1b study of evorpacept in combination with Merck's KEYTRUDA (pembrolizumab) and chemotherapy for the treatment of patients with HNSCC (ASPEN-01) are planned to be presented in the fourth quarter of 2021.
- Initiation of a Phase 1b clinical trial with evorpacept in combination with Zymeworks' zanidatamab in patients with advanced HER2-expressing breast cancer and other solid tumors is expected in the second half of 2021.
- Initiation of a Phase 1 clinical trial evaluating evorpacept in combination with azacitidine and venetoclax in patients with acute myeloid leukemia ("AML") (ASPEN-05) is planned in the second half of 2021.
- Initiation of a randomized Phase 2 trial of evorpacept in combination with Herceptin (trastuzumab), CYRAMZA (ramucirumab) and paclitaxel in second- or third-line treatment of patients with HER2-positive G/GEJ cancer (ASPEN-06) is expected in the second half of 2021.
- Results of a Phase 1 clinical trial of evorpacept in combination with azacitidine in patients with myelodysplastic syndromes ("MDS") and the initiation of the Phase 2 clinical trial in MDS (ASPEN-02) are expected in the fourth quarter of 2021.

Second Quarter 2021 Financial Results:

- **Cash and Cash Equivalents:** Cash and cash equivalents as of June 30, 2021, were $410.0 million. ALX Oncology continues to believe 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 $16.3 million, or $0.40 per basic and diluted share and $14.0 million, or $4.41 per basic and diluted share for the three months ended June 30, 2021 and 2020, respectively. Non-GAAP net loss attributable to common stockholders was $14.0 million for the three months ended June 30, 2021, as compared to $10.7 million for the three months ended June 30, 2020. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.
- **Related-party Revenue:** Related-party revenue for the three months ended June 30, 2021 was nil compared to $0.5 million for the prior-year period. The decrease in related-party revenue relates to the termination of the Tollnine Agreement as of July 1, 2020.
- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of evorpacept. These expenses for the three months ended June 30, 2021 were $11.2 million, compared to $7.7 million for the prior-year period. The increase of $3.5 million was primarily attributable to an increase of $3.7 million in clinical and development costs due to higher expenses associated with increased pre-clinical, clinical and other research costs in advancement of our current lead product candidate, evorpacept, an increased personnel-related costs of $1.1 million primarily due to headcount growth, and an increase of $0.3 million other research and development costs primarily driven by milestone payments triggered by the initiation of our Phase 2 trials, offset by a decrease of $1.6 million in stock-based compensation expense primarily resulting from the modification of stock options in the second quarter of 2020 whereas there was no such modification in 2021.
- **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, 2021 were $5.1 million, compared to $3.2 million for the prior-year period. This increase of $1.9 million was primarily attributable to an increase in stock-based compensation expense of $1.0 million primarily resulting from additional stock option award grants at higher fair values, an increase in personnel-related costs of $0.5 million due to headcount growth, and a $0.4 million increase in other general and administrative costs related to being a public company, including directors and officers liability insurance premiums.

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 AML 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Related-party revenue	$ —	$ 527	$ —	$ 1,182
Operating expenses:				
Research and development	11,213	7,663	21,062	11,491
General and administrative	5,086	3,172	9,445	4,645
Cost of services for related-party revenue	—	479	—	1,075
Total operating expenses	16,299	11,314	30,507	17,211
Loss from operations	(16,299)	(10,787)	(30,507)	(16,029)
Interest expense	(3)	(219)	(6)	(434)
Other income (expense), net	28	(305)	54	(298)
Loss before income taxes	(16,274)	(11,311)	(30,459)	(16,761)
Income tax provision	—	(20)	—	(24)
Net loss and comprehensive loss	(16,274)	(11,331)	(30,459)	(16,785)
Cumulative dividends allocated to preferred stockholders	—	(2,641)	—	(4,624)
Net loss attributable to common stockholders	$ (16,274)	$ (13,972)	$ (30,459)	$ (21,409)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (4.41)	$ (0.76)	$ (6.78)
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	40,247,110	3,164,707	40,151,802	3,157,387

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 409,964	$ 434,219
Total assets	$ 421,289	$ 436,054
Total liabilities	$ 16,275	$ 6,209
Total stockholders' equity	$ 405,014	$ 429,845

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, as reported	$ (16,274)	$ (13,972)	$ (30,459)	$ (21,409)
Adjustments:				
Stock-based compensation expense	2,237	2,853	4,037	3,004
Accretion of term loan	—	113	—	221
Mark-to-market adjustment on financial instruments	—	308	—	408

Total adjustments	2,237	3,274	4,037	3,633
Non-GAAP net loss attributable to common stockholders	$ (14,037)	$ (10,698)	$ (26,422)	$ (17,776)

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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