ALX Oncology Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Clinical Development and Operational Highlights and Upcoming Milestones

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SOUTH SAN FRANCISCO, Calif., Feb. 28, 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 fourth quarter and year ended December 31, 2021 and provided clinical development and operational highlights.

“ALX Oncology achieved key milestones in 2021 to advance our lead program, evorpacept, a next-generation CD47 blocker, through multiple clinical trials,” said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. “Notable accomplishments included initiating two Phase 2 trials in head and neck squamous cell carcinoma (“HNSCC”) and presenting encouraging Phase 1b data from the ASPEN-01 trial in gastric/gastroesophageal junction (“GEJ”) cancer and HNSCC, along with early Phase 1a data from the ASPEN-02 trial in myelodysplastic syndromes (“MDS”). Data from these trials also showed evorpacept to be well tolerated when combined with anti-cancer antibodies and multi-agent chemotherapy regimens in solid tumors and with azacitidine in MDS.”

Dr. Pons added: “2022 is expected to be another productive year with the anticipated initiation of a randomized Phase 2/3 clinical trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel in patients with 2nd line or greater gastric/GEJ cancer and the expected completion of enrollment and dose optimization data readout from our Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with MDS. The design of evorpacept, with an inactive Fc, continues to set us apart from competing CD47 blockers to date. Our data suggest that evorpacept’s inactive Fc approach shows greater tolerability than CD47 blocking approaches using an active Fc domain, several of which have shown significant cytopenias in the clinic. Additionally, our initial clinical data show anti-tumor activity on par or better than other such agents.”

Anticipated Key Clinical Milestones for 2022

- Initiation of a randomized Phase 2/3 clinical trial of evorpacept in combination with Herceptin® (trastuzumab), Cyramza® (ramucirumab) and paclitaxel in patients with 2nd line or greater gastric/GEJ cancer (ASPEN-06).
- Dose optimization readout of a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with MDS (ASPEN-02).
- Initiate and provide updates on investigator sponsored clinical trials with evorpacept.
- Provide updates on ongoing collaboration with Zymeworks in HER2-expressing breast cancer and other solid tumors.
- Select development candidate(s) from preclinical pipeline.

Recent Clinical Developments for Evorpacept (ALX148)

- **U.S. Food and Drug Administration (“FDA”) Granted Orphan Drug Designation (“ODD”) for Evorpacept for the Treatment of Patients with Gastric/GEJ Cancer**
    - In January 2022, ALX announced that the U.S. FDA granted ODD to evorpacept, a next-generation CD47 blocker, for the treatment of patients with gastric/GEJ cancer.
- **Presented Initial Phase 1a Clinical Data in Combination with Azacitidine in Patients with MDS (ASPEN-02) at ASH**
    - In December 2021, the Company presented initial clinical data from its ongoing trial evaluating evorpacept in combination with azacitidine for the treatment of patients with previously untreated higher-risk or relapsed or refractory MDS. The new data, shared in a poster at the 63rd American Society of Hematology (“ASH”) Annual Meeting [Abstract #2601], show that the combination of evorpacept and azacitidine is active and well-tolerated. Patient accrual is ongoing in the Phase 1b dose optimization part of the study.
- **Presented Updated Phase 1b Clinical Trial Data in Combination with Pembrolizumab with and without Chemotherapy in Patients with HNSCC and in Combination with Trastuzumab, Ramucirumab, and Paclitaxel in Patients with Gastric/GEJ Cancer (ASPEN-01) at SITC**

- In November 2021, updated results from Phase 1b study (ASPEN-01) evaluating patients with solid tumor malignancies were presented at the Society for Immunotherapy of Cancer's 36 th Anniversary Annual Meeting [Abstract #498]. ALX Oncology reported updated results from the gastric/GEJ 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.

- **Initiation of a Phase 1a Clinical Trial in Combination with Venetoclax and Azacitidine in Acute Myeloid Leukemia (ASPEN-05)**

  - In October 2021, the first patient was dosed in the Phase 1/2 ASPEN-05 study evaluating the combination of evorpacept with venetoclax and azacitidine for the treatment of patients with acute myeloid leukemia ("AML"). The Phase 1 portion will characterize the safety 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.

- **Initiation of a Phase 1b/2 Clinical Trial in Combination with Zanidatamab 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.

Recent Corporate Updates

- **Acquired Privately Held ScalmiBio Inc.:** In October 2021, ALX Oncology acquired ScalmiBio which further expanded its pipeline with plans to develop novel antibody-drug conjugates ("ADCs") based on ScalmiBio's SHIELD platform.

Full Year and Fourth Quarter 2021 Financial Results:

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2021 were $363.7 million. ALX Oncology believes its cash and cash equivalents is sufficient to fund planned operations through mid-2024.

- **Related-party Revenue:** There was no related-party revenue for the three months ended December 31, 2021 and 2020. There was no related-party revenue for the year ended December 31, 2021, compared to $1.2 million for the prior-year period. The decrease in related-party revenue relates to the termination of the research and development agreement with Tallac Therapeutics, Inc. in July 2020.

- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of the Company's current lead product candidate, evorpacept, and R&D employee-related expenses. These expenses for the three months ended December 31, 2021, were $20.9 million, compared to $12.1 million for the prior-year period. Expenses for the three months ended December 31, 2021 included $4.7 million of acquired in-process research and development expenses related to the acquisition of ScalmiBio. R&D expenses for the year ended December 31, 2021, were $60.2 million, compared to $29.0 million for the prior-year period.

- **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 December 31, 2021, were $7.6 million, compared to $5.7 million for the prior-year period. G&A expenses for the year ended December 31, 2021, were $23.4 million, compared to $14.8 million for the prior-year period.

- **Net loss:** GAAP net loss attributable to common stockholders was $28.4 million for the fourth quarter ended December 31, 2021, or $0.70 per basic and diluted share, as compared to a net loss of $18.8 million for the fourth quarter ended December 31, 2020, or $0.50 per basic and diluted share. GAAP net loss for the year ended December 31, 2021 was $83.5 million, or $2.07 per basic and diluted share, as compared to $50.9 million, or $2.76 per basic and diluted share, for the year ended December 31, 2020. Non-GAAP net loss was $22.8 million for the fourth quarter ended December 31, 2021, as compared to a net loss of $16.3 million for the fourth quarter ended December 31, 2020. Non-GAAP net loss for the year ended December 31, 2021 was $69.5 million, as compared to $43.8 million for the year ended December 31, 2020. 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 and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Related-party revenue	$ —	$ —	$ —	$ 1,182
Operating expenses:				
Research and development	20,894	12,142	60,170	28,961
General and administrative	7,578	5,683	23,385	14,809
Cost of services for related-party revenue	—	—	—	1,075
Total operating expenses	28,472	17,825	83,555	44,845
Loss from operations	(28,472)	(17,825)	(83,555)	(43,663)
Interest expense	(3)	(151)	(13)	(811)
Other income (expense), net	16	5	84	(404)
Loss on early debt extinguishment	—	(621)	—	(621)
Loss before income taxes	(28,459)	(18,592)	(83,484)	(45,499)
Income tax benefit (provision)	21	(182)	21	(241)
Net loss and comprehensive loss	(28,438)	(18,774)	(83,463)	(45,740)
Cumulative dividends allocated to preferred stockholders	—	—	—	(5,202)
Net loss attributable to common stockholders	$ (28,438)	$ (18,774)	$ (83,463)	$ (50,942)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.50)	$ (2.07)	$ (2.76)
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	40,527,314	37,642,897	40,308,050	18,485,343

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 363,667	$ 434,219
Total assets	$ 380,183	$ 436,054
Total liabilities	$ 17,134	$ 6,209
Accumulated deficit	$ (201,985)	$ (118,522)
Total stockholders' equity	$ 363,049	$ 429,845

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

	Three Months Ended	Year Ended

	December 31,		December 31,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, as Reported	$ (28,438)	$ (18,774)	$ (83,463)	$ (50,942)
Adjustments:				
Stock-based compensation expense	5,686	1,743	13,914	5,436
Accretion of term loan	—	82	—	421
Mark-to-market adjustment on financial instruments	—	—	—	650
Loss on early debt extinguishment	—	621	—	621
Total adjustments	5,686	2,446	13,914	7,128
Non-GAAP net loss attributable to common stockholders	$ (22,752)	$ (16,328)	$ (69,549)	$ (43,814)

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), (3) mark-to-market adjustment on financial instruments (which include preferred stock warrants and derivatives) and (4) loss on early debt extinguishment. 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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