ALX Oncology Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Clinical Development and Operational Highlights and Upcoming Milestones

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BURLINGAME, Calif., March 18, 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 fourth quarter and year ended December 31, 2020 and provided clinical development and operational highlights.

"ALX made substantial progress in 2020 towards advancing our lead development candidate, ALX148, marked by a growing body of positive data reported in solid tumors, including encouraging Phase 1b clinical data in combination with antibodies and standard chemotherapy in patients with gastric/gastroesophageal junction ("G/GEJ") cancer and head and neck squamous cell carcinoma ("HNSCC")," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology.

"In 2021, we are focused on reporting our Phase 1b full clinical results and initiating several clinical trials, including two randomized Phase 2 studies of ALX148 in combination with KEYTRUDA® (pembrolizumab) in patients with HNSCC, and the start of a Phase 1b clinical trial with ALX148 in combination with Zymeworks' zanidatamab in patients with advanced HER2-expressing breast cancer and other solid tumors in the first half of the year. In addition, randomized Phase 2 studies in myelodysplastic syndromes ("MDS") and G/GEJ cancer will initiate in the second half of a very exciting year," Dr. Pons continued.

Anticipated Key Clinical Milestones for 2021

- Full results of a Phase 1b clinical trial with ALX148 in combination with Herceptin® (trastuzumab), Cyramza® (ramucirumab) and paclitaxel in patients with second line or greater ("≥2L") G/GEJ cancer (ASPEN-01) is planned to be presented in mid-2021.
- Initiation of two randomized Phase 2 studies with ALX148 in combination with KEYTRUDA in patients with HNSCC are planned in the first half of 2021. The first study (ASPEN-03) will evaluate the efficacy of ALX148 in combination with KEYTRUDA for the first line ("1L") treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC. The second study (ASPEN-04) will evaluate ALX148 in combination with KEYTRUDA and standard 5-fluorouracil and platinum chemotherapy for the 1L treatment of patients with metastatic or unresectable, recurrent HNSCC.
- Initiation of a Phase 1b clinical trial with ALX148 in combination with Zymeworks' zanidatamab in patients with advanced HER2-expressing breast cancer and other solid tumors in the first half of 2021.
- Full results of a Phase 1b study of ALX148 in combination with Merck's KEYTRUDA (pembrolizumab) and chemotherapy for the treatment of patients with HNSCC (ASPEN-01) is planned to be presented in the second half of 2021.
- Initiation of a Phase 1 clinical trial evaluating ALX148 in combination with azacitidine and venetoclax in patients with acute myeloid leukemia ("AML") (ASPEN-05) in the second half of 2021.
- Initiation of a randomized Phase 2 trial of ALX148 in combination with Herceptin (trastuzumab), Cyramza (ramucirumab) and paclitaxel in second- or third-line ("2L or 3L") treatment of patients with G/GEJ cancer (ASPEN-06) is expected in the second half of 2021.
- Results of a Phase 1 clinical trial of ALX148 in combination with azacitidine in patients with MDS and the initiation of the Phase 2 clinical trial in MDS (ASPEN-02) are expected in the fourth quarter 2021.

Recent Clinical Developments for ALX148

- **Announced Collaboration with Tallac Therapeutics on Novel Class of Cancer Immunotherapeutics**
  - In March 2021, ALX Oncology and Tallac Therapeutics ("Tallac"), a privately held biopharmaceutical company, announced a collaboration to jointly develop, manufacture, and commercialize a novel class of cancer immunotherapeutics. The collaboration builds on ALX Oncology's expertise in developing therapies that block the

CD47 checkpoint pathway and expands its immuno-oncology pipeline with Tallac's pipeline of next generation immunotherapies derived from its novel Toll-like Receptor Agonist Antibody Conjugate ("TRAAC") platform. ALX Oncology and Tallac expect to submit an Investigational New Drug application by the end of 2022.

- **Presented Updated Data at the 62nd American Society of Hematology Annual Meeting from the ASPEN-01 Phase 1b Study of ALX148 in Combination with Rituximab in Patients with Advanced Relapsed/Refractory ("r/r") non-Hodgkin lymphoma ("NHL")**

    - In December 2020, ALX Oncology reported updated clinical data from its ongoing trial evaluating ALX148 in combination with rituximab for the treatment of advanced r/r NHL. ALX148 in combination with rituximab was well tolerated with no dose limiting toxicities observed.

    - As of the data cutoff of October 1, 2020, 33 subjects had been treated with ALX148 administered at 10 or 15 mg/kg once weekly ("QW") with standard regimens of rituximab. In response-evaluable subjects (n=10) who received ALX148 at 15 mg/kg QW, the objective response rate ("ORR") was 70.0%. In response-evaluable subjects (n=22) who received ALX148 at 10 mg/kg QW, the ORR was 40.9%. A statistically significant improvement in clinical response was demonstrated with increased ALX148 exposure across the doses evaluated (p=0.023).

- **Announced Collaboration with Zymeworks Inc. to Conduct Phase 1b Study to Evaluate Zanidatamab with ALX148 in Patients with HER2 Expressing Breast Cancer**

    - In November 2020, ALX Oncology announced a collaboration with Zymeworks to jointly run a clinical trial to evaluate the combination of Zymeworks' zanidatamab, a HER2-targeted bispecific antibody, and ALX148, a next-generation CD47 blocker, for the treatment of patients with advanced HER2-expressing breast cancer and other solid tumors. Under the collaboration, Zymeworks will conduct an open label, multi-center Phase 1b study to assess the safety and efficacy of the combination of zanidatamab and ALX148 in subjects with HER2-positive breast cancer, HER2-low breast cancer, and non-breast HER2-expressing solid tumors.

- **Presented New Data at the SITC 35th Anniversary Annual Meeting from ASPEN-01 Phase 1b Study of ALX148 in Combination with Standard Chemotherapy and Antibody Regimens in Patients with G/GEJ Cancer and HNSCC.**

    - In November 2020, ALX Oncology reported preliminary data from the G/GEJ cancer patient cohort receiving ALX148 plus trastuzumab plus chemotherapy. In patients with ≥2L HER2 positive G/GEJ cancer (n=14), whose tumors have progressed upon prior trastuzumab therapy, ALX148 in combination with trastuzumab plus ramucirumab and paclitaxel demonstrated an initial ORR of 64.3% that compares favorably with historical data. In addition, updated data from patients with ≥2L HER2 positive G/GEJ cancer receiving ALX148 plus trastuzumab suggested promising clinical activity after their tumors have progressed upon prior trastuzumab therapy.

    - ALX Oncology also reported preliminary data from a HNSCC patient cohort receiving ALX148 plus pembrolizumab plus chemotherapy. In patients with first line HNSCC who have not received prior treatment for advanced disease (n=4), ALX148 demonstrated an initial ORR of 75.0%, including a complete response, in combination with pembrolizumab plus 5-fluorouracil and platinum. In addition, updated data from subjects who were treatment naïve to a PD-1/PD-L1 inhibitor for their ≥2L HNSCC and who received ALX148 plus pembrolizumab suggested greater clinical activity than with pembrolizumab as a monotherapy.

Recent Operational Highlights:

- **Appointed New Member to the Board of Directors**. In March 2021, ALX Oncology appointed Sophia Randolph, M.D., Ph.D. to its Board of Directors. Dr. Randolph has served as Chief Medical Officer of ALX Oncology since June 2016 and will continue in this role.

- **Added to the NASDAQ Biotechnology Index®.** In December 2020, ALX Oncology was added to the NASDAQ Biotechnology Index® (NASDAQ: NBI) effective Monday, December 21, 2020.

- **Raised Gross Proceeds of $208 Million in Oversubscribed Follow-on Public Offering.** In December 2020, ALX Oncology announced the closing of an oversubscribed underwritten follow-on public offering yielding aggregate gross proceeds of approximately $208.0 million. All of the shares in the offering were offered by ALX Oncology.

Full Year and Fourth Quarter 2020 Financial Results:

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2020 were $434.2 million. ALX Oncology believes its current cash and cash equivalents are sufficient to fund planned operations through 2024.

- **Related-party Revenue:** There was no related-party revenue for the three months ended December 31, 2020, compared to $1.2 million for the prior-year period. There was $1.2 million related-party revenue for the year ended December 31, 2020, compared to $4.8 million for the prior-year period. The decrease in related-party revenue relates to the termination of the research and development agreement with Tallac 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 ALX148. These expenses for the three months ended December 31, 2020, were $12.1 million, compared to $6.7 million for the prior-year period. These expenses for the year ended December 31, 2020, were $29.0 million, compared to $16.3 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, 2020, were $5.7 million, compared to $1.1 million for the prior-year period. These expenses for the year ended December 31, 2020, were $14.8 million, compared to $3.3 million for the prior-year period.

- **Net Loss:** GAAP net loss attributable to common stockholders was $18.8 million for the fourth quarter ended December 31, 2020, or $0.50 per basic and diluted share, as compared to a net loss of $8.8 million for the fourth quarter ended December 31, 2019, or $2.83 per basic and diluted share. GAAP net loss for the year ended December 31, 2020 was $50.9 million, or $2.76 per basic and diluted share, as compared to $23.3 million, or $7.56 per basic and diluted share, for the year ended December 31, 2019. Non-GAAP net loss was $16.3 million for the fourth quarter ended December 31, 2020, as compared to a net loss of $8.7 million for the fourth quarter ended December 31, 2019. Non-GAAP net loss for the year ended December 31, 2020 was $43.8 million, as compared to $23.0 million for the year ended December 31, 2019. 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, ALX148, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. ALX148 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 ALX148 for the treatment of a range of solid tumor indications as well as MDS and AML. For more information, please visit ALX Oncology's website at www.alxoncology.com.

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 ALX148. 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Related-party revenue	$ —	$ 1,213	$ 1,182	$ 4,796
Operating expenses:				
Research and development	12,142	6,735	28,961	16,306
General and administrative	5,683	1,108	14,809	3,313
Cost of services for related-party revenue	—	1,103	1,075	4,360
Total operating expenses	17,825	8,946	44,845	23,979
Loss from operations	(17,825)	(7,733)	(43,663)	(19,183)

Interest expense	(151)	(21)	(811)	(21)
Other expense, net	5	(1)	(404)	(5)
Loss on early debt extinguishment	(621)	—	(621)	—
Loss before income taxes	(18,592)	(7,755)	(45,499)	(19,209)
Income tax provision	(182)	(9)	(241)	(34)
Net loss and comprehensive loss	(18,774)	(7,764)	(45,740)	(19,243)
Cumulative dividends allocated to preferred stockholders	—	(1,071)	(5,202)	(4,028)
Net loss attributable to common stockholders	$ (18,774)	$ (8,835)	$ (50,942)	$ (23,271)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.50)	$ (2.83)	$ (2.76)	$ (7.56)
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	37,642,897	3,122,204	18,485,343	3,076,461

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 434,219	$ 9,017
Total assets	$ 436,054	$ 10,676
Total liabilities	$ 6,209	$ 10,952
Convertible preferred stock	$ —	$ 70,363
Total stockholders' equity (deficit)	$ 429,845	$ (70,639)

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
GAAP net loss attributable to common stockholders, as reported	$ (18,774)	$ (8,835)	$ (50,942)	$ (23,271)
Adjustments:				
Stock-based compensation expense	1,743	75	5,436	297
Accretion of term loan	82	11	421	11
Mark-to-market adjustment on financial instruments	—	—	650	—
Loss on early debt extinguishment	621	—	621	—
Total adjustments	2,446	86	7,128	308
Non-GAAP net loss attributable to common stockholders	$ (16,328)	$ (8,749)	$ (43,814)	$ (22,963)

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 within our reconciliation of our GAAP to Non-GAAP net loss. 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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