# ALX Oncology Reports Third Quarter 2020 Financial Results and Provides Clinical Development and Operational Highlights

November 12, 2020

BURLINGAME, Calif., Nov. 12, 2020 (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 third quarter ended September 30, 2020, and clinical development and operational highlights.

"We are very pleased to report that during the third quarter we continued to make substantial progress in advancing our next generation anti-CD47 therapeutic, ALX148, in clinical trials in advanced gastric/gastroesophageal junction cancer and head and neck squamous cell cancers, as well as securing a clinical trial collaboration with Merck to study the combination of ALX148 with KEYTRUDA® in the setting of first line, metastatic or unresectable, recurrent head and neck squamous cell cancer," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "In addition, subsequent to the third quarter, we announced the first patient has been dosed in the Phase 1/2 ASPEN-02 study evaluating the combination of ALX148 with azacitidine for the treatment of patients with higher-risk myelodysplastic syndromes. We also recently presented further encouraging data for ALX148 from the ASPEN-01 Phase 1b Study at the 35th Annual SITC meeting, including a 64% ORR in advanced gastric cancer patients treated with ALX148 in combination with trastuzumab and the current chemotherapeutic standard of care. We look forward to providing further updates as we continue to advance ALX148 as a potential treatment for a range of solid tumor indications and hematologic malignancies."

**Recent Clinical Developments for ALX148**

- **Presented New Data from the ASPEN-01 Phase 1b Study of ALX148 in Combination with Standard Chemotherapy and Antibody Regimens in Patients with Gastric/Gastroesophageal Junction Cancer ("GC") and Head and Neck Squamous Cell Carcinoma ("HNSCC") at the SITC 35th Anniversary Annual Meeting [Abstract #404].**
    - In November 2020, ALX Oncology reported new preliminary data from the GC patient cohort receiving ALX148 plus trastuzumab plus chemotherapy. In patients with ≥2L HER2 positive GC (n=14), whose tumors have progressed upon prior trastuzumab therapy, ALX148 demonstrated an initial objective response rate ("ORR") of 64% in combination with trastuzumab plus ramucirumab and paclitaxel that compares favorably with historical data. In addition, updated data from patients with ≥2L HER2 positive GC receiving ALX148 plus trastuzumab suggested promising clinical activity after their tumors have progressed upon prior trastuzumab therapy.
    - ALX Oncology also reported new preliminary data from the HNSCC patient cohort receiving ALX148 plus pembrolizumab plus chemotherapy. In initial patients with 1L HNSCC who have not received prior treatment for their advanced disease (n=4), ALX148 demonstrated an initial ORR of 75%, including a complete response, in combination with pembrolizumab plus 5-fluorouracil and platinum. In addition, updated data from patients who have never been treated with a PD-1/PD-L1 inhibitor for their ≥2L HNSCC and who received ALX148 plus pembrolizumab suggested clinical activity beyond that expected from pembrolizumab monotherapy.
- **Collaboration Initiated with Merck on Phase 2 Immuno-Oncology Studies Evaluating ALX148, Targeting CD47, in Combination with KEYTRUDA® (pembrolizumab) in Patients with Head & Neck Cancer.** In September 2020, ALX Oncology entered into a clinical trial collaboration with Merck to evaluate the combination of ALX148 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for the treatment of patients with HNSCC. ALX Oncology will conduct a Phase 2 program comprising two separate Phase 2 studies. The first study will evaluate the efficacy of ALX148 in combination with KEYTRUDA for the first line treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent HNSCC. The second study will evaluate ALX148 in combination with KEYTRUDA and standard chemotherapy for the first line treatment of patients with metastatic or unresectable, recurrent HNSCC.
- **Announced the first patient has been dosed in the Phase 1/2 ASPEN-02 study evaluating the combination of ALX148 with azacitidine for the treatment of patients with higher-risk myelodysplastic syndromes ("MDS").** With the first patient dosed in October 2020, the Phase 1 part of the study is expected to characterize the safety of ALX148 in combination with azacitidine in patients with relapsed/refractory or previously untreated higher-risk MDS. Upon completion of the Phase 1, the Phase 2 component of the study will be initiated to evaluate the efficacy of the combination in patients with previously untreated higher-risk MDS.

**Operational Highlights:**

- **Named Leading Oncology Experts to Scientific Advisory Board.** In October 2020, ALX Oncology announced the formation of the Company's Scientific Advisory Board ("SAB") with three leading oncology experts. The members of the ALX Oncology SAB include Keith Flaherty, M.D. (Chair), Charles M. Baum, M.D., Ph.D. and Kipp Weiskopf, M.D., Ph.D.

- **Added to Russell 2000® and 3000® Indexes.** In September 2020, ALX Oncology was added as a member of the Russell 2000® and 3000® Indexes effective as of September 18, 2020, as part of Russell's quarterly additions of select initial public offering ("IPO") companies.

**Conference Call on November 16th at 5:00 p.m. EST**

**New ALX148 Data from the Phase 1b GC Expansion Cohort in ASPEN-01**

ALX Oncology will host a conference call on Monday, November 16, 2020 at 5:00 p.m. EST to discuss the updated results from the GC expansion cohort in ASPEN-01, the ALX148 Phase 1b study, which was presented at the SITC 35th Anniversary Annual Meeting. In addition to ALX Oncology's executive management team, Dr. Yung-Jue Bang, Professor Emeritus and former Director of Cancer Research Institute, Seoul National University College of Medicine and Hospital, South Korea, will be featured on the call to discuss the latest ALX148 clinical data in patients with GC.

To access the conference call, please dial (844) 467-7655 (local) or (409) 983-9840 (international) at least 10 minutes prior to the start time and refer to conference ID 4766826. Presentation slides will be available to download under "News & Events" (see "Events") in the Investors section of the ALX Oncology website at www.alxoncology.com.

**Third Quarter 2020 Financial Results:**

- **Cash and Cash Equivalents:** Cash and cash equivalents as of September 30, 2020 were $259.5 million. ALX Oncology believes its cash and cash equivalents is sufficient to fund planned operations through 2023.

- **Related-party Revenue:** There was no related-party revenue for the quarter ended September 30, 2020, compared to $1.3 million for the corresponding period in 2019. 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 ALX148. These expenses for the three months ended September 30, 2020, were $5.3 million, compared to $2.2 million for the three months ended September 30, 2019. The increase of $3.1 million was primarily due to an increase of $2.9 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, ALX148 and an increase of $0.6 million in personnel-related costs, partially offset by a decrease of $0.4 million in stock-based compensation expense.

- **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 September 30, 2020, were $4.5 million, compared to $0.9 million for the prior-year period. This increase of $3.5 million was primarily due to an increase in stock-based compensation expense of $1.0 million, an increase in professional service costs of $0.6 million, additional $0.4 million in directors and officers liability insurance premium, increased personnel-related costs of $1.2 million due to higher headcount and additional other G&A costs of $0.3 million.

- **Net loss:** Net loss attributable to common stockholders was $10.8 million and $4.1 million for the three months ended September 30, 2020, and 2019, respectively. Included in the $10.8 million loss for the three months ended September 30, 2020, was $0.6 million related to cumulative dividends allocated to preferred shareholders, which, along with prior cumulative dividends, were converted into 2.6 million shares of common stock at the IPO. Non-GAAP net loss was $9.1 million and $3.0 million for the three months ended September 30, 2020, and 2019, respectively. A reconciliation of GAAP to non-GAAP financial results can be found in a table at the end of this press 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 and myelodysplastic syndromes. 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 and the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of ALX148. clinical pipeline 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 Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2020, 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)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Related-party revenue | $ — | $ 1,256 | $ 1,182 | $ 3,583 |
| Operating expenses: | | | | |
| Research and development | 5,328 | 2,210 | 16,819 | 9,571 |
| General and administrative | 4,481 | 938 | 9,126 | 2,205 |
| Cost of services for related-party revenue | — | 1,142 | 1,075 | 3,257 |
| Total operating expenses | 9,809 | 4,290 | 27,020 | 15,033 |
| Loss from operations | (9,809) | (3,034) | (25,838) | (11,450) |
| Interest expense | (226) | — | (660) | — |
| Other expense, net | (111) | (2) | (409) | (4) |
| Loss before income taxes | (10,146) | (3,036) | (26,907) | (11,454) |
| Income tax provision | (35) | (8) | (59) | (25) |
| Net loss and comprehensive loss | (10,181) | (3,044) | (26,966) | (11,479) |
| Cumulative dividends allocated to preferred stockholders | (578) | (1,071) | (5,202) | (2,957) |
| Net loss attributable to common stockholders | $ (10,759) | $ (4,115) | $ (32,168) | $ (14,436) |

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

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 259,484 | $ 9,017 |
| Total assets | $ 262,449 | $ 10,676 |
| Total liabilities | $ 10,433 | $ 10,952 |
| Convertible preferred stock | $ — | $ 70,363 |
| Total stockholders' equity/(deficit) | $ 252,016 | $ (70,639) |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| GAAP net loss, as reported | $ (10,181) | $ (3,044) | $ (26,966) | $ (11,479) |
| Adjustments: | | | | |
| Stock-based compensation expense | 689 | 86 | 3,693 | 222 |
| Accretion of term loan | 118 | — | 339 | — |

| | | | | |
|---|---|---|---|---|
| Mark-to-market adjustment on financial instruments | 242 | — | 650 | — |
| Total adjustments | 1,049 | 86 | 4,682 | 222 |
| Non-GAAP net loss | $ (9,132) | $ (2,958) | $ (22,284) | $ (11,257) |

**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“ is not based on any standardized methodology prescribed by GAAP and represent GAAP net loss adjusted to exclude (1) stock-based compensation expense, (2) debt offering costs (interest expense related to ALX Oncology’s term loan offering costs) and (3) mark-to market adjustment on financial instruments (which include preferred stock warrants and derivatives) 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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