# ALX Oncology Announces New Data from ASPEN-01, the Phase 1b Study of ALX148, Showing Promising Initial Clinical Responses in Patients with Advanced Solid Tumors

November 9, 2020

**-- ORR of 64% Observed in Patients with ≥2L HER2 Positive Gastric/Gastroesophageal Junction Cancer**

**-- ORR of 75% and One Complete Response Observed in Patients with 1L Head and Neck Cancer**

**-- ALX Oncology to Host Conference Call on November 16 at 5:00pm EST**

BURLINGAME, Calif., Nov. 09, 2020 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, today announced new results from ASPEN-01, the ALX148 Phase 1b study, evaluating patients with solid tumor malignancies at the Society for Immunotherapy of Cancer's 35 th Anniversary Annual Meeting [abstract 404].

ALX Oncology reports new preliminary data from the gastric/gastroesophageal junction cancer ("GC") patient cohort receiving ALX148 plus trastuzumab plus chemotherapy, and from the head and neck squamous cell carcinoma ("HNSCC") patient cohort receiving ALX148 plus pembrolizumab plus chemotherapy. In addition, updated data are presented from the GC patient cohort receiving ALX148 plus trastuzumab, and from the HNSCC patient cohort receiving ALX148 plus pembrolizumab. All data reflect response evaluable patients as of October 1, 2020.

- In patients with ≥2L HER2 positive GC (n=14), whose tumors have progressed upon prior trastuzumab therapy, ALX148 demonstrates a promising initial objective response rate (ORR) of 64% in combination with trastuzumab plus ramucirumab and paclitaxel that compares favorably with historical data.
- In initial patients with 1L HNSCC who have not received prior treatment for their advanced disease (n=4), ALX148 demonstrates a promising initial ORR of 75%, including a complete response, in combination with pembrolizumab plus 5-fluorouracil and platinum.
- Updated data from patients with ≥2L HER2 positive GC receiving ALX148 plus trastuzumab suggests promising clinical activity after their tumors have progressed upon prior trastuzumab therapy.
- 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 suggests clinical activity beyond that expected from pembrolizumab monotherapy.
- Preliminary data suggests that ALX148 can be safely combined with multi-agent chemotherapy regimens studied with no maximum tolerated dose reached. The maximum administered dose of ALX148 in combination was 15 mg/kg once per week.

"This remarkable emerging data suggest that ALX148 in combination with the standard chemotherapy based regimens studied may induce meaningful clinical benefit in patients with advanced HER2 positive gastric as well as head and neck cancers," said Dr Keun-Wook Lee, Professor of Internal Medicine at Seoul National University College of Medicine, and Chief of The Clinical Trials Center at Seoul National University Bundang Hospital, South Korea.

"To our knowledge, these data are the first to support this degree of clinical activity in patients with solid tumors by a CD47 targeted agent," said Dr. Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "Importantly, these results and ALX148's favorable tolerability profile further differentiate it from other CD47 targeted approaches, and we look forward to continuing its clinical development in our robust phase 2 program."

**Conference Call on November 16th at 5:00pm EST**

ALX Oncology will host a conference call on Monday, November 16, 2020 at 5:00 p.m. EST to further discuss the new GC data from ASPEN-01, the Phase 1b study of ALX148 that 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.

**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 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 August 27, 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.

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