ALX Oncology to Present ALX148 Clinical Data at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting

October 14, 2020

New data will be presented from the phase 1b study of ALX148, a next generation CD47 blocker, in combination with standard chemotherapy and antibody regimens in patients with gastric/gastroesophageal junction (GC) cancer and head and neck squamous cell carcinoma (HNSCC)

BURLINGAME, Calif., Oct. 14, 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 that ALX148 clinical results have been selected for presentation at the SITC 35th Anniversary Annual Meeting, November 9 –14, 2020.

The abstract for our presentation appeared briefly and in error on the SITC website this morning, prior to its intended release on November 9th 2020, and as a result the abstract is provided in full below.

Poster Presentation Details

Title: ALX148, a CD47 blocker, in combination with standard chemotherapy and antibody regimens in patients with gastric/gastroesophageal junction (GC) cancer and head and neck squamous cell carcinoma (HNSCC) (*Abstract 404*)

Presentation Time: November 11 – 14, 2020, 9:00am – 5:00pm ET

Location: Virtual Poster Hall

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Full Abstract

Background: CD47 is a myeloid checkpoint up-regulated by tumors to evade the anticancer immune response. ALX148 is a high affinity CD47-blocking fusion protein with an inactive Fc region designed to safely enhance anticancer therapeutics [1,2]. ALX148 in combination with standard chemotherapy and antibody regimens was evaluated in patients (pts) with advanced HER2-positive GC or HNSCC.

Methods: Pts with previously treated advanced HER2-positive GC or untreated advanced HNSCC received ALX148 (A) 10 mg/kg QW or 15 mg/kg QW in combination with trastuzumab (T) + ramucirumab (ram) + paclitaxel (pac) as 2nd or later-line treatment or pembrolizumab (P) + 5FU + platinum (cisplatin or carboplatin) as 1st line therapy, respectively. The primary endpoint was dose limiting toxicity (DLT). Tumor response, pharmacokinetic (PK), and pharmacodynamic (PD) markers were assessed in all pts. Preliminary data from enrolling cohorts, and follow-up data from pts with GC administered A+T, and with HNSCC administered A+P are also reported as of 30June2020.

Results: Fifty-five pts enrolled into this portion of the study. Twelve patients with ≥2L GC received A+T+ram+pac and were evaluated for safety. No DLTs, were reported, and the ALX148 maximum administered dose was 15 mg/kg QW. Out of the 9 pts who experienced any adverse event, 7 pts reported treatment-related adverse events (TRAE). The most common TRAEs were low grade diarrhea, fatigue, pruritus and rash (each n=2,17%). Nine of the 12 patients were response-evaluable and reported a 66% ORR with 6PR and 3SD (including one ongoing near PR, ↓29.6%). Three patients with 1L HNSCC were administered A+P+5FU+platinum. No DLTs were reported and accrual to 15 mg/kg QW continues. Three pts experienced any AE, none were treatment-related. Of 3 evaluable patients with HNSCC, 2PR and 1SD were reported. Initial ALX148 combination PK and CD47

target occupancy are similar to that of single agent administration. Response duration and survival follow-up of 19 pts with HER2-positive GC administered A+T (2nd or later-line; 21% ORR) and of 10 pts with checkpoint inhibitor naïve HNSCC administered A+P (2nd or later-line; 40% ORR) will be reported. Results of all cohorts will be updated at time of presentation.

Conclusions: Initial data suggests the myeloid checkpoint inhibitor, ALX148, is well tolerated in combination with the above anticancer antibodies, T-cell checkpoint inhibitor, and cytotoxic chemotherapy regimens with early anticancer signals in GC and HNSCC that compare favorably with historic controls. No MTD has been reached in any combination to date and accrual to chemotherapy combination regimens is ongoing. ClinicalTrials.gov identifier NCT03013218.

References:

1. Kauder S, Kuo T, Harrabi O, Chen A, Sangalang E, et al. ALX148 blocks CD47 and enhances innate and adaptive antitumor immunity with a favorable safety profile. PLoS ONE. 2018;13(8).

2. Chow L, Gainor J, Lakhani N, et al. A phase I study of ALX148, a CD47 blocker, in combination with standard anticancer antibodies and chemotherapy regimens in patients with advanced malignancy. Journal of Clinical Oncology 2020; 38:15_suppl, 3056-3056.

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 advance ALX148 into clinical development for the treatment of myelodysplastic syndromes and to continue clinical development for the treatment of a range of solid tumor indications. For more information, please visit ALX Oncology's website at https://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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