ALX Oncology Presents Phase 1 Study Results of ALX148 in Combination with Standard Anti-Cancer Antibodies and Chemotherapy Regimens in Patients with Advanced Solid Tumors

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Final Results from Fully Enrolled ALX148 Plus Pembrolizumab and ALX148 Plus Trastuzumab Dose Expansion Cohorts Presented at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting

BURLINGAME, Calif.--(BUSINESS WIRE)--ALX Oncology Holdings Inc., a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced the final results from the fully enrolled ALX148 plus pembrolizumab and ALX148 plus trastuzumab portions of the Phase 1 clinical program at the 2020 ASCO Annual Meeting [Abstract #3056]. In addition, preliminary data were presented from patients administered ALX148 plus standard chemotherapy-containing regimens.

As of April 01, 2020, eighty-nine patients with advanced solid tumors were administered ALX148 in combination with standard regimens of: 1) pembrolizumab, 2) trastuzumab, 3) pembrolizumab plus 5-fluorouracil plus platin, or 4) trastuzumab plus ramucirumab plus paclitaxel. Expansion cohorts comprising patients with previously treated advanced squamous cell carcinoma of the head and neck (HNSCC) and advanced gastric/gastroesophageal junction cancer (G/GEJ) demonstrated objective responses with the following key results in response-evaluable patients:

- ALX148 plus pembrolizumab (n=20): Subjects with advanced HNSCC whose tumors had progressed on standard first-line therapy demonstrated an objective response rate (ORR) of 20% and a disease control rate of 30%.

- Subjects with advanced HNSCC who had never received prior checkpoint inhibitor therapy (n=10) demonstrated an ORR of 40%, median progression-free survival (PFS) of 4.61 months, and median overall survival (OS) that was not reached with a median follow-up of 17.9 months.

- ALX148 plus trastuzumab (n=19): Subjects with advanced HER2 positive G/GEJ whose tumors had progressed on standard first-line therapy, including trastuzumab, demonstrated an ORR of 21%, median PFS of 2.17 months, and median OS of 11.5 months.

ALX148 displayed a favorable safety profile with no exposure-dependent cytopenia observed across the dose range evaluated. Preliminary data suggest that ALX148 can be combined with chemotherapy-containing regimens with objective responses observed in patients with HNSCC and G/GEJ disease.

“We believe the compelling clinical activity and tolerability observed with ALX148 in combination with a variety of anti-cancer antibodies and a checkpoint inhibitor suggests that ALX148 has the potential to become a cornerstone therapy for the treatment of patients with cancer,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. “Notably, the initial safety profile of ALX148 in combination with chemotherapy may support broad therapeutic potential for ALX148 in patients in need of novel chemotherapy-based therapies early in the course of their disease.”

About ALX Oncology

ALX Oncology is a 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 activity 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.

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