ALX Oncology Presents Clinical Biomarker Data from ALX148 Clinical Trial Solid Tumor Combination Cohorts at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)

DUBLIN, Ireland and BURLINGAME, Calif. – November 6, 2019 – ALX Oncology, a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, will present clinical and pharmacodynamic biomarker data from the solid tumor combination cohorts of the ongoing ALX148 Phase 1 clinical program at the SITC 34th Annual Meeting [Abstract P449].

As of September 23, 2019, eighty-two patients with advanced malignancies were administered ALX148 in combination with standard regimens of either trastuzumab (n=30) or pembrolizumab (n=52). Objective responses were observed in expansion cohorts for response-evaluable patients with gastric/gastroesophageal junction cancer (G/GEJ) and squamous cell carcinoma of the head and neck (HNSCC). A summary of results is described below.

- Patients with HER2 positive G/GEJ (n=19) whose tumors had progressed on prior systemic therapy, including HER2-targeted therapy, demonstrated an objective response rate (ORR) of 21% and a disease control rate (DCR) of 26%.

- Patients with HNSCC (n=20) whose tumors had progressed on prior platinum therapy, demonstrated an ORR of 20% and a DCR of 30%. In checkpoint inhibitor-naïve subjects (n=10), an ORR of 40% and a DCR of 40% were observed.

- ALX148 was well tolerated with no maximum tolerated dose reached. Treatment-related adverse events were mostly of low grade and frequency.

- Complete CD47 target occupancy was observed throughout the dosing interval with no impact on circulating immune cell populations following ALX148 combination treatments.

- Immunohistochemistry analysis using paired pre- and on-study tumor biopsies showed a statistically significant increase in intratumoral macrophages in pembrolizumab and trastuzumab combinations, and an increase in intratumoral CD8+ cells in combination with pembrolizumab.

- RNA expression analysis from paired tumor biopsies suggest increased dendritic cells, cytotoxic cells, as well as gene signatures associated with antigen presentation, myeloid cell activity and tumor inflammation following ALX148 in combination with pembrolizumab.

“These exciting clinical responses and pharmacodynamic changes within the tumor microenvironment observed with ALX148 combinations support our hypothesis that blocking CD47 with an Fc-inactive molecule can enhance the anti-cancer innate and adaptive immune response in patients with advanced solid tumor malignancies,” said Jaume Pons, Ph.D., President and Chief Executive Officer of ALX Oncology. “ALX148 as a myeloid checkpoint inhibitor has the potential to become a new cornerstone of immune therapy. We continue to advance ALX148 development in populations in need of novel treatments.”

About ALX Oncology

ALX Oncology is a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint mechanism, which is exploited by cancer cells to evade the immune system. Our lead candidate, ALX148, is a first-in-class fusion protein comprised of an engineered high affinity CD47 binding domain of SIRPα linked to an inactive Fc region of human immunoglobulin. ALX148 is designed to maximize the clinical benefit of antibody-based therapies and is in clinical development for a broad range of tumor types. www.alxoncology.com

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