ALX Oncology Presents New Data from Fully Enrolled ALX148 Clinical Trial Combination Cohorts for the Treatment of Patients with Advanced Solid Tumors

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New Clinical Data Presented at the 2019 American Society of Clinical Oncology (ASCO) in Chicago, IL

DUBLIN, Ireland and BURLINGAME, Calif. – June 1, 2019 – ALX Oncology, a clinical-stage immuno-oncology company developing therapies to block the CD47 myeloid checkpoint mechanism, today announced new results from its Phase 1 ALX148 solid tumor program at the 2019 ASCO Annual Meeting [Abstract #2514]. As of April 18, 2019, eighty-two patients with various 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 both gastric/gastroesophageal junction cancer (G/GEJ) and squamous cell carcinoma of the head and neck (HNSCC). Key results are:

- In response-evaluable patients with HER2 positive G/GEJ (n=18) whose tumors had failed prior HER2-targeted therapy, an overall response rate (ORR) of 22% and a disease control rate (DCR) of 28% were observed.
- In patients with HNSCC (n=19) whose tumors had failed prior platinum therapy, an ORR of 16% and a DCR of 26% were observed. In checkpoint naïve subjects (n=10), an ORR of 30% and a DCR of 30% were observed.
- ALX148 was well tolerated and the most common treatment-related adverse event in combination with trastuzumab was grade 1/2 fatigue (27%), and with pembrolizumab was grade 1/2 increased AST (15%).
- Preliminary data from paired pre- and on-study tumor biopsies from combination cohorts showed a statistically significant increase in intra-tumoral macrophages following ALX148 treatment, consistent with ALX148's mechanism of action as a myeloid checkpoint inhibitor.

"Emerging anti-tumor activity of ALX148 combined with anti-cancer antibodies supports our hypothesis that blocking CD47 with an Fc-inactive molecule can enhance the anti-cancer immune response in patients with varying solid tumor malignancies," said Sophia Randolph M.D., Ph.D., Chief Medical Officer of ALX Oncology. "With its clinical activity and consistent safety profile, ALX148 may become a new cornerstone of immune therapy. We are excited to continue evaluating its clinical benefit in populations in need of novel treatments."

About ALX148

ALX148, designed for combination therapy, is a fusion protein comprised of an engineered high affinity CD47 binding domain of SIRPα linked to an inactive Fc region of human immunoglobulin. ALX148 potently and specifically binds CD47 and blocks its interaction with SIRPα, thus inhibiting a key immune checkpoint mechanism exploited by cancer cells. In preclinical studies, ALX148 bridges innate and adaptive immunity to maximize anti-tumor response in combinations with targeted anti-cancer antibodies and checkpoint inhibitors via Fc-dependent and Fc-independent mechanisms. No adverse effects on CD47-expressing normal blood cells were seen in ALX148 preclinical studies.

The ALX148 Phase 1 clinical trial is a two-part study that evaluates the safety, pharmacokinetics, and pharmacodynamics of ALX148. Enrollment to the combination therapy portion in which ALX148 is administered with approved anti-cancer antibodies is ongoing. For more information about the Phase 1 study, please visit clinicaltrials.gov, identifier number NCT03013218.

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 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.

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