# ALX Oncology's ALX148 Receives Two Fast Track Designations from FDA for the Treatment of Patients with Head and Neck Squamous Cell Carcinoma and Patients with Gastric or Gastroesophageal Junction Adenocarcinoma

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DUBLIN, Ireland and BURLINGAME, Calif. – February 18, 2020 – ALX Oncology, a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, today announced that the U.S. Food and Drug Administration (FDA) has granted two Fast Track designations for its lead candidate, ALX148, for the first-line treatment of patients with head and neck squamous cell carcinoma (HNSCC), and for the second-line treatment of patients with HER2-positive gastric or gastroesophageal junction (gastric/GEJ) carcinoma. Data supporting these Fast Track designations were based on an open-label, multicenter Phase 1 clinical trial of ALX148 in combination with pembrolizumab or trastuzumab.

"FDA's decision to grant Fast Track designation to ALX148 is an important recognition of ALX Oncology's promising clinical data. This designation reflects the potential for ALX148 to be an important advancement in the treatment of patients with HNSCC and HER2-positive gastric/GEJ cancer," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. "We are encouraged by the initial data from our Phase 1 clinical trial that showed a 40 percent objective response rate (ORR) in checkpoint inhibitor-naive HNSCC patients whose tumors had progressed on prior platinum therapy, and a 21 percent ORR in gastric/GEJ patients where all responders' disease had progressed upon at least one prior anti-HER2 containing regimen. We look forward to working closely with the FDA on the clinical development of ALX148 for patients with cancer."

## About FDA Fast Track Designation

The FDA's Fast Track program is designed to facilitate the development and expedite the review of medicines that may treat serious or life-threatening conditions and address significant unmet medical needs. The designation provides the opportunity for more frequent meetings with the FDA over the course of drug development. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review if relevant criteria are met, as well as for Rolling Review, which enables a drug company to submit portions of the Biologic License Application to the FDA as they are completed.

## About HNSCC and Gastric/GEJ

HNSCC is a serious and life-threatening disease with poor prognosis despite current available standard of care therapies. There were 53,000 new cases of head and neck cancer in the U.S. with 10,860 estimated deaths in 2019 alone.

Gastric/GEJ cancer is also a serious and life-threatening disease, and prognosis is poor with existing standard of care treatment. Gastric/GEJ is the third leading cause of cancer death globally. Approximately 20 percent of patients who develop gastric/GEJ in their lifetime will present with HER2-positive disease.

## 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, a next generation CD47 myeloid checkpoint inhibitor, 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 anti-cancer therapeutics and is in clinical development for a broad range of tumor types. For more information about the clinical study, please visit clinicaltrials.gov, identifier number NCT03013218.

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