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

November 7, 2018

Updated Clinical Data Presented at the Society for Immunotherapy of Cancer's (SITC) 33 rd Annual Meeting in Washington, D.C.

DUBLIN, Ireland and **BURLINGAME**, Calif. – November 7, 2018 – ALX Oncology, a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, today announced updated results from its Phase 1 ALX148 solid tumor program in patients with advanced malignancy at SITC's 33 rd Annual Meeting. The data will be further discussed in an oral presentation.

In the trial, fifty-seven patients with advanced solid tumor malignancies have been administered ALX148 in combination with standard regimens of either pembrolizumab or trastuzumab as of the Oct 12, 2018 data cutoff. ALX148 was generally well tolerated in combination and no maximum tolerated dose was reached. The most common treatment related adverse events were Fatigue (9%) and ALT increase (7%). While the majority of 18 evaluable dose expansion patients had undergone only one initial response assessment, preliminary anti-tumor activity and decreased tumor burden were seen across all cohorts and combinations, including patients whose tumors are resistant/refractory to prior checkpoint inhibitors or trastuzumab.

"Intended for combination treatments, ALX148 is designed to avoid the dose-limiting toxicities associated with other CD47-targeted approaches in the clinic while maximizing the efficacy of antibody-based therapies," said Sophia Randolph M.D., Ph.D., Chief Medical Officer of ALX Oncology." The favorable safety profile and preliminary anti-cancer activity of ALX148 in combination with standard regimens of pembrolizumab and trastuzumab support our hypothesis. ALX148 exhibits an encouraging profile with respect to tolerability, pharmacokinetics and CD47 target occupancy, which allows it to be administered using a simple weekly regimen. With broad therapeutic potential across many types of cancer, we are excited to continue evaluating the clinical benefit of ALX148."

Presentation Details

Title: A phase 1 study of ALX148: CD47 blockade in combination with anticancer antibodies to bridge innate and adaptive immune responses for advanced malignancy
Oral Session
Date/Time: Saturday, November 10, 12:55 p.m.
Oral Presentation Location: 204ABC
Presenter: Nehal Lakhani, M.D., Ph.D. – START-Midwest
Poster Session
Poster Number: P335
Poster Location: Hall E
Date/Time: Friday, Nov. 9 from 8 a.m. - 8 p.m. and Saturday, Nov. 10 from 8 a.m. - 8:30 p.m.

ALX further presented data on the clinical pharmacokinetics (PK) and pharmacodynamics of ALX148. The PK properties of ALX148 are similar to anti-CD47 antibodies with a projected half-life of 16 days at the current dosing regimen of 10 mg/kg once weekly. This ALX148 dosing regimen is equivalent to 20 mg/kg once weekly of an anti-CD47 antibody and achieves complete CD47 target occupancy.

Presentation Details

Title: Pharmacokinetic and pharmacodynamic characterization of ALX148, a CD47 blocker, in patients with advanced malignancy and non-Hodgkin lymphoma
Poster number: P340
Poster Location: Hall E
Date/Time: Friday, Nov. 9 from 8 a.m. - 8 p.m. and Saturday, Nov. 10 from 8 a.m. - 8:30 p.m.

About ALX148

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 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 via Fc-dependent and Fc-independent mechanisms to enhance anti-tumor response in combination with targeted anti-cancer

antibodies and checkpoint inhibitors with no adverse effect on CD47-expressing normal blood cells. 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.

Contacts

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