Alexo Therapeutics Presents Preliminary Results from ALX148 Phase 1 Clinical Trial in Patients with Advanced Solid Tumors and Lymphoma

-Data presented at the American Society of Clinical Oncology (ASCO)
in Chicago, Illinois -

DUBLIN, Ireland and BURLINGAME, Calif. – June 04, 2018 – Alexo Therapeutics, a clinical-stage immuno-oncology company developing therapies to block the CD47 checkpoint mechanism, presented data today from the first-in-human Phase 1 study of its lead candidate, ALX148, at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. Preliminary results from the trial (NCT03013218) showed that ALX148 is generally well tolerated as a single agent and in combinations in patients with advanced solid tumors and non-Hodgkin lymphoma.

"ALX148 has been designed to safely enhance the activity of established anti-cancer antibodies," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of Alexo. "Whether in combination with T cell checkpoint inhibition, targeted anti-cancer antibodies or as a single agent, no maximum tolerated dose of ALX148 was reached. The molecular weight of ALX148 is half that of an antibody, and therefore has potentially greater tumor penetration. ALX148 is able to achieve linear pharmacokinetics and complete CD47 target occupancy in the clinic at doses that are approximately half that of an anti-CD47 antibody. ALX148 has demonstrated single agent and combination safety in the clinic, and we are excited to evaluate ALX148 in combination as a potential treatment option in an expanded population of cancer patients at doses expected to saturate CD47 at tumor sites."

As of May 2018, ALX148 was intravenously administered over a dose range of 0.3 mg/kg to 30 mg/kg as a single agent or in combination with standard regimens of pembrolizumab, trastuzumab or rituximab in 43 patients with advanced malignancy. The most common treatment related adverse events were Fatigue (14%) and Headache (11%). Most treatment-related adverse events were Grade 1 or 2 and occurred as sole events. Three out of the initial five evaluable patients in combination have ongoing stable disease as a best response as of the data cut off. The trial will evaluate ALX148 administered at 10 mg/kg, once weekly, in the combination setting in expanded cohorts of patients with solid tumors and non-Hodgkin lymphoma.

About ALX148

ALX148 is a fusion protein comprised of an engineered high affinity CD47 binding domain of SIRP α linked to an inactive Fc region of human immunoglobulin. ALX148 potently and specifically binds CD47 and blocks its interaction with SIRP α, thus inhibiting a key immune checkpoint mechanism exploited by cancer cells. In preclinical studies, ALX148 bridges innate and adaptive immunity 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. ALX148 is currently being investigated in a Phase 1 study in combination with checkpoint inhibitors and targeted anti-cancer antibodies (NCT03013218).

About Alexo Therapeutics

Alexo Therapeutics 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 SIRP α linked to an inactive Fc region of human immunoglobulin. ALX148 is designed to enhance the efficacy of antibody-based therapies and is in clinical development for a broad range of tumor types. www.alexotherapeutics.com

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