ALX Oncology Presents Preliminary Phase 1 Study Results of ALX148 in Combination with Rituximab in Patients with Relapsed or Refractory Non-Hodgkin Lymphoma

June 12, 2020

Preliminary Results from Fully Enrolled ALX148 Plus Rituximab Combination Cohort Presented at the 25th Congress of the European Hematology Association (EHA)

BURLINGAME, Calif.--(BUSINESS WIRE)--ALX Oncology Holdings Inc., a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced preliminary results from the fully enrolled ALX148 plus rituximab combination cohort of the Phase 1 clinical program at the 25th Annual Congress of EHA [abstract #EP1247]. As of April 1, 2020, 33 patients with relapsed or refractory non-Hodgkin Lymphoma (NHL) were administered ALX148 at 10 or 15 mg/kg once per week (QW) in combination with a standard rituximab regimen. The following key results were observed in response-evaluable subjects:

- ALX148 in combination with a standard regimen of rituximab is well tolerated with no maximum tolerated dose reached. The maximum administered dose is 15 mg/kg QW (molar equivalent to 30 mg/kg QW an antibody) with no exposure-dependent cytopenia observed across the exposure range evaluated.
- ALX148 10mg/kg plus rituximab (n=22): In all subjects, an overall objective response rate (ORR) of 40.9% and median progression-free survival (mPFS) of 7.4 months were observed.
    - In patients with aggressive NHL (n=15) an ORR of 33.3% and median duration of response (mDOR) of 5.6 months were observed.
    - In patients with indolent NHL (n=7) an ORR of 57.1% was observed and mDOR was not reached.
    - Three patients achieved complete response.
- ALX148 15mg/kg plus rituximab (n=11): In all subjects, an ORR of 54.6% was observed and mPFS was not reached.
    - In patients with aggressive NHL (n=7) an ORR of 42.9% was observed and mDOR was not reached.
    - In patients with indolent NHL (n=4) an ORR of 75% was observed and mDOR was not reached.
    - Two patients achieved complete response.
- ALX148 demonstrates linear pharmacokinetics at 10 mg/kg and 15 mg/kg QW with near complete peripheral CD47 target occupancy in combination with rituximab at both dose levels.

“With no exposure-dependent cytopenias observed, and a greater response rate observed in the higher dosing cohort of heavily pre-treated subjects with NHL, we believe this study provides compelling evidence for the potential of ALX148 in treating hematologic malignancies,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. “The higher ALX148 exposure levels observed in subjects with objective responses is encouraging evidence for the pharmacologic activity of ALX148 and supports higher dose administration in future trials for patients with cancer.”

About ALX Oncology

ALX Oncology is a clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. ALX Oncology’s lead product candidate, ALX148, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. ALX148 has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. ALX Oncology intends to advance ALX148 into clinical development for the treatment of myelodysplastic syndromes and to continue clinical development for the treatment of a range of solid tumor indications.

Media Contact

Karen Sharma
MacDougall
(781) 235-3060
alx@macbiocom.com

Investor Contact

Peter Garcia

Chief Financial Officer, ALX Oncology
(650) 466-7125 Ext. 113
peter@alxoncology.com