ALX Oncology Announces First Patient Dosed in ASPEN-02, a Phase 1/2 Study of ALX148 in Combination with Azacitidine in Patients with Myelodysplastic Syndrome

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First of multiple planned studies of ALX148 in patients with myeloid malignancies

BURLINGAME, Calif., Oct. 28, 2020 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc. (“ALX Oncology”) (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced the first patient has been dosed in the Phase 1/2 ASPEN-02 study evaluating the combination of ALX148, a next-generation CD47 blocker, with azacitidine for the treatment of patients with higher-risk myelodysplastic syndrome (“MDS”).

The Phase 1 part of the study is expected to characterize the safety of ALX148 in combination with azacitidine in patients with relapsed/refractory or previously untreated higher-risk MDS. Upon completion of the Phase 1, the Phase 2 component of the study will be initiated to evaluate the efficacy of the combination in patients with previously untreated higher-risk MDS.

This study has been initiated based on promising preclinical data of ALX148 in combination with azacitidine in myeloid leukemia models, and clinical data generated by ALX Oncology in an ongoing Phase 1 trial (NCT03013218) evaluating ALX148 in combination with other anti-cancer agents in over 150 patients with various malignancies, including non-Hodgkins lymphoma, gastric/gastroesophageal junction cancer (“GC”), and head and neck squamous cell carcinoma (“HNSCC”). Data from the Phase 1 study provides the basis for ALX148’s Fast Track Approvals in GC and HNSCC granted by the U.S. Food and Drug Administration.

“We are looking forward to evaluating the addition of ALX148 to azacitidine in patients with advanced MDS who are in need of effective new therapies,” said Guillermo Garcia-Manero, M.D., Professor and Chief of Section of Myelodysplastic Syndromes, Department of Leukemia at MD Anderson Cancer Center. “ALX148 was designed for use in combination with a range of agents to maximize anti-cancer activity while minimizing associated toxicity.”

“Through blockade of the CD47 myeloid checkpoint pathway, ALX148 bridges the innate and adaptive immune responses to cancer. This study builds upon the compelling combination activity observed in patients with ALX148 and multiple other anti-cancer agents,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. “Our goal is to transform treatment options for patients with cancer by developing ALX148 as a foundational checkpoint immunotherapy.”

The ASPEN-02 trial is registered under NCT04417517. ALX Oncology owns worldwide commercial rights to ALX148.

About Myelodysplastic Syndrome (“MDS”)

MDS represents a group of blood cancers characterized by ineffective production of healthy red blood cells, white blood cells, and platelets. This can lead to anemia with a potential need for frequent transfusions, infections, and a risk for transformation into leukemia. Over 10,000 people are estimated to be diagnosed with MDS in the U.S. each year. The average survival rate for those with higher-risk MDS is approximately 18 months.

About ALX Oncology

ALX Oncology is a publicly-traded, 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 hematologic malignancies, including MDS and acute myeloid leukemia, and to continue clinical development in multiple solid tumor indications.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such forward-looking statements are based on ALX Oncology’s beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology’s actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These statements include but are not limited to statements regarding ALX Oncology’s clinical pipeline and the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of ALX148. These and other risks are described more fully in ALX Oncology’s filings with the Securities and Exchange Commission (“SEC”), including ALX Oncology’s Quarterly Report on Form 10-Q, filed with the SEC on August 27, 2020, and other documents ALX Oncology subsequently files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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