ALX Oncology Receives U.S. FDA Orphan Drug Designation for Evorpacept for the Treatment of Patients with Acute Myeloid Leukemia

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SOUTH SAN FRANCISCO, Calif., June 29, 2022 (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 that the U.S. Food and Drug Administration (“FDA”) granted orphan drug designation (“ODD”) to evorpacept, a next-generation CD47 blocker, for the treatment of patients with acute myeloid leukemia (“AML”).

“Receiving orphan drug designation in AML, and previously in gastric cancer, from the FDA is an important regulatory milestone and reflects the FDA’s recognition of evorpacept’s potential to improve clinical outcomes in patients with these advanced cancers,” said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. “In our ongoing Phase 1/2 ASPEN-05 study (NCT04755244), we are excited to evaluate the combination of evorpacept with venetoclax and azacitidine in patients with previously untreated AML who are not candidates for intensive induction therapy or with relapsed/refractory AML.”

The FDA’s Office of Orphan Products Development grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for qualified clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

About Acute Myeloid Leukemia

AML is an aggressive blood cell cancer that can rapidly progress and lead to death if not treated promptly. AML is the most common form of acute leukemia in adults, with an estimated 20,050 new cases and 11,540 deaths from AML in the United States in 2022. Due to advanced age and comorbidities at the time of diagnosis, a significant number of patients are not considered eligible for intensive and potentially curative therapies. Despite advances in available care, the estimated 5-year survival for patients in the United States with AML remains only 31%.

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, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpacept 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 continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. 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 and other risks are described more fully in ALX Oncology’s filings with the Securities and Exchange Commission (“SEC”), including ALX Oncology’s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology 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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