ALX Oncology Announces Clinical Trial Collaboration with Sanofi to Evaluate Evorpacept in Combination with SARCLISA (isatuximab-irfc) in Patients with Multiple Myeloma

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SOUTH SAN FRANCISCO, Calif., April 25, 2023 (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 it has entered into a clinical trial collaboration and supply agreement with Sanofi to evaluate the combination of evorpacept, a next generation CD47 blocker, and SARCLISA (isatuximab-irfc), Sanofi's monoclonal antibody that targets a specific epitope on the CD38 receptor on multiple myeloma cells, for the treatment of patients with relapsed or refractory multiple myeloma ("RRMM"). SARCLISA is approved in multiple countries, including the U.S., in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received ≥ 2 prior therapies. SARCLISA is also approved in multiple countries in combination with carfilzomib and dexamethasone for the treatment of patients with RRMM who have received 1-3 prior lines of therapy and in the E.U. for patients with multiple myeloma who have received at least 1 prior therapy.

Under the terms of the agreement, Sanofi will conduct a Phase 1/2 study to evaluate the safety, efficacy, pharmacokinetics and biomarker data of evorpacept in combination with SARCLISA and dexamethasone in patients with RRMM. Part 1 will evaluate dosing of evorpacept in combination with standard doses of SARCLISA and dexamethasone to identify a recommended dose. Part 2 will investigate the efficacy and safety of this combination in an expanded population of patients with RRMM. ALX Oncology will supply evorpacept and Sanofi will supply SARCLISA for this study.

"We are thrilled to enter this collaboration with Sanofi that has the potential to advance a new combination therapy for patients with relapsed multiple myeloma who would benefit from novel effective treatment options," said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. "The combination of blocking both CD47 and CD38 has shown synergistic anti-tumor activity in preclinical studies, and this combination may re-sensitize tumors to anti-CD38 treatment or overcome anti-CD38 resistance. This collaboration expands our robust clinical development pipeline with evorpacept, which we intend to establish as a new and best-in-class foundational immunotherapy in both hematologic and solid tumors."

"At Sanofi, our vision of chasing the miracles of science is highlighted through partnerships that speak to our commitment of exploring, and developing, new regimens for patients living with multiple myeloma," stated Helgi Van de Velde, M.D., Ph.D., Head of Hematologic Malignancies Strategies and Late Development, Oncology, Sanofi. "We are excited about this clinical collaboration with ALX Oncology where we will be evaluating the combination of SARCLISA with evorpacept."

ALX Oncology owns worldwide commercial rights to evorpacept.

About Multiple Myeloma
Multiple myeloma ("MM") is the second most common hematologic malignancy, with more than 175,000 new diagnoses of MM worldwide annually (Globocan) and over 35,000 new diagnoses in the U.S. each year (American Cancer Society). Despite available treatments, MM remains an incurable malignancy and is associated with significant patient burden. Since MM does not have a cure, most patients will relapse. Relapsed MM is the term for when the cancer returns after treatment or a period of remission. Refractory MM refers to when the cancer does not respond or no longer responds to therapy.

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.

SARCLISA is a registered trademark of Sanofi.

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