Xencor Presents Initial Data from Phase 1 Study of XmAb®14045 in Acute Myeloid Leukemia at the 2018 ASH Annual Meeting

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MONROVIA, Calif., Dec. 3, 2018 /PRNewswire/ -- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing monoclonal antibodies for the treatment of autoimmune disease, asthma and allergic diseases, and cancer, today announced initial data from its ongoing Phase 1 dose-escalation study of XmAb®14045, a CD123 x CD3 bispecific antibody, in patients with relapsed/refractory acute myeloid leukemia (AML). The data were presented in an oral session at the 2018 American Society of Hematology (ASH) Annual Meeting by Farhad Ravandi, M.D., Professor of Medicine and Chief of the Section of Developmental Therapeutics in the Department of Leukemia at the University of Texas – MD Anderson Cancer Center.

Key Highlights

- 66 patients with relapsed/refractory AML received XmAb14045. Patients were a median of 61 years old and were heavily pretreated, having had a median of three prior therapies and 30% (n=20) with a history of allogeneic stem cell transplantation. 86% of patients (n=57) were refractory to their last therapy, and 53% (n=35) were categorized as adverse risk at diagnosis by the European LeukemiaNet (ELN 2017) system.
- A maximum tolerated dose (MTD) has not been reached. Cytokine release syndrome (CRS) was the most common toxicity occurring in 55% of patients (n=36). 6% of patients (n=4) experienced Grade 3 or 4 CRS. CRS was more severe on the initial dose and was generally manageable with premedication. Additional adverse events consistent with CRS but not reported as such, including chills, fever, tachycardia, hypotension and hypertension within 24 hours of infusion, were reported in an additional 29% of patients (n=19).
- 28% of evaluable patients with AML achieved either complete remission (CR) or CR with incomplete hematologic recovery (CRi) at the two highest initial dose levels studied (1.3 and 2.3 mcg/kg weekly; n=5/18).
- Two patients with responses were bridged to stem cell transplantation, and a third transplant-ineligible patient has remained in remission for 16+ weeks after discontinuation of therapy.

"We have observed multiple complete remissions in heavily pretreated, relapsed/refractory AML patients from XmAb14045 dosed weekly, and we continue to optimize dosing regimen," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "Xencor's XmAb technology enables bispecific antibodies to retain natural antibody properties, simplifying their use and production. Our platform enables the rapid development of new bispecific antibody drug candidates addressing a breadth of targets, and throughout 2019 we anticipate several new clinical trial initiations and additional data readouts."

The data presentation is available under Archived Scientific Presentations on the Events & Presentations page in the Investors section of www.xencor.com.

Analyst & Investor Event and Webcast Information
Xencor will host an analyst and investor event tonight from 8:00 to 10:00 p.m. PST with formal remarks at 8:30 p.m. PST. The formal remarks will feature a discussion of the data presented at ASH and Xencor's bispecific oncology pipeline. It will be webcast live and can be accessed under Events & Presentations in the Investors section of www.xencor.com, where it will be archived for 30 days.

About XmAb®14045
XmAb14045 is a tumor-targeted antibody that contains both a CD123 binding domain and a cytotoxic T-cell binding domain (CD3) in a Phase 1 clinical trial for the treatment of acute myeloid leukemia (AML) and other CD123-expressing hematologic malignancies. An XmAb® Bispecific Fc domain serves as the scaffold for these two antigen binding domains and confers long circulating half-life, stability and ease of manufacture on XmAb14045. CD123 is highly expressed on AML cells and leukemic stem cells, and it is associated with poorer prognosis in AML patients. Engagement of CD3 by XmAb14045 activates T cells for highly potent and targeted killing of CD123-expressing tumor cells.

About Xencor, Inc.
Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune diseases, asthma and allergic diseases and cancer. Currently, 12 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internal programs include: obexelimab (XmAb®5871) in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb®7195 in Phase 1 development for the treatment of asthma and allergic diseases;

XmAb®14045 in Phase 1 development for acute myeloid leukemia; XmAb®13676 in Phase 1 development for B-cell malignancies; XmAb®18087 in Phase 1 development for the treatment of neuroendocrine tumors and gastrointestinal stromal tumors; XmAb®20717 in Phase 1 development for the treatment of advanced solid tumors, and XmAb®22841, XmAb®23104 and XmAb®24306 in pre-clinical development for the treatment of multiple cancers. Xencor's XmAb antibody engineering technology enables small changes to the structure of monoclonal antibodies resulting in new mechanisms of therapeutic action. Xencor partners include Novartis, Amgen, MorphoSys, CSL, Alexion and Boehringer Ingelheim. For more information, please visit www.xencor.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are forward-looking statements within the meaning of applicable securities laws, including, but not limited to, the quotations from Xencor's president and chief executive officer and any expectations relating to Xencor's financial expectations and business, the timing and success of clinical trials, future product candidates, Xencor's research and development programs, partnering efforts and capital requirements. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements and the timing of events to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Such risks include, without limitation, the risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective for use as human therapeutics and other risks described in Xencor's public securities filings. For a discussion of these and other factors, please refer to Xencor's annual report on Form 10-K for the year ended December 31, 2017 as well as Xencor's subsequent filings with the Securities and Exchange Commission. All forward-looking statements are based on Xencor's current information and belief as well as assumptions made by Xencor. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Xencor undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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