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Xencor Doses First Patient in Lead Immuno-Oncology Bispecific Program XmAb14045 for the Treatment of Acute Myeloid Leukemia and Other CD123-Expressing Hematologic Malignancies

MONROVIA, Calif., Sept. 12, 2016 /PRNewswire/ -- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune diseases, asthma and allergic diseases and cancer, today announced that the first patient has been dosed in a Phase 1 clinical trial of XmAb®14045 for the treatment of acute myeloid leukemia (AML) and other CD123-expressing hematologic malignancies.

"XmAb14045 is a bispecific antibody that engages the immune system against AML," said Paul Foster, M.D., chief medical officer at Xencor. "Built on the scaffold of Xencor's XmAb bispecific Fc domain, XmAb14045 simultaneously binds to CD123, a protein on AML cells, and CD3, a protein on cytotoxic T cells, to activate a targeted immune response against the cancer cells. XmAb14045 has shown highly potent killing of tumor cells in preclinical studies and we look forward to studying its safety, tolerability and antitumor activity in clinical trials."

The purpose of the trial is to determine the safety and tolerability of weekly intravenous administration of XmAb14045 and to determine the maximally tolerated dose/dosing schedule. Approximately 60 patients with AML or other CD123-expressing hematologic malignancies will receive XmAb14045. XmAb14045 showed very effective and potent depletion of target cells in primate studies from a well-tolerated single IV dose.

XmAb14045 is Xencor's lead bispecific candidate within the company's broad portfolio of CD3 bispecific antibody immunotherapies. Xencor and Novartis share worldwide development costs for XmAb14045 with Xencor maintaining U.S. commercial rights and Novartis having commercial rights in the rest of the world. Xencor expects to advance additional candidates using Xencor's XmAb bispecific technology into the clinic by the end of 2017.

For more information about the XmAb14045 clinical trial please visit to www.clinicaltrials.gov (identifier: NCT02730312).

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 Phase 1 clinical trials 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 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's XmAb® Bispecific Technology
As opposed to traditional monoclonal antibodies that target and bind to a single antigen, bispecific antibodies are designed to elicit multiple biological effects that require simultaneous binding to two different antigen targets. Xencor's XmAb bispecific Fc domain technology is designed to maintain full-length antibody properties in a bispecific antibody, potentially enabling favorable in vivo half-life and simplified manufacturing.

Efforts at bispecific antibody design are typically frustrated by poor molecular stability, difficulties in production and short in vivo half-life. Xencor has engineered a series of Fc domain variants that spontaneously form stable, heterodimeric bispecific antibodies and that can be made and purified with standard antibody production methods. These bispecific Fc domains are used to generate a broad array of novel drug candidates in a range of molecule formats.

Xencor's initial bispecific programs are T-cell engaging cancer immunotherapies that bind to cancer cells at one end and bind to cytotoxic T-cells at the other end, resulting in a highly potent and targeted killing of cancer cells. The XmAb Fc domain format allows Xencor to tune the potency of the T-cell killing, potentially improving the tolerability of cancer immunotherapy.

About Acute Myeloid Leukemia
Acute Myeloid Leukemia (AML) is a cancer of the blood and bone marrow characterized by rapid growth of abnormal blood cells that interfere with production of normal cells. It is estimated 20,000 patients in the United States will be diagnosed with AML each year. Without treatment AML can progress quickly and become fatal. For more information, please visit

www.cancer.org.

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, 10 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internal programs include: XmAb5871 in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb7195 in Phase 1 development for the treatment of asthma and allergic diseases; XmAb14045 in Phase 1 development for acute myeloid leukemia; and XmAb13676 for B-cell malignancies and XmAb18087 for the treatment of neuroendocrine tumors, both in pre-clinical development. 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, Merck, CSL/Janssen, Alexion, Novo Nordisk 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 the quotation from Xencor's officer and any expectations relating to its business, research and development programs, including ongoing clinical trials and the XmAb bispecific antibody technology, including XmAb14045, XmAb13676, and XmAb18087, partnering efforts or its 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. All forward-looking statements are based on Xencor's current information and belief as well as assumptions made by Xencor. Readers are cautioned not to place undue reliance on such statements and Xencor disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.