Xencor Announces Partial Clinical Hold on Phase 1 Study of XmAb14045

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MONROVIA, Calif., Feb. 20, 2019 /PRNewswire/ -- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer, autoimmune diseases, asthma and allergic diseases, today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on its Phase 1 study of XmAb14045, a CD123 x CD3 bispecific antibody molecule being evaluated in patients with relapsed or refractory acute myeloid leukemia and other CD123-expressing hematologic malignancies. Patients currently on treatment and benefiting from treatment may continue treatment on the study. No new patients will be allowed to enroll in the study until the partial clinical hold is lifted by the FDA.

The partial clinical hold was initiated following recent safety reports Xencor submitted to the FDA on two patient deaths that were considered at least possibly related to XmAb14045. One patient experienced cytokine release syndrome (CRS) after their first dose, the treatment of which was complicated by the patient's decision to withdraw care. One patient developed acute pulmonary edema following several doses of XmAb14045. The FDA has placed the trial on partial clinical hold pending review of additional details regarding these events, safety and efficacy information across the study, and satisfactory review of amendments to the study protocol and related documents. Xencor will be working closely with the FDA to review these events and resolve the partial clinical hold.

"Patient safety is Xencor's highest concern," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "We are working with the investigators and the FDA and will provide an update when more information about resuming enrollment can be shared. Our ongoing Phase 1 studies evaluating our other CD3 bispecific antibodies, XmAb13676 and XmAb18087, are not affected."

About XmAb14045

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.

Xencor Forward Looking Statement

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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