Xencor Announces Partial Clinical Hold Lifted on Phase 1 Study of XmAb®14045

April 30, 2019

MONROVIA, Calif.--(BUSINESS WIRE)--Apr. 30, 2019-- 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 the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold that was placed on the 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. The decision follows discussion and agreement with the FDA on amendments to the study protocol, including guidance on the monitoring and clinical management of cytokine release syndrome.

“We are working with investigational sites to resume enrollment based on the amended protocol, through which we have sought to enhance the safety of patients participating in the study,” said Paul Foster, M.D., senior vice president and chief medical officer at Xencor.

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 cancer, autoimmune diseases, asthma and allergic diseases. Currently, 12 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's XmAb antibody engineering technology enables small changes to the structure of monoclonal antibodies resulting in new mechanisms of therapeutic action. 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, 2018 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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