Xencor Regains ex-U.S. Commercial Rights to XmAb®13676, CD20 x CD3 Bispecific Antibody

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-- Initial data from the ongoing Phase 1 study in patients with B-cell malignancies expected in 2019 --

-- Xencor and Novartis to continue co-developing XmAb®14045, a CD123 x CD3 bispecific antibody, in relapsed/refractory acute myeloid leukemia --

MONROVIA, Calif., Jan. 7, 2019 /PRNewswire/ -- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune disease, asthma and allergic disease and cancer, today announced it will regain rights to develop and commercialize XmAb13676, a CD20 x CD3 bispecific antibody, from Novartis effective June 20, 2019, due to strategic pipeline reprioritization by Novartis. Xencor granted Novartis co-development and ex-U.S. commercial rights in June 2016 through a collaboration and license agreement to develop and commercialize novel bispecific antibodies, including XmAb13676 and XmAb14045, and to access Xencor's XmAb® bispecific Fc and other Fc technologies. Currently XmAb13676 is being evaluated in an open-label Phase 1, multiple-dose, dose-escalation study to assess its safety, tolerability and preliminary anti-tumor activity in patients with B-cell malignancies, and initial data are expected in 2019.

"We continue to work closely with Novartis across multiple programs in the collaboration, and both companies are eager to advance XmAb14045 in clinical development. Recently we presented encouraging early data from our Phase 1 study in patients with relapsed/refractory AML, observing multiple complete remissions on a weekly dosing schedule, and we continue to optimize dose in that study. Novartis also has internal XmAb preclinical bispecific programs progressing," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "Xencor will continue to develop XmAb13676 as planned, and we believe its tuned potency holds potential for the treatment of patients with B-cell malignancies."

Under the terms of the collaboration agreement, Xencor and Novartis continue to share costs for the worldwide development of XmAb14045 with Xencor maintaining U.S. commercialization rights and Novartis having commercialization rights in the rest of the world, and worldwide development costs for XmAb13676 will be shared until June 2020. Novartis received worldwide rights to Xencor's bispecific technology to develop and commercialize four additional targets selected by Novartis. Xencor is eligible to receive clinical, regulatory and sales milestone payments for successful programs, as well as tiered, low double-digit royalties for sales of XmAb14045 outside of the U.S. and mid single-digit tiered royalties for worldwide sales of the four proprietary Novartis bispecific molecules.

About XmAb®13676

XmAb13676 is a tumor-targeted antibody that contains both a CD20 binding domain and a cytotoxic T-cell binding domain (CD3) in a Phase 1 clinical trial for the treatment of B-cell 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 XmAb13676. CD20 is highly expressed on B-cell tumors, including in chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL). Engagement of CD3 by XmAb13676 activates T cells for highly potent and targeted killing of CD20-expressing tumor cells.

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 the treatment of 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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