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Xencor Announces 2018 Priorities and Expected Milestones

MONROVIA, Calif., Jan. 5, 2018 /PRNewswire/ -- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune disease, asthma and allergic diseases, and cancer, today announced the company's 2018 priorities and expected clinical development and research milestones.

"Xencor has long been committed to leveraging the plug-and-play nature of our XmAb® Fc domains to develop a broad pipeline of antibody therapeutics, and ultimately deliver new medicines to patients with life-threatening and debilitating diseases," said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. "In 2018, we will make important strides toward achieving this vision. We expect several milestones across the 11 wholly-owned and partnered XmAb antibody programs currently in clinical development. Our lead internal program, XmAb®5871, is expected to begin its first Phase 3 trial, joining partnered programs ALXN1210 and MOR208 -- being developed by Alexion and MorphoSys, respectively -- in late-stage development. We also expect initial data from our Phase 2 trial of XmAb®5871 in systemic lupus erythematosus (SLE)."

"Turning to our bispecific oncology pipeline, we look forward to announcing first-in-human data for our two most advanced candidates, XmAb®14045 and XmAb®13676. We also plan to expand our clinical-stage bispecific pipeline in 2018, initiating Phase 1 trials of two programs and filing investigational new drug (IND) applications for two others, both of which target the tumor microenvironment. With a broad and prolific antibody engineering platform and deep antibody drug development pipeline, we have a number of robust catalysts ahead in 2018."

The Company's expected clinical development and research milestones are outlined below.

XmAb5871: XmAb5871 is a first-in-class monoclonal antibody that targets CD19 with its variable domain, and uses Xencor's XmAb immune inhibitor Fc domain to target FcγRIIb, a receptor that inhibits B-cell function. Final data from a Phase 2 trial in IgG4-Related Disease were presented in November 2017, and enrollment was completed in the Phase 2 trial in SLE in December.

Expected milestones for XmAb5871 in IgG4-RD:

- Initiate Phase 3 trial in the second half of 2018. Following a Type B End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA), Xencor expects this randomized, placebo-controlled, double-blinded trial to evaluate the addition of XmAb5871 to standard-of-care in approximately 250 to 350 patients with IgG4-RD.
- Seek scientific advice from the European Medicines Agency in early 2018.

Expected milestones for XmAb5871 in SLE:

- Announce initial data from Phase 2 trial in the fourth quarter of 2018.

Bispecific Oncology Pipeline: Xencor's initial bispecific antibody programs are tumor-targeted antibodies that contain both a tumor antigen binding domain and a cytotoxic T-cell binding domain (CD3). These bispecific antibodies activate T cells for highly potent and targeted killing of malignant cells. Their XmAb Fc domains confer long circulating half-lives, stability and ease of manufacture. Xencor is also expanding its bispecific pipeline to include a suite of tumor microenvironment activators that engage multiple targets, such as T-cell checkpoints or agonists.

Expected milestones for tumor-targeted bispecific antibodies:

- Announce initial data from Phase 1 study of XmAb14045 for the treatment of AML and other CD123-expressing

hematologic malignancies in 2018, pending alignment on timing with Novartis.
- Announce initial data from Phase 1 study of XmAb13676 for the treatment of B-cell malignancies in 2018, pending alignment on timing with Novartis.
- Initiate Phase 1 trial evaluating XmAb®18087 for the treatment of neuroendocrine tumors and GIST in the first quarter of 2018.

Expected milestones for tumor microenvironment-targeting bispecific antibodies:

- Initiate Phase 1 trial evaluating XmAb®20717, a PD-1 x CTLA-4 dual checkpoint inhibitor for the treatment of multiple oncology indications in 2018.
- File IND for XmAb®22841, a CTLA-4 x LAG-3 dual checkpoint inhibitor for the treatment of multiple oncology indications in 2018 and initiate a Phase 1 trial in 2019.
- File IND for XmAb®23104, a PD-1 x ICOS bispecific antibody for the treatment of multiple oncology indications in 2018 and initiate a Phase 1 trial in 2019.

XmAb®7195: XmAb7195 is a first-in-class monoclonal antibody that targets IgE with its variable domain and uses Xencor's XmAb immune inhibitor Fc domain to target FcγRIIb, resulting in three distinct mechanisms of action for reducing IgE. Data from the subcutaneous Phase 1b study were announced in November 2017 and Xencor is currently seeking a development partner for XmAb7195.

Pipeline Expansion: Xencor continues to apply the XmAb platform to create new drug candidates and is focused on developing additional bispecific molecules for the treatment of cancer.

Expected milestones for pipeline expansion:

- File IND for IL-15/IL-15Ra candidate for the treatment of multiple oncology indications in 2019;
- Create additional development candidates activating cytotoxic T-cells against tumor antigens and targeting the tumor microenvironment.

A slide presentation describing these research and development goals and other information will be available on the Investor page of the Company's website at www.xencor.com on Monday, January 8, 2018.

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, 11 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internal programs include: 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 pre-clinical development for the treatment of neuroendocrine tumors; and XmAb®20717 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, Merck, CSL/Janssen, 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 the quotation from Xencor's president and chief executive officer, and statements related to expectations relating to Xencor's financial expectations and business, the timing and future results of Xencor's research and development programs, the timing, results and expectations of clinical development and research milestones, Xencor's 2018 priorities, and the expansion of Xencor's pipeline. 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, including without limitation Xencor's Annual Report on Form 10-K for the year ended December 31, 2016. 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.

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