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Xencor's Lead Drug Candidate, XmAb5871, Receives Orphan Drug Designation from FDA for Treatment of IgG4-Related Disease

MONROVIA, Calif., May 11, 2017 /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, announced today that XmAb®5871 has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of IgG4-Related Disease (IgG4-RD), a newly defined fibro-inflammatory autoimmune disorder that is estimated to impact up to 40,000 patients in the United States.

"There currently are no approved therapies for IgG4-RD, an immune-mediated condition responsible for fibro-inflammatory lesions that can lead to irreversible damage to virtually any organ," said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. "New treatment options are clearly needed, and we are diligently moving XmAb5871 forward in clinical development to fill this void. Preliminary data from our Phase 2 study of XmAb5871 showed promising activity in patients with IgG4-RD, and we are on track to complete the study and report topline results by the end of this year. We are also planning to engage the FDA later this year to discuss future clinical trials and potential registration requirements in IgG4-RD."

The FDA's Orphan Drug Designation program provides orphan status to drugs defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the U.S. Orphan designation qualifies the sponsor of the drug for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

About XmAb®5871

XmAb®5871 is a first-in-class monoclonal antibody that targets CD19 with its variable domain and that uses Xencor's XmAb immune inhibitor Fc domain to target FcγRIIb, a receptor that inhibits B-cell function. XmAb5871 is the first drug candidate that Xencor is aware of that targets FcγRIIb inhibition. Xencor has demonstrated in multiple animal models and in initial human clinical trials that XmAb5871 inhibits B-cell function without destroying these important immune cells. Preliminary Phase 2 data presented at the American College of Rheumatology 2016 Annual Meeting showed that 82 percent of patients who received XmAb5871 achieved an initial response to therapy within 2 weeks of their first dose with responses deepening over time.

About IgG4-Related Disease

IgG4-Related Disease (IgG4-RD) is a rare fibro-inflammatory autoimmune disorder responsible for fibro-inflammatory lesions that can lead to irreversible damage to virtually any organ. IgG4-RD is estimated to impact up to 40,000 patients in the United States. The disease affects multiple organ systems and is characterized by a distinct microscopic appearance of diseased organs, including the presence of IgG4-positive plasmablast cells. This objective diagnostic criterion is atypical for autoimmune diseases and offers advantages for accurately identifying patients. There are currently no approved therapies for this newly recognized disorder and corticosteroids are the current standard of care.

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 any expectations relating to development of XmAb®5871, timing of clinical study results and engagement with FDA. 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.