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Xencor Initiates Two Phase 2 Trials of XmAb5871 in IgG4-Related Disease and Systemic Lupus Erythematosus

Advancing XmAb5871 in two indications with high unmet need and strong rationale for B-cell inhibition
Novel trial design for SLE intended to detect statistically significant treatment effect after 6 months of therapy

MONROVIA, Calif., March 7, 2016 /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, today announced dosing the first patient in a Phase 2 trial of XmAb®5871 in patients with IgG4-Related Disease (IgG4-RD). The Company also announced dosing the first patient in a Phase 2 trial of XmAb5871 in patients with Systemic Lupus Erythematosus (SLE).

"We are advancing XmAb5871 in IgG4-RD and SLE because of its potent, reversible B-cell inhibition and promising treatment effect demonstrated in a Phase 1b/2a study of patients with rheumatoid arthritis, as well as previous ex vivo results with XmAb5871 showing inhibition of SLE patient B-cell activation and humoral immunity," said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. "B-cell inhibition by XmAb5871 has potential in a number of autoimmune diseases, and we believe we can execute efficient clinical trials with clear outcomes in these indications and potentially address high unmet needs. In IgG4-RD, a newly defined disease, we have the opportunity to be at the forefront of providing a treatment for patients."

The Phase 2 pilot study in IgG4-RD is an open-label single-arm trial being conducted at Massachusetts General Hospital by Dr. John H. Stone. Approximately 15 patients with active IgG4-RD will receive intravenous (IV) administrations of XmAb5871 every 2 weeks for 6 months. The primary objective of the study is to evaluate the effect of every other week IV administration of XmAb5871 on the IgG4-RD Responder Index (RI) in patients with active IgG4-RD. Secondary and exploratory objectives are to determine the safety and tolerability profile, to characterize the pharmacokinetics and pharmacodynamics (change in biomarkers) and to characterize immunogenicity of every other week IV administration of XmAb5871 in patients with active IgG4-RD.

The Phase 2 SLE trial is a novel design to evaluate the ability of XmAb5871 to maintain the improvement in disease activity after a short course of intra-muscular (IM) steroid therapy and in the absence of immunosuppressant medication. This trial design was previously tested in an observational study by Dr. Joan T. Merrill of the Oklahoma Medical Research Foundation, who is the coordinating investigator for the XmAb5871 SLE trial. When background treatments are reduced, six month response rates to a brief course of steroids are known to be low without the addition of an effective therapy.

"The SLE trial is designed to assess the effect of XmAb5871 on SLE disease activity with a shorter time to endpoint and with fewer patients compared to standard SLE trials, which generally add new medications to the many medications already taken by the patient," said Paul Foster, M.D., chief medical officer of Xencor.

The Phase 2 study in SLE is a randomized, double-blind, placebo-controlled, multiple dose trial being conducted in the US at approximately 20 sites. Approximately 90 SLE patients will be enrolled with a 1:1 randomization of XmAb5871 to placebo. Patients will enter screening with active, non-organ threatening SLE. They will discontinue background immunosuppressive medication and receive a short course of IM steroids to quiet SLE disease activity. Patients who achieve the required disease activity improvement will be randomized to receive XmAb5871 or placebo every two weeks for up to 12 infusions (six months) and will be followed for loss of disease improvement. The primary objective of the study is to evaluate the ability of XmAb5871 to maintain SLE disease activity improvement achieved by a brief course of disease-suppressing IM steroid therapy. Secondary and exploratory objectives are to evaluate the time to loss of SLE disease activity improvement, to determine the safety and tolerability profile, to characterize the pharmacokinetics and pharmacodynamics (change in biomarkers), and to characterize immunogenicity of every other week IV administration of XmAb5871 in patients with SLE.

About IgG4-Related Disease
IgG4-Related Disease (IgG4-RD) is a rare fibro-inflammatory autoimmune disorder that we estimate impacts up to 40,000 patients in the United States. IgG4-RD affects multiple organ systems and is characterized by a distinct microscopic appearance of diseased organs, including the presence of IgG4-positive plasmablast cells that is required for diagnosis. 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. John H. Stone, M.D, MPH, director, clinical rheumatology at Massachusetts General Hospital has developed and is validating the IgG4-RD Responder Index, a proposed instrument to assess disease activity.

About Systemic Lupus Erythematosus
Systemic Lupus Erythematosus (SLE) is an inflammatory disease in which the body's immune system attacks its own healthy tissue. The disease affects an estimated 240,000 patients in the United States each year and can affect the skin, joints, kidneys, brain, and other organs. There is no cure for SLE and current standard of care includes taking immunosuppressant medications to control symptoms.

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, and demonstrated promising treatment effect in patients with rheumatoid arthritis, as well as ex vivo results showing inhibition of SLE patient B-cell activation and humoral immunity.

Complete data results from a Phase 1b/2a study of XmAb®5871 in patients with rheumatoid arthritis were presented at the American College of Rheumatology 2015 Annual Meeting as well as at the European League Against Rheumatism 2015 Annual Meeting. Ex vivo studies of SLE patient B cells were published in Journal of Immunology, 2011, 186(7):4223.

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, nine candidates that have been engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internally-discovered programs include: XmAb5871 in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb7195 in Phase 1a development for the treatment of asthma and allergic diseases; and XmAb5574/MOR208 which has been licensed to Morphosys AG and is in Phase 2 clinical trials for the treatment of chronic lymphocytic leukemia and non-Hodgkin lymphoma. 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 Amgen, Merck, Janssen R&D LLC, Alexion, Novo Nordisk 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 the U.S. securities laws, including statements associated with Xencor's research, expectations regarding future therapeutic and commercial potential of Xencor's technologies, programs, drug candidates, including XmAb5871. Because such statements are subject to risks and uncertainties, including risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective, actual results and the timing of events may differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning Xencor's programs and technology are described in additional detail in Xencor's SEC filings. These forward-looking statements speak as of the date on which they were made, are based upon Xencor's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Xencor disclaims any intention or obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact:
John Kuch, Vice President Finance, Xencor
Tel: 626-737-8013
jkuch@xencor.com

Corporate Communications Contact:
Jason I. Spark
Canale Communications for Xencor
Tel: 619-849-6005
jason@canalecomm.com