Xencor Announces Topline Results from Phase 2 Study of XmAb®5871 in Systemic Lupus Erythematosus and Selection of Late-Breaking Abstract for Presentation at the 2018 ACR Annual Meeting

October 5, 2018

- Positive trend in primary endpoint; proportion of efficacy-evaluable patients who did not experience loss of improvement (LOI) by Day 225 did not meet statistical significance (XmAb®5871 42% vs. placebo 28.6%, p = 0.18)
- Met secondary endpoint of time to LOI; risk of LOI reduced by 47% for patients treated with XmAb5871 (median time to LOI of 230 days vs. 131 days for patients on placebo, hazard ratio = 0.53, p = 0.0252)
- XmAb5871 well-tolerated and safety profile consistent with prior studies

MONROVIA, Calif., Oct. 5, 2018 /PRNewswire/ -- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing monoclonal antibodies for the treatment of autoimmune disease, asthma and allergic diseases, and cancer, today announced topline results from the randomized, double-blind, placebo-controlled Phase 2 study of XmAb®5871 in patients with systemic lupus erythematosus (SLE). The topline results have been selected for a late-breaking abstract session at the 2018 American College of Rheumatology (ACR) Annual Meeting, and the poster will be presented by the study's coordinating investigator, Joan T. Merrill, M.D., Oklahoma Medical Research Foundation (OMRF) Professor of Medicine at University of Oklahoma Health Science Center and head of the Clinical Pharmacology Research Program, on Tuesday, October 23 at 9:00 a.m. CT. The abstract (L14) is now available on the ACR conference website.

"In this study of XmAb5871 in SLE patients, the use of an innovative study design that limited polypharmacy allowed the effect on disease activity to be discriminated in a small, randomized patient population," said Dr. Merrill. "These encouraging results support further study of XmAb5871 in SLE."

The Phase 2 study of XmAb5871 enrolled 104 patients with moderate to severe, non-organ threatening SLE across 20 sites in the United States. Patients discontinued background immunosuppressive medication and received a short course of intramuscular steroids to quiet SLE disease activity. Patients achieving the required disease activity improvement (SLEDAI decrease ≥4 points, or ≥1 grade decrease in ≥1 BILAG A or B score) were randomized 1:1 to receive XmAb5871 (n = 52) or placebo (n = 52) every 14 days for up to 16 doses.

The primary endpoint of the study was the proportion of patients with no loss of improvement (LOI) (i.e., maintenance of improvement) in the efficacy-evaluable population, defined as those who completed Day 225, had LOI, or discontinued due to a drug-related adverse event. LOI was defined as a SLEDAI increase ≥4 points or a new BILAG A or B score and physician intent to treat with rescue medication.

In the primary endpoint analysis, improvement was maintained at Day 225 by 42% of patients (21/50) in the XmAb5871-treated arm, compared to 28.6% of patients (12/42) in the placebo-treated arm (p = 0.18). The efficacy-evaluable population excludes 10/52 (19%) placebo patients and 2/52 (4%) XmAb5871-treated patients who withdrew from the study for reasons other than LOI or adverse event. These exclusions led to higher placebo response rates compared to the intent-to-treat (ITT) population. In the ITT population, improvement was maintained by 40.4% of patients (21/52) in the XmAb5871-treated arm, compared to 23.1% of patients (12/52) in the placebo-treated arm (p = 0.06).

Secondary endpoints included evaluations of time to LOI and safety and tolerability of XmAb5871. Patients in the efficacy-evaluable population treated with XmAb5871 experienced a statistically significant longer time to LOI (median = 230 days, hazard ratio = 0.53, p = 0.025), compared to placebo-treated patients (median = 131 days), a 76% improvement in median time to LOI and a 47% reduction in risk of LOI.

Safety was consistent with previous trials. The most common adverse events (AEs) in XmAb5871-treated patients were transient, infusion-related gastrointestinal side effects during the first or second infusion. There were eight serious AEs (SAEs) in seven XmAb-treated patients and five SAEs in four placebo patients. No opportunistic infections or deaths were reported. The incidence of major organ flares was low (placebo arm: 2 nephritis, 1 enteritis, 1 systemic flare; XmAb5871 arm: 1 pneumonitis). All were treated and stabilized.

"Xencor completed this study to efficiently assess the potential of XmAb5871 in SLE, now the third indication where a promising treatment effect has been seen, after rheumatoid arthritis and IgG4-Related Disease," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "By year end, we plan to initiate a Phase 3 study of XmAb5871 in IgG4-RD, and we are exploring further development in SLE in the context of partnering. With six internal programs in autoimmune disease and cancer advancing in the clinic, we anticipate additional data readouts over the next two years."

About XmAb5871

XmAb®5871 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. XmAb5871 is the first drug candidate that Xencor is aware of that targets FcγRIIb inhibition. Xencor has demonstrated through multiple preclinical and early-stage clinical studies that XmAb5871 inhibits B-cell function without destroying these important immune cells and has demonstrated a promising treatment effect in rheumatoid arthritis and IgG4-related disease patients. XmAb5871 is

currently in clinical development for IgG4-RD and SLE. Xencor anticipates initiating a Phase 3 study of XmAb5871 in patients with IgG4-related disease during the second half of 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, 12 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 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.



View original content to download multimedia:http://www.prnewswire.com/news-releases/xencor-announces-topline-results-from-phase-2-study-of-xmab5871-in-systemic-lupus-erythematosus-and-selection-of-late-breaking-abstract-for-presentation-at-the-2018-acr-annual-meeting-300725016.html

SOURCE Xencor, Inc.

Investor Contact: John Kuch, Senior Vice President, Finance and Chief Financial Officer, 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