June 10, 2015

Xencor Reports Complete Data Results on XmAb5871 Program at European League Against Rheumatism (EULAR) 2015 Annual Meeting

MONROVIA, Calif., June 10, 2015 /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 reported complete data results from a Phase 1b/2a study of XmAb®5871 in patients with rheumatoid arthritis (RA). XmAb5871 was generally well tolerated and showed trends in improvement in RA disease activity by multiple disease activity measures and across multiple dose groups. These data will be presented during a poster session Friday, June 12th at the European League Against Rheumatism (EULAR) 2015 Annual Meeting in Rome, Italy.

"These data demonstrate clear signs of disease modifying activity in a patient population with active disease while on non-biologic disease modifying anti-rheumatic drug (DMARD) therapy," said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. "XmAb5871 has a novel mechanism of action that inhibits B-cell function without killing B-cells. This potent yet reversible B-cell inhibition differs from other B-cell targeting treatments and has potential clinical application across a number of autoimmune diseases, including IgG4-related disease (IgG4-RD) for which we expect to initiate an open-label pilot study later this year."

The two-part study was designed as a Phase 1b multiple center, randomized, placebo-controlled, double-blinded, multiple ascending dose clinical study (Part A) followed by Phase 2a cohort extension (Part B) at the top dose examined in Part A. The study enrolled patients with active RA on stable non-biologic DMARD therapy. Patients were randomized to receive ascending IV infusions of XmAb5871 (0.3, 1.0, 3.0 and 10.0 mg/kg) or placebo 14 days apart for six doses (Part A), followed by an expansion cohort at 10.0 mg/kg or placebo 14 days apart for six doses (Part B).

"Data from our XmAb5871 program further details the tolerability and response data in RA patients as a function of dose," said Paul Foster, M.D., chief medical officer of Xencor. "Although the trial was not designed to observe a statistically significant difference in efficacy results between XmAb5871 and placebo treated patients, sufficient efficacy trends were seen to warrant continued clinical development of XmAb5871 in autoimmune indications. A numerically increased proportion of patients with improved ACR response, DAS28-CRP score and EULAR response criteria were observed in the XmAb5871 treated groups compared to placebo."

Safety:
XmAb5871 was safe and generally well tolerated. The most common AEs in the XmAb5871 group were vomiting, headache and nausea. Nausea and vomiting occurred primarily during the first infusion, were generally of mild to moderate intensity and were self-limiting. Two subjects in the study experienced infusion-related reactions with hypotension (both at 10 mg/kg) and were discontinued. The nature and severity of these infusion reactions were consistent with those reported for other monoclonal antibody therapies. Two SAEs occurred in two XmAb5871 treated patients, both in the 10 mg/kg group: one infusion-related reaction with hypotension occurring during the second infusion, and one deep venous thrombosis with onset 22 days (> 6 half-lives) after the last infusion.

Efficacy:
The primary objective of the study was to determine safety and tolerability of multiple-dose XmAb5871. However a secondary objective of the study was to evaluate the effect of XmAb5871 on RA disease response as measured by changes in DAS28-CRP at Day 85 (2 weeks following the last dose) in Part B of the study. 15 XmAb5871-treated and 8 placebo-treated patients in Part B of the study completed all six infusions and disease activity assessments at Day 85. 33.3% of patients who received 10.0 mg/kg XmAb5871 in Part B achieved low disease activity or remission on Day 85 (13.3% and 20% respectively) compared to 0% in the placebo group. This difference was also seen when evaluating across both parts of the study; 41.7% of patients who received any dose of XmAb5871 in Part A or B had low disease activity or remission on Day 85 (16.7% low and 25.0% remission) as compared to only 6.7% of patients in the placebo group (0% low and 6.7% remission). ACR responses we also enhanced in XmAb5871 treated patients. In Part B, 86.7%, 40.0% and 20.0% of patients in the XmAb5871 treated group achieved an ACR20, ACR50 and ACR70 response, respectively, compared to 62.5%, 12.5% and 0% for the placebo group. In Part A and Part B together, there were increased numbers of ACR20, ACR50 and ACR70 responders in the XmAb5871 treated cohorts compared to placebo (77.8% vs. 46.7%, 33.3% vs. 13.3% and 13.9% vs. 0%). Similar trends in improvement in DAS28-ESR scores and EULAR response criteria were observed.

RA Disease Activity Measures
The improvement of RA disease activity was measured by composite scores that combine information from swollen joints,

tender joints, inflammatory biomarkers and clinical status. Disease activity scores have been developed by the American College of Rheumatology (ACR) and EULAR (DAS28). The ACR criteria measure improvement in clinical and laboratory disease activity parameters and are combined to form a composite score and are expressed as percentages of clinical response that are known as ACR20, ACR50, and ACR70. An ACR20 score represents at least a 20% improvement in these criteria and is considered a modest improvement in a patient's disease. An ACR50 and ACR70 represent a minimal 50% and 70% improvement in the response criteria, respectively, and each is considered evidence of a substantial improvement in a patient's disease.

The DAS28, or the Disease Activity Score, considers 28 tender and swollen joint counts, clinical status and levels of an inflammatory biomarker, typically either C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR). The DAS28 yields a score on a scale from 0 to 10 indicating current RA disease activity. The DAS28-CRP incorporates CRP as the inflammatory biomarker and the DAS28-ESR incorporates the ESR as the inflammatory biomarker. The EULAR response criteria classify individual response into 4 categories based on DAS28 scores; remission is ≤2.6, low disease activity is ≤ 3.2, moderate disease activity is ≤ 5.1, and high disease activity is > 5.1.

The abstract is available on the EULAR website at: https://b-com.mci-group.com/Abstract/Statistics/AbstractStatisticsViewPage.aspx?AbstractID=253446

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.

About Xencor, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of asthma and allergic diseases, autoimmune diseases and cancer. Currently, eight 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, which completed a Phase 1b/2a clinical trial for the treatment of rheumatoid arthritis and is in preparation for a clinical trial in IgG4-related disease in 2015; XmAb7195 in Phase 1a development for the treatment of asthma; and XmAb5574/MOR208 which has been licensed to Morphosys AG and is in Phase 2 clinical trials for the treatment of acute lymphoblastic 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 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 applicable securities laws, including any expectations relating to our business, research and development programs, including our XmAb5871 program, partnering efforts or our 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. 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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