



November 4, 2017

## **Xencor Presents Final Results from Phase 2 Study of XmAb®5871 in IgG4-Related Disease (IgG4-RD) at the American College of Rheumatology 2017 Annual Meeting**

- 12 of 15 (80%) patients completed the study and achieved the primary endpoint of at least a two-point reduction in the IgG4-RD Responder Index on Day 169 -**
- Eight patients achieved remission (IgG4-RD RI of zero) -**
- XmAb5871 well tolerated in patients with active IgG4-RD -**

MONROVIA, Calif., Nov. 4, 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, today announced the final results from a Phase 2 study of XmAb5871 in patients with active IgG4-RD. Data show that 12 of 15 patients completed the study, and all 12 achieved the primary endpoint of at least a two-point reduction in the IgG4-RD Responder Index (IgG4-RD RI) on Day 169. The data are being presented by John H. Stone, M.D., MPH, director of rheumatology at Massachusetts General Hospital, at the American College of Rheumatology (ACR) 2017 Annual Meeting in the Late-breaking Abstract session on Tuesday, November 7, 2017 from 7:30 p.m. - 9:00 p.m. EST.



"We are very encouraged by multiple clear signals of treatment benefit in this study - the achievement of the primary endpoint in all 12 patients that completed the study, the achievement of disease remission in more than 50% of patients, and the achievement of at least a five-point reduction in disease activity in 14 of 15 patients," said Paul Foster, M.D., chief medical officer of Xencor. "We expect to advance development of XmAb5871 into a Phase 3 trial in the second half of 2018."

"The clinical response in IgG4-RD patients treated with XmAb5871 is very impressive and reinforces my belief that this is a promising potential therapy," said Dr. John H. Stone, the principal investigator of the study. "We have learned a great deal about how to study this disease in the context of this trial."

### *Final Efficacy Data:*

Twelve of 15 patients (80%) completed the study and all 12 achieved the primary endpoint of at least a two-point reduction in the IgG4-RD RI on Day 169. None of the 12 required corticosteroids (CS) after month two. Eight patients achieved remission (IgG4-RD RI of 0 and no CS after two months) and the other four achieved IgG4-RD RI scores of  $\leq 4$  at Day 169. Fourteen of 15 patients (93%) achieved a decrease of  $\geq 5$  in the IgG4-RD RI. One patient had been on baseline CS for two years (15 mg/day) and was able to discontinue CS within two months. Four others received CS at the start of the trial and tapered off within two months.

### *Safety and Tolerability Data:*

XmAb5871 was well tolerated. Three patients had minor, transient GI side-effects during the first infusion; all completed the study. Two serious adverse events (SAEs) unrelated to XmAb5871 were observed in one patient, pneumonia and recurrence of pneumonia due to non-compliance (patient completed study). Three patients discontinued the study, as disclosed previously. One discontinued patient was atypical with laryngeal involvement only who did not respond to XmAb5871 or to subsequent rituximab. A second patient responded, but flared at 12 weeks and did not respond to subsequent rituximab therapy. The third patient responded but developed infusion-related symptoms including transient rash and arthralgias following the fifth infusion.

Plasmablasts were reduced 70-80% from baseline and B cells were reduced 40-55% from baseline, with decreases occurring within the first two weeks.

The presentation will be available on the 'Investors' page of Xencor's website under 'Events and Presentations' at [www.xencor.com](http://www.xencor.com).

Based on these results, Xencor plans to initiate a Phase 3 trial of XmAb5871 in IgG4-RD in 2H18.

#### *About the Clinical Trial*

IgG4-RD patients with active disease defined by an IgG4-RD Responder Index (RI) of  $\geq 3$  were administered XmAb5871 (5 mg/kg intravenously) every 14 days for 12 doses. The primary outcome measure was the proportion of patients on Day 169 with a decrease in the IgG4-RD RI of  $\geq 2$  points compared to baseline.

Fifteen patients were enrolled in the study, having a median IgG4-RD RI of 12 (range 2-30) with active inflammatory disease in a median of five organ systems (1-10). The organs most commonly affected were lymph nodes (73% of patients), submandibular glands (60%), parotid glands (53%), and lacrimal glands (47%). Five patients (33%) had kidney involvement, four (27%) had lung findings and three each (20%) had orbital lesions, nasal cavity involvement or heart/pericardium findings.

#### **Conference Call and Webcast:**

Xencor will host a conference call Tuesday, November 7, 2017 at 4:30 p.m. ET (1:30 p.m. PT) to discuss third quarter 2017 financial results and recent corporate updates, including the final results from its Phase 2 study of XmAb5871 in IgG4-RD.

The live call may be accessed by dialing (877) 359-9508 for domestic callers or (224) 357-2393 for international callers, and referencing conference ID number: 99272433. A live webcast of the conference call will be available online from the investor relations section of the company's website at [www.xencor.com](http://www.xencor.com). The webcast will be archived on the company's website for 30 days.

#### **About XmAb<sup>®</sup> 5871**

XmAb<sup>®</sup>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 systemic lupus erythematosus (SLE) patient B-cell activation and humoral immunity. XmAb5871 is currently in clinical development for IgG4-RD and SLE.

#### **About IgG4-Related Disease**

IgG4-Related Disease (IgG4-RD) is a rare fibro-inflammatory autoimmune disorder that is estimated to impact 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. 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 (RI), a proposed instrument to assess disease activity.

#### **About Xencor's XmAb<sup>®</sup> Immune Inhibitor Technology**

FcγRIIb (IIb), also called CD32b, is a receptor for Fc domains on B cells and other immune cells. When engaged, the IIb receptor blocks immune activation pathways and traffics bound soluble antigens out of circulation. Xencor has discovered a series of Fc domain variants with up to a 400-fold increase in binding affinity to FcγRIIb derived from just two amino acid changes. These XmAb<sup>®</sup> Immune Inhibitor Fc domains greatly heighten the properties of IIb receptor engagement and have potential as building blocks for drug candidates in autoimmune, allergic and inflammatory diseases.

#### **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<sup>®</sup> technology are in clinical development internally and with partners. Xencor's internal programs include: XmAb<sup>®</sup>5871 in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb<sup>®</sup>7195 in Phase 1 development for the treatment of asthma and allergic diseases; XmAb<sup>®</sup>14045 in Phase 1 development for acute myeloid leukemia; XmAb<sup>®</sup>13676 in Phase 1 development for B-cell malignancies; XmAb<sup>®</sup>18087 in pre-clinical development for the treatment of neuroendocrine tumors; and XmAb<sup>®</sup>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](http://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 officer and any expectations relating to its business, research and development programs, including ongoing clinical trials of XmAb5871, and the immune inhibitory Fc domain technology, partnering efforts or its capital requirements. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements, including those of the complete clinical trial of XmAb5871, 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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