

Xencor to Present Initial Data from the Phase 1 Study of XmAb®13676 in B-Cell Malignancies at the American Society of Hematology Annual Meeting

November 6, 2019

MONROVIA, Calif.--(BUSINESS WIRE)--Nov. 6, 2019-- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer, autoimmune diseases, asthma and allergic diseases, today announced that initial data from its ongoing Phase 1 dose-escalation study of XmAb[®] 13676, a CD20 x CD3 bispecific antibody, in patients with B-cell malignancies will be presented in a poster session during the 61st American Society of Hematology (ASH) Annual Meeting in Orlando, Florida on Monday, December 9, 2019.

"Initial results from dose-escalation cohorts demonstrate encouraging clinical activity in heavily pretreated patients with several subtypes of non-Hodgkin lymphoma, as well as chronic lymphocytic leukemia. The most common treatment-related adverse event has been fever. Cytokine release syndrome, the second most common adverse event, has been generally manageable with premedication," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor.

Key Highlights from the Abstract

The abstract with accepted data from the study are available through the ASH website. Updated results will be shared at the ASH Annual Meeting.

- At data cut off on June 28, 2019, 36 patients with relapsed/refractory non-Hodgkin's lymphoma (r/r NHL) and 8 patients with relapsed/refractory chronic lymphocytic leukemia (r/r CLL) had received XmAb13676. The study was designed in two parts: Part A to establish an initial priming dose and Part B to escalate dosing on subsequent administration. Prophylactic treatment for cytokine release syndrome (CRS) was mandated prior to each administration of XmAb13676.
- Patients with r/r NHL (n=36) had a median age of 61.5 years, a median of 3.5 prior therapies and had been diagnosed a median of 24.6 months prior to treatment. In the efficacy evaluable population and at doses ranging from 80 to 125 mcg/kg, objective responses were observed in 33% of patients (n=6/18), including 42% of DLBCL patients (n=5/12). CRS occurred in 42% of patients (n=15/36), and one patient receiving an initial dose of 125 mcg/kg experienced Grade 4 CRS. A priming dose of 45 mcg/kg was chosen for Part B.
- Patients with r/r CLL (n=8) had a median age of 76 years, a median of 4.5 prior therapies and had been diagnosed a median of 76.1 months prior to treatment. There was one complete response (Richter transformation) in five patients treated at the 20 mcg/kg dose level, the highest dose administered in the ongoing Part A of the study. CRS occurred in 25% of patients (n=2/8), and one patient experienced Grade 3 CRS.

Presentation Details

- Abstract: 4079
- Title: Preliminary Safety and Anti-tumor Activity of XmAb13676, an Anti-CD20 x Anti-CD3 Bispecific Antibody in Patients with Relapsed/Refractory Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia
- Presenter: Krish Patel, M.D., Director of the Lymphoma Program at Swedish Cancer Institute
- Session: 626. Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphomas)
 Results from Prospective Clinical Trials: Poster III
- Date & Time: Monday, December 9, 2019, 6:00 p.m. 8:00 p.m. EST
- Location: Orange County Convention Center, Hall B

XmAb[®]13676 is a tumor-targeted antibody that contains both a CD20 binding domain and a cytotoxic T-cell binding domain (CD3) in a Phase 1 clinical trial for the treatment of B-cell malignancies. An XmAb[®] bispecific Fc domain serves as the scaffold for these two antigen binding domains and confers long circulating half-life, stability and ease of manufacture on XmAb13676. CD20 is highly expressed on B-cell tumors, including in chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL). Engagement of CD3 by XmAb13676 activates T cells for highly potent and targeted killing of CD20-expressing tumor cells.

About Xencor, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer, autoimmune diseases, asthma and allergic diseases. Currently, 14 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's XmAb antibody engineering technology enables small changes to the structure of monoclonal antibodies resulting in new mechanisms of therapeutic action. 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, 2018 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.

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