Xencor Presents Updated Data from the Phase 1 Study of Vibecotamab in Acute Myeloid Leukemia at the 2020 ASH Annual Meeting

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MONROVIA, Calif.--(BUSINESS WIRE)--Dec. 6, 2020-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer and autoimmune disease, today announced updated data from its ongoing Phase 1 dose-escalation study of vibecotamab (XmAb®14045), a CD123 x CD3 bispecific antibody, in patients with relapsed or refractory acute myeloid leukemia (AML). The data were presented in an oral session at the 62nd American Society of Hematology (ASH) Annual Meeting by Farhad Ravandi, M.D., Professor of Medicine and Chief of the Section of Acute Myeloid Leukemia in the Department of Leukemia at the University of Texas - MD Anderson Cancer Center.

"Vibecotamab has meaningful clinical activity in relapsed AML, and responses appear to be associated with lower baseline disease burden, indicated by patients with lower blast percentages and lower PD1 expression on CD8+ and CD4+ T cells. This suggests possible strategies to select patients most likely to respond," said Dr. Ravandi. "Responses including CRs and CRis have been durable, lasting many months, in several patients."

"Additionally, we continue to observe that vibecotamab's primary toxicity, CRS, is generally mild-to-moderate in severity when observed, and our mitigation strategy, which includes a combination of dose-modifying measures, has been effective in limiting its severity," said Allen Yang, M.D., Ph.D., senior vice president and chief medical officer. "With a manageable profile and encouraging potential in certain patient populations, such as myelodysplastic syndromes and AML with minimal residual disease, we are now planning our next steps to develop vibecotamab for these patients, along with our partner Novartis."

Key Highlights from the Presentation

At data cut off on October 28, 2020, 112 patients with relapsed or refractory AML had received vibecotamab. Patients were a median of 64 years old and were heavily pretreated, having had a median of three prior therapies and 30% (n=34) with a history of allogeneic hematopoietic stem cell transplantation. 86% of patients (n=96) were refractory to their last therapy, and 62% (n=69) were categorized as adverse risk at diagnosis by the European LeukemiaNet (ELN 2017) system. The study is ongoing, and additional patients are being enrolled.

Cytokine release syndrome (CRS) was the most common toxicity occurring in 61% of patients (n=68), and 9% of patients (n=10) experienced CRS at Grade 3 or higher. The majority of CRS was observed in the first dose and was generally manageable with premedication. Additional mitigation measures included selecting a lower priming dose, avoiding weekly dose step-up, and more frequent dosing in the first week to allow a higher cumulative exposure and to avoid the potential CD123 antigen sink. There was no evidence of drug related myelosuppression. Neurological events were infrequent and primarily Grade 1 and Grade 2 headaches.

The efficacy analysis included 54 evaluable patients who received a dose of at least 0.75 mcg/kg, completed at least the first cycle of treatment and had at least one post-treatment disease assessment. Two patients achieved complete remission (CR), and three patients achieved a CR with incomplete hematologic recovery. Additionally, two patients reached a morphologic leukemia-free state, and one patient experienced partial remission, as assessed by the investigator. The overall response rate (ORR) was 15% (n=8/54).

Biomarker analyses suggest that low baseline leukemic burden and low PD-1 expression on CD4+ and CD8+ T cells are independent predictors of response. Seven responders had a baseline blast count less than or equal to 25% blasts in bone marrow. The ORR increased to 26% (n=7/27) when using this threshold to define the population with low disease burden for the analyses.

The presentation will be archived under "Events & Presentations" in the Investors section of the Company's website located at www.xencor.com.

About Vibecotamab

Vibecotamab (XmAb®14045) is a tumor-targeted antibody that contains both a CD123 binding domain and a cytotoxic T-cell binding domain (CD3) in a Phase 1 clinical trial for the treatment of acute myeloid leukemia (AML) and other CD123-expressing hematologic 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 vibecotamab. CD123 is highly expressed on AML cells and leukemic stem cells, and it is associated with poorer prognosis in AML patients. Engagement of CD3 by vibecotamab activates T cells for highly potent and targeted killing of CD123-expressing tumor cells.

About Xencor, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer and autoimmune diseases. Currently, 18 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 chief medical officer and any statements relating to the timing, expectations and success of clinical trials, product candidates and Xencor's research and development programs. 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, 2019 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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