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

November 4, 2020

MONROVIA, Calif.--(BUSINESS WIRE)--Nov. 4, 2020-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of cancer and autoimmune disease, today announced that data from the ongoing Phase 1 dose-escalation study of vibecotamab (XmAb®14045), a CD123 x CD3 bispecific antibody, in patients with relapsed/refractory acute myeloid leukemia (AML) will be presented in an oral session at the 2020 American Society of Hematology (ASH) Annual Meeting on Sunday, December 6, 2020.

"Data from the Phase 1 study of vibecotamab suggest that patients with AML having low baseline disease burden and specific T-cell signatures may be more likely to respond to treatment with vibecotamab. The primary toxicity, CRS, is generally mild-to-moderate in severity when observed and is manageable," said Allen Yang, M.D., Ph.D., senior vice president and chief medical offer at Xencor. "We continue to optimize dosing regimen in this study, and along with our partner Novartis, we are planning our next clinical trials to develop vibecotamab in patients, for whom an intermittently dosed, CD123-targeting antibody could be a needed therapeutic option."

Key Highlights from the Abstract

The accepted abstract is available on the ASH conference website.

- At data cut off for submitting the abstract, 104 patients with AML, one patient with B cell acute lymphoblastic leukemia and one patient with chronic myeloid leukemia had received vibecotamab. Patients had a median age of 63 years and were heavily pretreated, having a median of three prior therapies, and 30% (n=32/106) had undergone prior allogeneic stem cell transplantation.
- Patients received doses of vibecotamab ranging from 0.003 mcg/kg to 12 mcg/kg. The recommended initial priming dose was determined to be 0.75 mcg/kg. A maximum tolerated dose (MTD) was not reached.
- Cytokine release syndrome (CRS) was the most common toxicity occurring in 58% of patients (n=62), and 8% of patients (n=9) experienced CRS at Grade 3 or higher. The majority of CRS was observed on the first dose and was generally manageable with premedication. Additional adverse events consistent with CRS but not reported as such, including chills, fever, tachycardia and hypotension, were reported in an additional 24% of patients. No myelosuppression requiring dose modification or evidence of tumor lysis syndrome was observed.
- At dose levels of at least 0.75 mcg/kg (n=51), two patients achieved complete remission (CR), three patients achieved a CR with incomplete hematologic recovery, and two patients or morphologic leukemia-free state (ORR=14%).
- Patients with responses were characterized by lower disease burden and specific T-cell subtypes.

Presentation Details

- Abstract: 460
- Title: Complete Responses in Relapsed/Refractory Acute Myeloid Leukemia (AML) Patients on a Weekly Dosing Schedule of Vibecotamab (XmAb14045), a CD123 x CD3 T Cell-Engaging Bispecific Antibody; Initial Results of a Phase 1 Study
- Session: 613. Acute Myeloid Leukemia: Potpourri of Potential Practice Changing Studies
- Date & Time: Sunday, December 6, 2020, 2:30 p.m. PST

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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