Xencor to Present New Clinical Data from the Phase 1 Study of Plamotamab in Relapsed or Refractory Non-Hodgkin's Lymphoma at the American Society of Hematology Annual Meeting

November 3, 2022

MONROVIA, Calif.--(BUSINESS WIRE)--Nov. 3, 2022-- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered antibodies and cytokines for the treatment of cancer and autoimmune diseases, today announced that clinical data from expansion cohorts in its Phase 1 study of plamotamab, a CD20 x CD3 bispecific antibody, in patients with relapsed or refractory non-Hodgkin's lymphoma will be presented in a poster session during the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans, Louisiana on Monday, December 12, 2022.

"Plamotamab continues to be generally well tolerated and demonstrates encouraging clinical activity in our recommended intravenous dosing regimen," said Allen Yang, M.D., Ph.D., senior vice president and chief medical officer at Xencor. "Along with Janssen scientists, we plan to advance plamotamab as part of highly active chemotherapy-free regimens across B-cell cancers, importantly with tumor-selective, co-stimulatory CD28 bispecific antibodies. Xencor's first combination study, evaluating plamotamab in combination with tafasitamab plus lenalidomide, is enrolling patients with advanced, aggressive lymphoma."

Expansion cohorts in the Phase 1 study are actively recruiting patients with diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) and are dosing using the proposed intravenous recommended Phase 2 regimen to evaluate the safety and efficacy of plamotamab monotherapy. The recommended dose (RD) was previously identified as an intravenous, 50 mg flat dose every two weeks after step-up dosing during the first two cycles of treatment. Subcutaneous administration of plamotamab is currently being incorporated into the study.

Key Highlights from the Abstract

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

At data cut off on July 25, 2022, 36 patients with relapsed or refractory non-Hodgkin's lymphoma (NHL) had been enrolled on or before April 1, 2022 and received the RD. Patients had a median age of 67 years and had received a median of 4 prior therapies. At baseline, 11.1% of patients had stage III disease, and 69.4% had stage IV disease. Additionally, 50% of patients received CAR-T as a prior therapy.

The safety analysis included all 36 patients. The most common adverse event (AE) was cytokine release syndrome (CRS), which occurred in 72.2% of patients, with no patients experiencing Grade 3 or 4 CRS. Grade 3 AEs affecting greater than 10% of patients included anemia (19.4%), neutropenia (16.7%), neutrophil count decrease (16.7%) and thrombocytopenia (11.1%). AEs leading to plamotamab discontinuation occurred in five patients (13.9%).

The efficacy analysis included 25 evaluable patients at the RD. In patients with diffuse large B-cell lymphoma (DLBCL), the overall response rate (ORR) was 47.4% (9/19), and the complete metabolic response/complete response (CMR/CR) rate was 26.3% (5/19). In patients with follicular lymphoma, the ORR was 100% (6/6), and the CMR/CR rate was 50% (3/6).

Prior CAR-T therapy was received by 18 patients, and 13 patients, all with DLBCL, were evaluable for efficacy. The ORR for patients with prior CAR-T therapy was 46.2% (6/13), and the CMR/CR rate was 30.8% (4/13).

An analysis of the plamotamab exposure-response (ER) relationship from the dose-escalation portion of the Phase 1 study examined IL6 levels, CRS incidence, high-grade AEs and ORR. The ER analysis showed that during step-up dosing, the ratio of post-dose maximum plamotamab concentration (Cmax) to minimum pre-dose concentration (Ctrough) predicted CRS events, but in contrast, once the target dose was reached, there was no relationship of exposure to CRS. This analysis provides guidance for improving dosing regimens in future clinical studies of plamotamab.

Presentation Details

- Abstract 4262, "A Phase 1 Study of Plamotamab, an Anti-CD20 x Anti-CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Non-Hodgkin's Lymphoma: Recommended Dose Safety-Efficacy Update and Escalation Exposure-Response Analysis"
- Session: 626. Aggressive Lymphomas: Prospective Therapeutic Trials: Poster III
- Date & Time: Monday, December 12, 2022. 6:00 - 8:00 p.m. CST
- Location: Ernest N. Morial Convention Center, Hall D

About Plamotamab

Plamotamab is an investigational tumor-targeted XmAb® bispecific antibody that contains both a CD20 binding domain and a cytotoxic T-cell binding domain (CD3). CD20 is highly expressed across a range of B-cell tumors, including non-Hodgkin lymphoma (NHL). Engagement of CD3 by plamotamab activates T cells for highly potent and targeted killing of CD20-expressing tumor cells.

Safety and anti-tumor activity from the ongoing Phase 1 clinical study has indicated that plamotamab was generally well tolerated and demonstrated encouraging clinical activity as a monotherapy. Plamotamab is also being evaluated in a Phase 2 study, in combination with tafasitamab plus lenalidomide, in patients with relapsed or refractory diffuse large B-cell lymphoma. The study consists of two parts, a safety run-in intended to establish the safety of the triple combination and a two-arm, open-label cohort where patients will be randomized to receive either the triple combination or tafasitamab plus lenalidomide.

Xencor has entered an exclusive collaboration and worldwide license agreement with Janssen Biotech, Inc. (Janssen) to develop and commercialize plamotamab and novel XmAb B-cell targeting bispecific antibodies that are designed to conditionally activate T cells through the CD28 co-stimulatory receptor.

About Xencor

Xencor is a clinical-stage biopharmaceutical company developing engineered antibodies and cytokines for the treatment of patients with cancer and autoimmune diseases. More than 20 candidates engineered with Xencor's XmAb® technology are in clinical development, and three XmAb medicines are marketed by partners. Xencor's XmAb engineering technology enables small changes to a protein's structure that result in new mechanisms of therapeutic action. For more information, please visit www.xencor.com.

Forward-Looking Statements

Certain statements contained in this press release may constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include statements that are not purely statements of historical fact, and can generally be identified by the use of words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” and similar terms, or by express or implied discussions relating to clinical trial data for plamotamab generally, planned clinical trials, the quotations from Xencor's senior vice president and chief medical officer and other statements that are not purely statements of historical fact. Such statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Xencor and are subject to significant 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, including the ability of publicly disclosed preliminary clinical trial data to support continued clinical development and regulatory approval for specific treatments, in each case as 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, 2021 as well as Xencor's subsequent filings with the Securities and Exchange Commission. 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, as amended to date. 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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