Xencor Presents Data from Phase 1 Study of Plamotamab in Relapsed or Refractory Non-Hodgkin Lymphoma at the American Society of Hematology Annual Meeting

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MONROVIA, Calif.--(BUSINESS WIRE)--Dec. 12, 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 additional 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 lymphomas. Data will be presented by Krish Patel, M.D., Director of the Lymphoma Program at Swedish Cancer Institute, in a poster session today from 6:00 p.m. to 8:00 p.m. CST at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans, Louisiana.

“Patients with non-Hodgkin lymphomas need further therapy options which can be efficacious, well-tolerated and importantly, administered in a variety of settings,” said Dr. Patel. “In the Phase 1 monotherapy study of plamotamab, the recommended intravenous dose was well tolerated, and we are encouraged by the responses observed in the study. This was a cohort of patients that were heavily pretreated, enriched with adverse prognostic factors, and included poor risk histology, such as high-grade B cell lymphoma and activated B-cell DLBCL.”

“Our strategy is to develop plamotamab as part of multiple highly active chemotherapy-free regimens across B-cell cancers. Xencor’s first combination study, evaluating plamotamab with tafasitamab plus lenalidomide, is enrolling patients with advanced, aggressive lymphoma. Importantly, we are engineering novel B-cell targeted CD28 bispecific antibodies that may selectively enhance T-cell cytotoxic activity,” said Allen Yang, M.D., Ph.D., senior vice president and chief medical officer at Xencor. “Additionally, patients enrolling to the ongoing Phase 1 monotherapy study will now receive subcutaneous doses of plamotamab.”

At data cut off on August 24, 2022, 44 patients with relapsed or refractory non-Hodgkin lymphoma (NHL) had been enrolled before June 30, 2022 and received the recommended dose. Patients had a median age of 69 years and had received a median of 4 prior therapies. At baseline, 86% had advanced stage III or IV disease. Additionally, 50% of patients received CAR-T as a prior therapy.

The primary disease at enrollment for these patients was diffuse large B-cell lymphoma (DLBCL; n=26), high-grade B-cell lymphoma (HGBCL; n=6), follicular lymphoma (FL; n=10), and other lymphoma (n=2).

Safety Analysis

The safety profile of plamotamab was consistent with previous results. The most common Grade 3 or 4 treatment-emergent adverse events (AEs) across all patients were neutropenia (25.0%), anemia (15.9%) and lymphopenia (11.4%). Grade 3 immune effector cell-associated neurotoxicity syndrome was observed in one patient (2.3%). AEs leading to plamotamab discontinuation occurred in nine patients (20.5%), including four patients (9.1%) who discontinued due to COVID-19. Cytokine release syndrome (CRS), the most common AE, was observed in 70.5% of patients, and no patients experienced Grade 3 or 4 CRS.

Efficacy Analysis

The efficacy analysis included both evaluable and intent-to-treat (ITT) patient populations. Responses were assessed based on the Lugano Classification.

In the efficacy evaluable population of patients with DLBCL or HGBCL, the overall response rate (ORR) was 52.0% (13/25), and the complete response rate was 24.0% (6/25). For patients who received prior CAR-T therapy, the ORR was 50.0% (8/16), and the CR rate was 25.0% (4/16). In the ITT population, the ORR was 43.8% (14/32), and the complete response rate was 18.8% (6/32). The median duration of response (mDOR) for both populations was 126 days.

In the efficacy evaluable population of patients with FL, the ORR was 87.5% (7/8), and the CR rate was 50.0% (4/8). In the ITT population, the ORR was 80.0% (8/10), and the CR rate was 40.0% (4/10). The mDOR for both populations had not been reached.

Dose Exposure-Response Analysis

An analysis of the plamotamab exposure-response (ER) relationship from the dose-escalation portion of the Phase 1 study examined IL-6 levels, CRS incidence, high-grade AEs and overall response. First-dose CRS was related to maximum plamotamab concentration (Cmax). The probability of CRS with step-up dosing, however, was better modeled using the magnitude of the step-up increment, as measured by the ratio of Cmax after dosing to the concentration prior to that dosing (Ctrough). Once the target dose was reached, there was no relationship of exposure to high-grade CRS. This analysis indicates the potential for a wide therapeutic window at the target dose and provides guidance for improving dosing regimens in future clinical studies of plamotamab.

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

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 co-stimulation.

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 management and study investigator 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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For Investors:
Charles Liles
cliles@xencor.com
626-737-8118

For Media:
Jason I. Spark
Evoke Canale
jason.spark@evokegroup.com
619-849-6005

Source: Xencor, Inc.