Xencor Presents Data from Phase 1 Study of Plamotamab in B-cell Non-Hodgkin Lymphomas at the ASH Annual Meeting

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MONROVIA, Calif.--(BUSINESS WIRE)--Dec. 12, 2021-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and autoimmune diseases, today announced updated data from its Phase 1 dose-escalation study of plamotamab, a CD20 x CD3 bispecific antibody, in patients with B-cell 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. EST at the 63rd American Society of Hematology (ASH) Annual Meeting in Atlanta, Georgia.

“Plamotamab is generally well tolerated and demonstrates encouraging clinical activity in heavily pretreated patients at our recommended intravenous Phase 2 dose of 50 mg flat dosing every two weeks following step-up dosing. Additionally, our pharmacokinetic modeling supports subcutaneous administration, which we plan to incorporate next year into our ongoing Phase 1 monotherapy study,” said Allen Yang, M.D., Ph.D., senior vice president and chief medical officer at Xencor. “We are especially encouraged that these results support the potential for a differentiated safety profile and better outcomes for patients when plamotamab is combined with other agents in a chemotherapy-free regimen. To that end, early next year we will initiate the first combination study, with tafasitamab and lenalidomide, in patients with relapsed or refractory diffuse large B cell lymphoma. Additionally, our new worldwide collaboration with Janssen for advancing plamotamab development expands our strategy to develop multiple highly active chemotherapy-free regimens across B-cell cancers, importantly with tumor-selective, co-stimulatory CD28 bispecific antibodies.”

Study Design

The Phase 1 study of plamotamab was originally designed in two parts: Part A to establish an initial priming dose with fixed, weight-based dosing regimens and Part B to escalate dosing on administrations after the priming dose (doses between 80 and 360 mcg/kg). A third part, Part C, was added to establish a step-up dosing regimen with higher, flat and less frequent dosing.

The Part C schedule, an intravenous, 50 mg flat dose every two weeks after step-up dosing during the first two cycles of treatment, was generally well tolerated and was determined to be the recommended Phase 2 dose.

Expansion cohorts are actively recruiting patients with diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) and are dosing using the recommended Phase 2 regimen to further evaluate the safety and efficacy of plamotamab monotherapy.

Safety Analysis

The safety population included 50 patients in Part B (38 DLBCL, 12 FL) and 14 patients in Part C (8 DLBCL, 4 FL, 1 marginal zone lymphoma, 1 mantle cell lymphoma). Patients were heavily pretreated, had a median age of 61.5 years, had a median of 4 prior therapies and had been diagnosed a median of 26.5 months prior to treatment.

In Part C of the study, patients had generally more advanced disease and poorer responses to prior therapy. The Part C population had a median age of 64 years, had a median of 5 prior therapies and had been diagnosed a median of 30.5 months prior to treatment. Of the 14 patients in Part C, eight patients received prior CAR-T and three patients received NK cell therapy. Two of these patients received both. All eight patients with DLBCL received prior CAR-T therapy.

The most common Grade 3 or 4 treatment-emergent adverse events (AEs) across all patients were anemia (21%), neutropenia (19%), hypophosphatemia (11%), thrombocytopenia (11%) and lymphopenia (10%). Four patients (5%) experienced Grade 3 or 4 cytokine release syndrome (CRS), each instance on the first dose, and no patients experienced Grade 3 or 4 CRS in Part C of the study. The rate of CRS of any grade fell from 74% in Part B to 57% in Part C. CRS was generally manageable with premedication.

In Part C, safety events were generally mild or moderate in severity. Grade 3 or 4 AEs experienced by more than 5% of patients included anemia (14%), lymphopenia (14%) and one patient each (7%) experiencing neutropenia, thrombocytopenia, decreases in neutrophil count, transaminase increases, fatigue and gamma-glutamyl transferase increases. Nervous system events did not lead to discontinuations, and no related neurotoxicity greater than Grade 2 was observed.

Efficacy Analysis

The efficacy analysis included 47 evaluable patients with either DLBCL or FL who were treated in Part B (n=38) or in Part C (n=9). Responses were assessed based on the Lugano Classification. The objective response rate (ORR) was 51% (24/47), and complete responses (CR) were observed in 12 patients (26%).

In part C of the study, the ORR was 100% (4/4) for patients with follicular lymphoma (FL), and CRs were observed in two patients (50%). For patients with diffuse large B-cell lymphoma, the ORR was 40% (2/5), and a CR was observed in one patient (20%). All 5 evaluable patients with DLBCL received prior CAR-T therapy, and two evaluable patients with DLBCL received prior NK cell therapy.

At the data cut off, the median duration of response for weight-based dosing cohorts and Part C was 225 days for patients with DLBCL and 171 days for patients with FL, with six patients continuing to respond to plamotamab monotherapy.

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.

Plamotamab is currently being evaluated in a Phase 1 clinical study for the treatment of patients with CD20-expressing hematologic malignancies, including NHL. Preliminary safety and anti-tumor activity from the Phase 1 study indicates that plamotamab is generally well tolerated and demonstrates encouraging clinical activity as a monotherapy.

Xencor has entered an exclusive collaboration and worldwide license agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, 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, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and autoimmune diseases. Currently, 22 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 proteins resulting 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 the 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, 2020 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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