Xencor Reports Fourth Quarter and Full Year 2023 Financial Results

February 27, 2024

-- Clinical development focus on high-potential XmAb® T cell engagers and selective dual checkpoint inhibitor, vudalimab --

-- Vudalimab (PD-1 x CTLA-4) monotherapy generally well tolerated with encouraging clinical benefit for patients with high-risk mCRPC who have advanced beyond standard of care therapy --

-- Management to Host Conference Call at 4:30 p.m. ET Today --

PASADENA, Calif.--(BUSINESS WIRE)--Feb. 27, 2024-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered antibodies for the treatment of cancer and other serious diseases, today reported financial results for the fourth quarter and full year ended December 31, 2023 and provided a review of recent business and clinical highlights. The Company also presented encouraging early clinical data from its Phase 2 study of vudalimab monotherapy for patients with clinically defined high-risk metastatic castration-resistant prostate cancer (mCRPC).

“We begin 2024 with a focus on advancing our high-potential XmAb CD3 and CD28 T-cell engagers for the treatment of patients with solid tumors and the evaluation of our PD-1 x CTLA-4 dual checkpoint inhibitor, vudalimab, in patients with metastatic castration-resistant prostate cancer and front-line non-small cell lung cancer,” said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. “This focused pipeline is supported by our strong financial foundation. In 2023, we significantly strengthened our balance sheet with our partial royalty monetization and milestone payments and royalties from our partners, for which we received more than $325 million in proceeds.

“The growing validation of T-cell engagers in solid tumors has encouraged us to build a range of new XmAb bispecific T-cell engager candidates, and we plan to select our next candidate for clinical development this year.”

Vudalimab (PD-1 x CTLA-4) Monotherapy in Patients with High-Risk mCRPC

Xencor is advancing vudalimab, a selective dual checkpoint inhibitor, in multiple clinical studies, including a Phase 2 monotherapy study (Study XmAb717-05) in patients with clinically defined high-risk metastatic castration-resistant prostate cancer (mCRPC). Early data from the study indicates that vudalimab has been generally well tolerated and associated with response to treatment in multiple patients who have visceral or lymph node metastases.

At the February 7, 2024 data cut off, 14 patients with clinically defined high-risk mCRPC had been treated with vudalimab every three weeks at a flat dose of 1000 mg, or 1200 mg for patients greater than 80 kg. Patients were a median of 72 years old and were heavily pretreated, having a median of four lines of prior therapy. 79% (11/14) of patients had metastatic disease at diagnosis; all patients had measurable disease.

The efficacy-evaluable population included 12 patients who had baseline and at least one post-baseline RECIST assessment. The objective response rate was 33% (4/12). Three patients had a confirmed partial response per RECIST 1.1 guidelines, and one additional patient had an unconfirmed partial response. An additional two patients experienced a best overall response of stable disease. Prostate-specific antigen (PSA) reductions of more than 90% from baseline (PSA90) were observed in 25% (3/12) of evaluable patients.

The safety analysis included all 14 patients. The most common immune-related adverse events of any grade were rash (29%) and alanine transaminase (ALT) increases (21%). Treatment-emergent adverse events led to treatment discontinuation for two patients (14%). One Grade 5 adverse event of autoimmune hepatitis was deemed treatment related; there have been no known additional cases of Grade 5 autoimmune hepatitis among three clinical studies with more than 240 patients treated with vudalimab.

Additional Vudalimab Clinical Studies and 2024 Priorities

Enrollment of patients with mCRPC in the study of vudalimab in combination with chemotherapy (Study XmAb717-04) is ongoing; revised chemotherapy dosing regimens are being evaluated, as previously disclosed.

In the fourth quarter of 2023, the Company dosed the first patient in a Phase 1b/2 study (Study XmAb717-06) evaluating vudalimab as a first-line treatment in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC).

Xencor plans to:

- Continue enrollment and provide a data update and decision whether to advance vudalimab as a monotherapy for patients with mCRPC in the first half of 2025.
- Continue enrollment and provide a data update and decision whether to advance vudalimab in combination with

chemotherapy for patients with mCRPC in the first half of 2025.
- Continue to enroll the Phase 1b part of a study of vudalimab in front-line metastatic NSCLC.

Additional Program Highlights and 2024 Priorities

- **XmAb819 (ENPP3 x CD3):** XmAb819 is a bispecific antibody in Phase 1 clinical development for patients with advanced clear-cell renal cell carcinoma (ccRCC). XmAb819 is designed to engage the immune system, activating T cells for highly potent and targeted killing of tumor cells expressing ENPP3, an antigen highly expressed on kidney cancers. Xencor's XmAb 2+1 multivalent format used in XmAb819 enables greater selectivity of ENPP3-expressing tumor cells compared to normal cells, which express lower levels of ENPP3. During 2024, Xencor plans to advance the ongoing Phase 1 dose-escalation study toward target dose levels.

- **XmAb808 (B7-H3 x CD28):** XmAb808 is a tumor-selective, co-stimulatory CD28 bispecific antibody in Phase 1 clinical development. XmAb808 binds to the broadly expressed tumor antigen B7-H3 and is constructed with the XmAb 2+1 format. Co-stimulation is required for T cells to achieve full activation, and targeted CD28 bispecific antibodies may provide conditional co-stimulation of T cells when the antibodies are bound to tumor cells. During 2024, Xencor plans to advance the ongoing Phase 1 dose-escalation study toward target dose levels.

- **XmAb541 (CLDN6 x CD3):** XmAb541 is a bispecific antibody being developed for patients with advanced ovarian cancer and other solid tumor types. XmAb541 is designed to engage the immune system, activating T cells for highly potent and targeted killing of tumor cells expressing Claudin-6 (CLDN6), a tumor-associated antigen. Xencor's XmAb 2+1 multivalent format used in XmAb541 enables greater selectivity for cells expressing CLDN6 over similarly structured Claudin family members, which may be expressed on normal tissue. During the first half of 2024, Xencor plans to dose the first patient in a Phase 1 dose-escalation study.

- **Engineered Cytokines:** Xencor has been conducting Phase 1 studies evaluating engineered cytokines XmAb564 (IL2-Fc in autoimmune disease) and XmAb662 (IL12-Fc in solid tumors). In the first half of 2024, Xencor plans to conclude studies of XmAb564 and XmAb662, complete internal data packages, and pause further development of both programs until after assessments of future data from competitor programs in this class and safety and biomarker data from Xencor's studies.

Recent Partnership Developments

- **Janssen Biotech, Inc., a Johnson & Johnson Company:** JNJ-9401 (PSMA x CD28) and JNJ-1493 (CD20 x CD28) are clinical-stage XmAb bispecific antibodies that J&J is developing for patients with prostate cancer and B-cell malignancies, respectively. Both programs entered Phase 1 clinical development during the fourth quarter of 2023, and Xencor received $20 million in development milestones. J&J also selected two B-cell targeting CD28 bispecific antibody candidates for further development, and Xencor received an additional $7.5 million in research milestones. In the fourth quarter of 2023, Xencor completed enrollment in subcutaneous dose-escalation cohorts of a Phase 1 study evaluating plamotamab.

Corporate Update: In January 2024, Xencor reduced its workforce to align resources with the company's clinical development focus on high potential T cell engaging bispecific antibodies and a more narrowly defined clinical program to evaluate vudalimab. The workforce reductions affected approximately 10% of positions at the Company.

Financial Guidance: Based on current operating plans, Xencor expects to end 2024 with between $475 million and $525 million in cash, cash equivalents and marketable debt securities, and to have cash to fund research and development programs and operations into 2027.

Financial Results for the Fourth Quarter and Full Year Ended December 31, 2023

Cash, cash equivalents, and marketable debt securities totaled $697.4 million as of December 31, 2023, compared to $584.5 million on December 31, 2022.

Total revenue for the fourth quarter ended December 31, 2023 was $44.7 million compared to $21.6 million for the same period in 2022. Revenues earned in the fourth quarter of 2023 were primarily from the research and milestone revenue from the two J&J collaboration agreements, and royalty revenue from Alexion and MorphoSys, compared to the same period in 2022, which were primarily royalty revenue from the Alexion and Vir agreements and research collaboration revenue from the second J&J collaboration. Revenues for the full year 2023 were $168.3 million compared to $164.6 million for the same period in 2022. Revenues for the full year 2023 were primarily milestone revenue from Alexion, Gilead, J&J, Omeros and Zenas and collaboration revenue from the second J&J collaboration, compared to the same period in 2022, which were earned primarily royalties from Alexion, MorphoSys and Vir, milestone revenue from Astellas and collaboration revenue from the second J&J collaboration.

Research and development (R&D) expenses for the fourth quarter ended December 31, 2023 were $63.0 million compared to the same period in 2022 which were $51.5 million. R&D expenses for the year ended December 31, 2023 were $253.6 million compared to $199.6 million for the same period in 2022. Increased R&D spending for fourth quarter and full year 2023, compared to amounts for the same periods in 2022, reflects additional spending on XmAb bispecific antibody programs including XmAb541, vudalimab and early-stage research programs.

General and administrative (G&A) expenses for the fourth quarter ended December 31, 2023 were $15.3 million compared to $12.8 million for the same period in 2022. G&A expenses for the full year ended December 31, 2023 were $53.4 million compared to $47.5 million for the same period in 2022. Increased G&A spending for the fourth quarter and full year 2023, compared to amounts for the same periods in 2022, reflects additional

compensation costs on general and administrative staffing and spending on professional fees.

Other income for the fourth quarter ended December 31, 2023 was $20.2 million compared to $30.1 million in the same period in 2022. Other income for both periods represents unrealized gain from the change in fair value of equity securities and interest income earned on investments. Other income for the full year ended December 31, 2023 was $18.2 million, compared to $28.0 million in the same period in 2022, which reflects a net decrease in unrealized gain from equity securities, partially offset by an increase in interest income in 2023.

Non-cash, stock-based compensation expense for the full year ended December 31, 2023 was $53.8 million compared to $48.9 million for the same period in 2022.

Net loss for the fourth quarter ended December 31, 2023 was $19.1 million or $(0.31) on a fully diluted per share basis, compared to net loss of $12.0 million or $(0.20) on a fully diluted per share basis, for the same period in 2022. For the full year ended December 31, 2023 net loss was $126.1 million or $(2.08) on a fully diluted per share basis, compared to net loss of $55.2 million or $(0.93) on a fully diluted per share basis, for the same period in 2022. Greater net loss reported for the fourth quarter ended December 31, 2023, compared to the same period in 2022, is primarily due to increased R&D spending. Greater net loss for the full year 2023, compared to the same period in 2022, is primarily due to increased R&D spending, a decrease in other income and an increase in tax expense in 2023.

The total shares outstanding were 60,998,191 as of December 31, 2023, compared to 59,997,713 as of December 31, 2022.

Conference Call and Webcast

Xencor will host a conference call and webcast today at 4:30 p.m. ET (1:30 p.m. PT) to discuss the financial results, provide a corporate update and review the clinical update of vudalimab monotherapy in mCRPC.

The live webcast may be accessed through “Events & Presentations” in the Investors section of the Company’s website, located at investors.xencor.com. Telephone participants may register to receive a dial-in number and unique passcode that can be used to access the call. A recording will be available for at least 30 days.

About Xencor

Xencor is a clinical-stage biopharmaceutical company developing engineered antibodies for the treatment of patients with cancer and other serious 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 proteins 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 Xencor’s business, including, but not limited to, statements regarding planned presentations of clinical data, planned clinical trials, projected financial resources, the quotations from Xencor's president and chief executive 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, 2023 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.

Xencor, Inc.
Selected Consolidated Balance Sheets Data
(in thousands, except share and per share data)

	December 31,	
	2023	**2022**
Cash, cash equivalents and marketable debt securities - current	$ 551,515	$ 580,631
Other current assets	71,645	94,711
Marketable debt securities - long term	145,892	3,826
Other long-term assets	183,640	167,098
Total assets	$ 952,692	$ 846,266
Total current liabilities	84,709	63,844
Deferred income - long term	125,183	—
Other long term liabilities	73,667	54,926

Total liabilities	283,559	118,770
Total stockholders' equity	669,133	727,496
Total liabilities and stockholders' equity	$ 952,692	$ 846,266

Xencor, Inc.
Consolidated Statements of Loss
(in thousands, except share and per share data)

	Three months Ended December 31,		Year ended December 31,	
	2023	**2022**	**2023**	**2022**
	(Unaudited)			
Revenue	$ 44,689	$ 21,610	$ 168,338	$ 164,579
Operating expenses				
Research and development	63,046	51,452	253,598	199,563
General and administrative	15,272	12,751	53,379	47,489
Total operating expenses	78,318	64,203	306,977	247,052
Loss from operations	(33,629)	(42,593)	(138,639)	(82,473)
Other income, net	20,177	30,136	18,200	27,965
Loss before income tax	(13,452)	(12,457)	(120,439)	(54,508)
Income tax expense	5,811	(415)	5,811	673
Net loss	(19,263)	(12,042)	(126,250)	(55,181)
Net loss attributable to non-controlling interest	(163)	—	(163)	—
Net loss attributable to Xencor, Inc.	(19,100)	(12,042)	(126,087)	(55,181)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities available-for-sale	1,999	2,924	8,243	(5,442)
Comprehensive loss attributable to Xencor, Inc.	$ (17,101)	$ (9,118)	$ (117,844)	$ (60,623)
Net loss per common share attributable to Xencor, Inc.:				
Basic and Diluted	$ (0.31)	$ (0.20)	$ (2.08)	$ (0.93)
Weighted average common shares used to compute net loss per share attributable to Xencor, Inc.				
Basic and Diluted	60,847,854	59,912,038	60,503,283	59,652,461

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