Xilio Therapeutics Reports Pipeline and Business Progress and Third Quarter 2021 Financial Results

December 2, 2021

Anticipate First Patient Dosing in Phase 1/2 Clinical Trial for XTX202, a Tumor-Selective IL-2, in First Quarter of 2022

Advancing Phase 1/2 Clinical Trial for XTX101, a Tumor-Selective Anti-CTLA-4

Successfully Closed IPO in Fourth Quarter of 2021, Raising Approximately $130 Million in Gross Proceeds to Advance Pipeline of Tumor-Selective Immuno-Oncology Programs

WALTHAM, Mass., Dec. 02, 2021 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a biotechnology company developing tumor-selective immuno-oncology therapies for patients with cancer, today reported recent pipeline and business progress and third quarter 2021 financial results.

“Xilio made significant progress in 2021 as we transitioned to a clinical stage organization with XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody, and XTX202, a tumor-selective IL-2, in clinical development,” said René Russo, Pharm. D., president and chief executive officer of Xilio. “With the recent completion of our IPO and a strong and experienced team in place, we are well-positioned to leverage our geographically precise solutions (GPS) platform to advance our pipeline of immuno-oncology therapies that have the potential to achieve meaningful anti-tumor activity while minimizing serious, systemic effects for the benefit of cancer patients.”

Recent Pipeline and Business Progress

Cytokine Programs

- In October 2021, the U.S. Food and Drug Administration (FDA) cleared Xilio’s investigational new drug application (IND) to evaluate XTX202, a tumor-selective interleukin-2 (IL-2), as a potential treatment for patients with solid tumors. XTX202 is designed to localize activity in the tumor microenvironment, with the goal of overcoming the known toxicity challenges of existing IL-2 therapies while achieving enhanced anti-tumor activity.
- In November 2021, at the Society for Immunotherapy in Cancer’s 36 th Annual Meeting, Xilio reported data from preclinical studies for XTX301, a tumor-selective interleukin-12 (IL-12). Findings demonstrated selective anti-tumor activity and favorable tolerability with minimal systemic effects observed in mouse models evaluating a murine surrogate for XTX301 and non-human primate models evaluating XTX301.

Checkpoint Inhibitor Program

- In September 2021, Xilio initiated patient dosing in its Phase 1/2 clinical trial evaluating XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody, for the treatment of solid tumors as a monotherapy and in combination with pembrolizumab, an anti-PD-1. XTX101 is designed to improve upon the therapeutic index of existing anti-CTLA-4 therapies by overcoming their historical potency and tolerability limitations, as well as the inability to use existing anti-CTLA-4 therapies at their full dose in combination with other immuno-oncology therapies.

Recent Business Highlights

- On October 26, 2021, Xilio closed its initial public offering (IPO). In connection with the IPO, Xilio issued and sold 7,353,000 shares of common stock at a public offering price of $16.00 per share, and on November 1, 2021, Xilio issued and sold an additional 766,106 shares of common stock at a public offering price of $16.00 per share pursuant to the partial exercise by the underwriters of their option to purchase additional shares. Xilio received aggregate gross proceeds of approximately $129.9 million or aggregate net proceeds of approximately $116.3 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by Xilio.
- Appointed Tim Hunt as Xilio’s chief culture and corporate affairs officer in October 2021.
- Appointed Sara Bonstein, chief financial officer of Insmed, Inc., to Xilio’s board of directors in August 2021.

Anticipated Milestones in 2022

Xilio currently anticipates the following milestones in 2022:

- Initiation of a Phase 1/2 clinical trial to evaluate XTX202 in multiple solid tumor types in the first quarter of 2022

- Presentation of preliminary data for the monotherapy cohort of the Phase 1/2 clinical trial evaluating XTX101 in patients with advanced solid tumors in the middle of 2022
- Presentation of preliminary Phase 1 data for XTX202 in patients with multiple solid tumor types in the second half of 2022
- Presentation of preliminary data from the combination cohort for the Phase 1/2 clinical trial evaluating XTX101 in patients with advanced solid tumors in the second half of 2022
- Submission of an IND for XTX301 in the second half of 2022

Third Quarter 2021 Financial Results

- **Cash Position and Guidance:** Cash and cash equivalents were $99.8 million as of September 30, 2021, compared to $19.2 million as of December 31, 2020. Cash and cash equivalents as of September 30, 2021 do not include $116.3 million in estimated net proceeds from Xilio's October 2021 IPO. Xilio believes that its existing cash and cash equivalents, together with the net proceeds from its IPO, will enable it to fund its operating expenses and capital expenditure requirements into 2024.
- **Research & Development (R&D) Expenses:** R&D expenses were $10.5 million for the third quarter of 2021, compared to $11.5 million for the third quarter of 2020. This decrease was primarily driven by lower comparable costs associated with manufacturing development activities for the XTX101 and XTX202 programs, partially offset by higher personnel-related costs due to increased headcount and preclinical research and clinical development expenses.
- **General & Administrative (G&A) Expenses:** G&A expenses were $5.5 million for the third quarter of 2021, compared to $3.2 million for the third quarter of 2020. This increase was primarily driven by higher personnel-related costs due to increased headcount and higher professional fees related to ongoing business activities and preparations related to operating as a public company.
- **Net Loss:** Net loss was $16.3 million for the third quarter of 2021, compared to $14.8 million for the third quarter of 2020.

About Xilio Therapeutics

Xilio Therapeutics is a biotechnology company focused on harnessing the immune system to achieve deep and durable clinical responses to improve the lives of patients with cancer. The company is using its proprietary geographically precise solutions (GPS) platform to rapidly engineer novel molecules, including cytokines and other biologics, that are designed to optimize their therapeutic index. These molecules are designed to localize activity within the tumor microenvironment without systemic effect, resulting in the potential to achieve enhanced anti-tumor activity. Xilio is building a pipeline of wholly-owned, tumor-selective, GPS-enabled cytokine and checkpoint inhibitor product candidates, including XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody; XTX202, a tumor-selective IL-2; XTX301, a tumor-selective IL-12; and XTX401, a tumor-selective IL-15. For more information, please visit www.xiliotx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding plans, strategies, timelines and expectations for Xilio's current or future approved product candidates, including without limitation, plans and timing related to the initiation of a Phase 1/2 clinical trial for XTX202, the presentation of preliminary clinical data for XTX101 and XTX202 and the submission of an IND for XTX301; the potential benefits of any of Xilio's current or future product candidates in treating patients; Xilio's ability to fund its operating expenses and capital expenditure requirements with its cash and cash equivalents; and Xilio's strategy, goals and anticipated financial performance, milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to ongoing and planned research and development activities, including initiating, conducting or completing preclinical studies and clinical trials and the timing and results of such preclinical studies or clinical trials; the delay of any current or planned preclinical studies or clinical trials or the development of Xilio's current or future product candidates; preclinical and clinical supply of current or future product candidates; Xilio's advancement of multiple early-stage programs; Xilio's ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; results from preclinical studies or clinical trials for Xilio's product candidates, which may not support further development of such product candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of current or future clinical trials; Xilio's ability to obtain, maintain and enforce patent and other intellectual property protection for current or future product candidates; Xilio's ability to obtain and maintain sufficient cash resources to fund current or future operating expenses and capital expenditure requirements; and the impact of the COVID-19 pandemic on Xilio's business, operations, strategy, goals and anticipated milestones. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Xilio's filings with the U.S. Securities and Exchange Commission (SEC), including Xilio's final prospectus related to its initial public offering, and any other filings that Xilio makes with the SEC in the future. Any forward-looking statements contained in this press release represent Xilio's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Xilio explicitly disclaims any obligation to update any forward-looking statements.

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XILIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 99,767	$ 19,238
Other assets	20,958	17,079
Total assets	120,725	36,317
Liabilities and Stockholders' Deficit		
Liabilities	34,292	41,602
Convertible preferred stock	222,888	78,002
Stockholders' deficit	(136,455)	(83,287)
Total liabilities, convertible preferred stock and stockholders' deficit	120,725	36,317

XILIO THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses [1]				
Research and development	$ 10,470	$ 11,460	$ 39,836	$ 26,243
General and administrative	5,491	3,163	15,652	7,725
Total operating expenses	15,961	14,623	55,488	33,968
Loss from operations	(15,961)	(14,623)	(55,488)	(33,968)
Other income (expense), net				
Other expense, net	(290)	(196)	(611)	(479)
Total other income (expense), net	(290)	(196)	(611)	(479)
Net loss and comprehensive loss	$ (16,251)	$ (14,819)	$ (56,099)	$ (34,447)
Net loss per share, basic and diluted	$ (21.27)	$ (24.19)	$ (76.18)	$ (72.02)
Weighted average common shares outstanding, basic and diluted	763,869	612,657	736,416	478,283

[1] Operating expenses include the following amounts of non-cash equity-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expense	$ 378	$ 183	$ 864	$ 240
General and administrative expense	713	500	2,023	690
Total equity-based compensation expense	$ 1,091	$ 683	$ 2,887	$ 930