CARGO Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

May 14, 2024

- 26 sites activated and over 20 patients dosed in the potentially pivotal Phase 2 clinical study, FIRCE-1 of firicabtagene autoleucel (firi-cel) (CRG-022); Currently on-track for interim results expected in 1H25 -

- Independent Data Monitoring Committee (IDMC) recommended continuation of FIRCE-1 without modifications -

- Ongoing follow-up from the Stanford Phase 1 study for firi-cel[1] to be presented at the 2024 European Hematology Association (EHA) Congress, highlighting median overall survival of 25.7 months and favorable safety profile at the dose level selected for CARGO's Phase 2 Study -

SAN CARLOS, Calif., May 14, 2024 (GLOBE NEWSWIRE) -- **CARGO Therapeutics, Inc. (NASDAQ: CRGX)**, a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients, today reported financial results for the first quarter ended March 31, 2024 and provided a business update.

"We're off to a strong start to 2024 following our successful IPO. Our Phase 2 study for firi-cel is progressing as planned with 26 activated trial sites, more than 20 patients dosed, positive safety review from the IDMC and continued impressive manufacturing success. Importantly, ongoing follow-up from the Stanford Phase 1 study demonstrated favorable efficacy, durability and safety results, which continues to reinforce our conviction in firi-cel to become a meaningful treatment advancement with the potential for curative outcomes for patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy," said Gina Chapman, President and Chief Executive Officer of CARGO. "Beyond our lead program, we are also pleased to be making headway with our IND-enabling activities for our most advanced preclinical asset, CRG-023, which incorporates a tri-specific CAR T with CD2 co-stimulation. 2024 will be an exciting year for CARGO as we execute on our FIRCE-1 study, which is currently on track for interim analysis in the first half of 2025, while advancing our next-generation cell therapy pipeline."

Corporate Highlights

- **FIRCE-1 Phase 2 clinical study updates:** Currently 26 sites have been activated and over 20 patients have been dosed with impressive manufacturing success. Further, the IDMC completed its review of safety data with a recommendation for FIRCE-1 to continue to enroll patients without modifications to the protocol.
- **Phase 1 clinical study updates:** Ongoing follow-up from Stanford University's Phase 1 study for firi-cel (NCT04088890) to be presented at EHA. The most recent update reflects data cut-off as of February 1, 2024, which demonstrated:
  - A favorable overall response rate (ORR) and complete response (CR) rate of 68% and 53%, respectively, was maintained for all patients treated (n=38) at a median follow up of 31.4 months.
  - Of the 20 patients achieving CR, there have been no additional patient relapses since the last data cut in November of 2023.
  - New data for Dose Level 1* (DL1) (n=29) at a median follow-up of 29.8 months included:
    - Median overall survival (mOS) is 25.7 months (95% CI: 9.2, NE).
    - Estimated 2-year survival remains at 52%.
    - The median progression-free survival (PFS), duration of response, and OS have not been reached for patients who achieved a CR.
    - No grade 3 or higher cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) events occurred at DL1.

**Dose being evaluated in CARGO's ongoing FIRCE-1 Phase 2 clinical study of firi-cel.*

- **Dr. Kapil Dhingra, M.B.B.S., named to Board of Directors**: In April, CARGO announced the appointment of Dr. Kapil Dhingra, M.B.B.S., to the Company's Board of Directors. Dr. Dhingra is a medical oncologist and a physician-scientist bringing more than 25 years of strategic

clinical development experience in oncology, including cell therapy, with a proven track record in drug development, patient care and academic research.

First Quarter 2024 Financial Highlights

- **Cash Position**: As of March 31, 2024, CARGO had cash, cash equivalents and marketable securities of $375.9 million, providing expected cash runway into 2026.
- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter of 2024 were $30.5 million, which included $1.7 million of non-cash stock-based compensation expense.
- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter of 2024 were $10.3 million, which included $2.2 million of non-cash stock-based compensation expense.
- **Net Loss**: Net loss for the first quarter of 2024 was $35.8 million, or $0.87 per share, including non-cash stock-based compensation and depreciation expenses of $3.9 million and $0.6 million, respectively.

About CARGO Therapeutics
CARGO Therapeutics, Inc. is a clinical-stage biotechnology company positioned to advance next- generation, potentially curative cell therapies for cancer patients. CARGO's programs, platform technologies, and manufacturing strategy are designed to directly address the limitations of approved cell therapies, including limited durability of effect, safety concerns and unreliable supply. CARGO is currently evaluating its lead program, firicabtagene autoleucel (firi-cel) (CRG-022), an autologous CD22 chimeric antigen receptor (CAR) T-cell therapy candidate, in a potentially pivotal Phase 2 clinical study in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy. CARGO also plans to evaluate firi-cel (CRG-022) in patients at earlier stages of disease, including LBCL and other hematologic malignancies. Beyond its lead program, CARGO is leveraging its proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic "cargo" designed to enhance CAR T-cell persistence and trafficking to tumor lesions, as well as to help safeguard against tumor resistance and T-cell exhaustion. This includes the CRG-023 program, which incorporates a tri-specific CAR T with CD2 co-stimulation. CARGO's founders are pioneers and world-class experts in CAR T-cell therapy, and its team has significant experience and success in developing, manufacturing, launching and commercializing oncology and cell therapy products. For more information, please visit the CARGO Therapeutics website at https://cargo-tx.com/.
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[1] Firicabtagene autoleucel (firi-cel) (CRG-022) is CARGO Therapeutics' autologous CD22 CAR T-cell product candidate. The underlying CAR of which the Company exclusively licensed was the construct evaluated by Stanford University in a Phase 1 clinical trial in patients with large B-cell lymphoma whose disease relapsed or was refractory to CD19 CAR T-cell therapy. The Company's CRG-022 Investigational New Drug application included a comprehensive package in which CARGO performed and demonstrated analytical comparability of CRG-022 produced using the intended commercial process to the CRG-022 produced using the process used for the Stanford Phase 1 clinical trials. CARGO cannot assure that the FDA will agree with its claim of comparability and the sufficiency of the data to support it when it files its Biologics License Application.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements about: advancement of CARGO's clinical and preclinical programs; the potential benefits of CARGO's product candidates; and timing of data reports, including the release of interim data from the Company's ongoing Phase 2 clinical trial of firi-cel (CRG-022). Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the company's ability to obtain necessary capital to fund its clinical programs; the early stages of clinical development of the company's product candidates; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers, including CROs; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. For a detailed discussion of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to CARGO's business in general, please refer to the risk factors identified in the Company's filings with the Securities and Exchange Commission (SEC), including but not limited to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 to be filed on or about the date hereof. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. CARGO's results for the quarter ended March 31, 2024 are not necessarily indicative of its operating results for any future periods.

CARGO Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three months ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 30,503	$ 12,562
General and administrative	10,303	2,685
Total operating expenses	**40,806**	**15,247**
Loss from operations	(40,806)	(15,247)
Other income, net	4,995	2,500
Net loss	**$ (35,811)**	**$ (12,747)**
Other comprehensive loss:		
Unrealized loss on marketable securities	(279)	—
Comprehensive loss	**$ (36,090)**	**$ (12,747)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (21.36)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	40,995,901	596,738

CARGO Therapeutics, Inc.
Condensed Balance Sheet Data
(in thousands)

	March 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 81,526	$ 405,732
Marketable securities	294,387	—
Other assets	46,516	47,304
Total assets	**$ 422,429**	**$ 453,036**
Liabilities and Stockholders' Equity		
Liabilities	$ 49,217	$ 47,650
Stockholders' equity	373,212	405,386
Total liabilities and stockholders' equity	**$ 422,429**	**$ 453,036**

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