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

November 12, 2024

- 57 patients dosed in the potentially pivotal Phase 2 clinical study, FIRCE-1 of firicabtagene autoleucel (firi-cel); on track for interim analysis in 1H25 -

- CRG-023 pre-clinical data to be presented at ASH 2024; IND submission anticipated Q1'25 with Phase 1 initiation planned for 2025 -

- Anup Radhakrishnan, CFO of CARGO Therapeutics, appointed as COO and CFO -

SAN CARLOS, Calif., Nov. 12, 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 third quarter ended September 30, 2024, and provided a business update.

"We are pleased to report another quarter of strong execution underscored by continued progress in our FIRCE-1, Phase 2 study of firi-cel in addition to meaningful pipeline advancements," said Gina Chapman, President and Chief Executive Officer of CARGO. "With 57 patients dosed and continued, strong manufacturing success, we remain on track to report our interim analysis in the first half of 2025. We also anticipate a clear path forward to advancing CRG-023, our innovative tri-specific CAR T product candidate, into the clinic following our successful pre-IND meeting with the FDA and we are excited to share more at the upcoming ASH meeting."

Chapman continued, "I'd also like to recognize Anup Radhakrishnan on his appointment to Chief Operating Officer in addition to his current role as CFO. Anup has been instrumental in transforming CARGO from a private to public company, including establishing and scaling our corporate infrastructure, achieving operational excellence, leading our successful IPO, and overseeing our corporate and capital formation strategies. His leadership over the years has not only enabled our progress and execution across our programs but also positioned CARGO for future growth."

Corporate Highlights

- **Firi-cel:**
  - Currently 57 patients have been dosed across all cohorts with strong manufacturing success in the FIRCE-1, Phase 2 clinical study of firi-cel in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy.
  - The Independent Data Monitoring Committee (IDMC) completed its safety and futility assessment during the third quarter and recommended the continuation of the FIRCE-1 study without modification.
  - CARGO expects to complete its interim analysis and report the results in the first half of 2025.
- **CRG-023:**
  - During the third quarter, CARGO completed a successful pre-Investigational New Drug (IND) meeting with the FDA, obtaining guidance on the development program and the data package to be provided in the IND.
  - IND application submission for CRG-023 in Non-Hodgkin's lymphoma anticipated in the first quarter of 2025; first patient dosed planned for 2025.
  - CARGO will present CRG-023 pre-clinical data at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition. The abstract cites CRG-023 construct design as well as pre-clinical data demonstrating durable anti-tumor activity following repeated challenge from tumor cells expressing all three antigens (CD19, CD20, CD22), sustained tumor clearance when only a single antigen is expressed, and robust in vivo, anti-lymphoma activity in low CAR T dose levels.
- **Corporate:**

- CARGO today announced the appointment of Anup Radhakrishnan, Chief Financial Officer (CFO), as Chief Operating Officer (COO) and CFO. In this role, Mr. Radhakrishnan will continue to oversee CARGO's financial and business strategy, while also providing operational leadership to drive the execution of CARGO's strategic goals across the enterprise.

Third Quarter 2024 Financial Highlights

- **Cash Position**: As of September 30, 2024, our cash, cash equivalents and marketable securities were $404.8 million, which we believe will be sufficient to fund our expected operations through 2026.
- **Research and Development (R&D) Expenses**: R&D expenses for the three and nine months ended September 30, 2024 were $35.9 million and $103.9 million, respectively, which included $1.9 million and $5.2 million of non-cash stock-based compensation expenses, respectively.
- **General and Administrative (G&A) Expenses**: G&A expenses for the three and nine months ended September 30, 2024 were $11.2 million and $33.3 million, respectively, which included $3.0 million and $7.9 million of non-cash stock-based compensation expenses, respectively.
- **Net Loss**: Net loss for the three and nine months ended September 30, 2024 was $41.9 million, or $0.88 per share, and $122.1 million, or $2.77 per share, respectively, including non-cash stock-based compensation of $4.9 million and $13.1 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 firicabtagene autoleucel (firi-cel), 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 has developed proprietary cell engineering platform technologies which it leverages 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 novel tri-specific CAR T with CD2 co-stimulation that is designed to provide more patients across a broad range of B-cell malignancies with durable responses by addressing several known causes of relapse, resulting in a potential best-in-class CAR T-cell therapy. CARGO's leadership and team have significant experience in developing, engineering, manufacturing, 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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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: the initiation, timing, progress, advancement, and results of CARGO's clinical and preclinical programs; the potential benefits of CARGO's product candidates; the timing of data reports, including the release of interim data from CARGO's ongoing Phase 2 clinical trial of firi-cel; CARGO's strategic plans for its business and product candidates; and CARGO's expectations that its current cash, cash equivalents and marketable securities will be sufficient to fund its expected operations through 2026. 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 and the product candidates involving novel technologies; clinical and preclinical development being a lengthy and expensive process with uncertain outcomes; interim, "topline" and preliminary data from the company's clinical trials and preclinical studies as well as any favorable data from trials conducted by third-parties, including Stanford University or the NCI, may not be replicated in the company's clinical trials or predictive of future results; 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 September 30, 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 three and nine months ended September 30, 2024 are not necessarily indicative of its operating results for any future periods.

Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 35,932	$ 22,233	$ 103,893	$ 48,724
General and administrative	11,180	6,478	33,343	13,030
Total operating expenses	**47,112**	**28,711**	**137,236**	**61,754**
Loss from operations	(47,112)	(28,711)	(137,236)	(61,754)
Other income (expense), net	5,204	(6,760)	15,169	(4,316)
Net loss	**$ (41,908)**	**$ (35,471)**	**$ (122,067)**	**$ (66,070)**
Other comprehensive loss:				
Unrealized loss on marketable securities	958	—	635	—
Comprehensive loss	**$ (40,950)**	**$ (35,471)**	**$ (121,432)**	**$ (66,070)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.88)	$ (47.37)	$ (2.77)	$ (98.15)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	47,664,309	748,862	44,014,886	673,175

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

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 71,176	$ 405,732
Marketable securities	333,672	—
Other assets	46,113	47,304
Total assets	**$ 450,961**	**$ 453,036**
Liabilities and Stockholders' Equity		
Liabilities	$ 50,083	$ 47,650
Stockholders' equity	400,878	405,386
Total liabilities and stockholders' equity	**$ 450,961**	**$ 453,036**

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