CG Oncology Reports First Quarter 2024 Financial Results and Provides Business Updates

May 09, 2024

- Cretostimogene Monotherapy Demonstrated 75.2% Complete Response (CR) Rate at Any Time in Bacillus Calmette Guerin (BCG)-Unresponsive, High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)
- First Patient Dosed in PIVOT-006 Phase 3 Clinical Trial of Cretostimogene in Intermediate-Risk NMIBC (IR-NMIBC)
- Final Results from CORE-001 Phase 2 Clinical Trial of Cretostimogene in Combination with Pembrolizumab in BCG-Unresponsive HR-NMIBC will be presented at ASCO 2024
- Completed Oversubscribed and Upsized $437 Million Initial Public Offering that Extends Expected Runway Through 2027

IRVINE, Calif., May 09, 2024 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON), a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients with bladder cancer, today reported financial results for the first quarter ended March 31, 2024, and provided business updates.

“2024 is a transformative year for CG Oncology, with our oversubscribed and upsized $437 million IPO on NASDAQ and our recent presentation at AUA of interim data showing a 75.2% CR rate at any time in BCG-Unresponsive HR-NMIBC from our BOND-003 Phase 3 clinical trial, which potentially supports cretostimogene monotherapy as backbone therapy in this disease with significant unmet need,” said Arthur Kuan, Chairman & Chief Executive Officer of CG Oncology. “In the coming months we look forward to sharing final results from our CORE-001 Phase 2 clinical trial of crestostimogene in combination with pembrolizumab and final results from our BOND-003 Phase 3 registrational clinical trial of cretostimogene monotherapy by the end of the year.”

Corporate Highlights

- **Completed Oversubscribed and Upsized Initial Public Offering that extends expected runway through 2027.**
- **Cretostimogene Monotherapy Demonstrated 75.2% CR Rate at Any Time in BCG-Unresponsive HR-NMIBC.** On May 3rd at AUA in the paradigm-shifting, practice-changing clinical trials in urology session, the Company announced data from the BOND-003 Phase 3, single arm, open label, registrational study evaluating the efficacy and safety of cretostimogene monotherapy in patients with HR-NMIBC unresponsive to BCG, showed that 75.2% of patients (79 out of 105 [95% confidence interval (CI), 65-83]) achieved a CR at any time, as of the cutoff date of April 1, 2024.
- **First Patient Dosed in PIVOT-006 Phase 3 Clinical Trial of Cretostimogene in IR-NMIBC.** In February, the Company announced the first patient was dosed in PIVOT-006, a Phase 3, open-label, two-arm trial enrolling up to 364 IR-NMIBC patients, one arm to be administered cretostimogene following the standard of care TURBT with the second arm receiving the standard of care TURBT only. The primary endpoint of this trial is overall recurrence-free survival (RFS), with secondary endpoints including RFS at 12 and 24 months and progression-free survival.
- **Final Results from CORE-001 Phase 2 Clinical Trial of Cretostimogene in Combination with Pembrolizumab in BCG-Unresponsive HR-NMIBC to be presented at ASCO 2024.**

Anticipated Next Milestones

- BOND-003 (BCG-Unresponsive, HR-NMIBC): Final results from the Phase 3 clinical trial of cretostimogene monotherapy by the end of 2024.
- CORE-001 (BCG-Unresponsive, HR-NMIBC): Final results from the Phase 2 clinical trial of crestostimogene in combination with pembrolizumab in June 2024 at the 2024 ASCO Annual Meeting.

First Quarter 2024 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of March 31, 2024, were $566.5 million, compared with $187.7 million as of December 31, 2023. Based on cash, cash equivalents and marketable securities, as of March 31, 2024, and current operating plans, the Company expects its cash runway to be sufficient to fund operations through 2027.
- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter ended March 31, 2024 were $17.2 million compared with $7.8 million for the first quarter ended March 31, 2023 due to the progression of and increase in clinical trials expense supporting the development of cretostimogene in multiple indications.
- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter ended March 31, 2024 were $5.8 million compared with

$2.1 million for the first quarter ended March 31, 2023. The increase in G&A is primarily attributed to an increase in headcount in the company's general and administrative functions to support the business as a public company.

- **Net Loss**: Net loss attributable to common stockholders was $16.9 million, or ($0.36) per share, for the first quarter ended March 31, 2024, compared to $12.4 million, or ($3.22) per share, for the first quarter ended March 31, 2023.

About CG Oncology
CG Oncology is a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. CG Oncology sees a world where urologic cancer patients may benefit from our innovative immunotherapies to live with dignity and have an enhanced quality of life. To learn more, please visit: www.cgoncology.com.

Forward-Looking Statements
CG Oncology cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, statements regarding our anticipated cash runway, future results of operations and financial position; the anticipated timing and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene, including anticipated next milestones in our development pipeline; and the timing and likelihood of regulatory filings and approvals for cretostimogene. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data becomes available; potential delays in the commencement, enrollment and completion of clinical trials, including the CORE-001, BOND-003 and PIVOT-006 trials; we may use our capital resources sooner than expected and they may be insufficient to allow us to achieve our anticipated milestones; our dependence on third parties in connection with manufacturing, shipping and clinical and preclinical testing; results from earlier clinical trials and preclinical studies not necessarily being predictive of future results; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; and other risks described in our filings with the SEC, including under the heading "Risk Factors" in our annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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