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

Aug 08, 2024

– Final positive safety and efficacy findings from CORE-001 study of Cretostimogene Grenadenorepvec in combination with Pembrolizumab in BCG-Unresponsive NMIBC simultaneously published online by *Nature Medicine* and featured at ASCO 2024 –

– Announced 54% complete response (CR) rate in the intention-to-treat population at 24-month landmark and meets primary endpoint in the CORE-001 study –

– Demonstrated 75.2% CR rate in High-Risk, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer in Cretostimogene Monotherapy BOND-003 study –

– Initiated and dosed first patient in Expanded Access Program for Cretostimogene Grenadenorepvec; Enrollment ongoing –

IRVINE, Calif., Aug. 08, 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 second quarter ended June 30, 2024, and provided business updates.

"This quarter, with the BOND-003 monotherapy data presented at AUA, and the CORE-001 combination data presented at ASCO and subsequently published in *Nature Medicine*, we affirmed the potential for cretostimogene, our novel oncolytic immunotherapy candidate, to be used as a bladder-sparing backbone therapy for NMIBC," said Arthur Kuan, Chairman & Chief Executive Officer of CG Oncology. "We demonstrated our commitment to bladder cancer patients by initiating our Expanded Access Program in June, and we're encouraged by the strong enrollment that we've seen to date. Additionally, we strengthened our team across key functions to ensure that we have the optimal organizational structure for this stage of our growth. We look forward to sharing primary results from our BOND-003 registrational study of cretostimogene monotherapy later this year, and progressing toward submitting our Biologics License Application."

Corporate Highlights

- **Presented Positive Final Results from CORE-001 Phase 2 Clinical Trial of Cretostimogene in Combination with Pembrolizumab in BCG-Unresponsive HR-NMIBC at ASCO 2024.** In June, the Company presented positive final results from its CORE-001 Phase 2 study of cretostimogene grenadenorepvec in combination with pembrolizumab in BCG-Unresponsive HR-NMIBC at ASCO 2024, showing a 54% CR rate at the 24-month landmark and meeting the primary endpoint of the study.
    - As of the data cutoff on February 5, 2024, the CR rate in the intention-to-treat (ITT) population at 12-months and any time, was 57% (20/35) (95% confidence interval [CI], 40-73%) and 83% (29/35) **(**95% CI, 70-95%), respectively. As of May 17, 2024, the CR rate in the ITT population at 24 months was 54% (19/35) (95% CI, 37-71%).
    - Of the patients in a CR at 12 months, 95% of patients (19/20) maintained a CR for another 12 months.
    - Progression-free survival (PFS) at 24 months is 100% with no patients progressing to muscle invasive cancer or metastatic disease.

The results were subsequently published in *Nature Medicine*. The CORE-001 Phase 2 trial was conducted in collaboration with Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

- **Cretostimogene Monotherapy Demonstrated 75.2% CR Rate at Any Time in BCG-Unresponsive HR-NMIBC.** In May, 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, which showed that 75.2% of patients (79 out of 105 [95% CI, 65-83]) achieved a CR at any time, as of the cutoff date on April 1, 2024. There were no Grade 3 or greater adverse effects and no treatment related discontinuations
- **Initiated Expanded Access Program for Cretostimogene Grenadenorepvec.** In June, the Company announced that it has initiated an expanded access program (EAP) for cretostimogene grenadenorepvec in the U.S. for patients with NMIBC who are unresponsive to BCG and meet certain program eligibility criteria. The first patient has been dosed in the EAP and enrollment in the study is ongoing.

Anticipated Next Milestones

- BOND-003 (BCG-Unresponsive, HR-NMIBC): Primary results from the Phase 3 clinical trial of cretostimogene monotherapy by the end of 2024.

Second Quarter 2024 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of June 30, 2024, were $552.9 million, compared with $566.5 million as of March 31, 2024. Based on cash, cash equivalents and marketable securities as of June 30, 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 second quarter ended June 30, 2024 were $18.5 million compared

with $9.8 million for the second quarter ended June 30, 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 second quarter ended June 30, 2024 were $7.5 million compared with $2.5 million for the second quarter ended June 30, 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 $18.9 million, or ($0.28) per share, for the second quarter ended June 30, 2024, compared to $11.6 million, or ($3.93) per share, for the second quarter ended June 30, 2023.

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy being evaluated in BOND-003, a Phase 3 clinical trial for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) therapy. Cretostimogene is also being evaluated in a Phase 3 monotherapy clinical trial (PIVOT-006) in intermediate-risk NMIBC patients. In addition, cretostimogene is being evaluated in an investigator-sponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer. Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

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 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 Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K and other filings that we make with the SEC from time to time (which are available at http://www.sec.gov). 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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