CG Oncology Reports First Quarter 2025 Financial Results and Provides Business Updates

May 13, 2025

- Updated BOND-003 clinical results presented at AUA showing best-in-disease durability and tolerability data for Cohort C with 24-month complete response rate of 42.3% by K-M -
- Promising early signal in Cohort P with 90.5% high-grade recurrence free survival at 3 and 9 months by K-M -
- New enrollment completion date for Phase 3 PIVOT-006 in intermediate-risk non-muscle invasive bladder cancer (NMIBC) expected in the second half of 2025 -
- Initiated CORE-008 Cohort CX evaluating the combination of cretostimogene and gemcitabine in patients with high-risk (HR) BCG-exposed NMIBC -

IRVINE, Calif., May 13, 2025 (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, 2025, and provided business updates.

“In 2025, we made further progress advancing cretostimogene monotherapy as a bladder-sparing backbone therapy for patients with NMIBC,” said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology. “With best-in-disease durability and tolerability data from the BOND-003 Cohort C registrational trial recently presented at AUA, we are well positioned to initiate our BLA submission in the second half of the year for the treatment of patients with HR NMIBC unresponsive to BCG. Our clinical programs have been carefully designed to address different stages of bladder cancer and tumor types. If approved, I’m confident that cretostimogene is well positioned to become backbone therapy in NMIBC, potentially addressing more than 70% of the market opportunity in need of a new and innovative therapy.”

Corporate Highlights

- **Presented Best-in-Disease Durability and Tolerability Data in BOND-003 Cohort C and Promising Early Signal in Cohort P for Cretostimogene at a Plenary Session at the American Urological Association (AUA) Annual Meeting.** On April 26th at the AUA Annual Meeting, the Company presented best-in-disease durability and tolerability data from Cohort C of the Phase 3 BOND-003 clinical trial that showed a 75.5% complete response (CR) at any time, with 34 confirmed CRs at 24 months and 9 patients pending their 24-month assessment as of the cutoff date of March 14, 2025. The 12- and 24-month CR rates are 50.7% and 42.3% by K-M estimation respectively. Median duration of response is 28 months and is ongoing. Notably, 97.3% of patients were free from progression to muscle invasive disease at 24 months. Additionally, Cohort P, which is in patients with BCG-unresponsive Ta/T1 papillary disease without carcinoma in situ (CIS), showed an estimated 90.5% high-grade recurrence-free survival at 3 and 9 months in 24 treated patients.
- **Initiated CORE-008 Cohort CX clinical trial of cretostimogene + gemcitabine in HR BCG-exposed NMIBC.** In April, the Company initiated CORE-008 Cohort CX evaluating the combination of cretostimogene and gemcitabine, given either concurrently or sequentially, in patients with HR BCG-exposed NMIBC, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease.

Anticipated Next Milestones in the Second Half of 2025

- Initiation of BLA submission for cretostimogene monotherapy in HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease
- PIVOT-006 (intermediate-risk NMIBC): Phase 3 enrollment completion
- BOND-003 Cohort P (HR BCG-unresponsive NMIBC in Ta/T1 disease without CIS): Topline data from the Phase 3 clinical trial of cretostimogene monotherapy
- CORE-008 Cohort A (HR BCG-naïve NMIBC with CIS +/- Ta/T1): Topline data from the Phase 2 clinical trial of cretostimogene monotherapy

First Quarter 2025 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of March 31, 2025,

were $688.4 million, compared with $742.0 million as of December 31, 2024. Based on current operating plans, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations into the first half of 2028.

- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter ended March 31, 2025 were $27.5 million compared with $17.2 million for the first quarter ended March 31, 2024. The increase was primarily due to an increase in clinical trial expenses, including CMC costs, and an increase in compensation costs due to increased headcount.
- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter ended March 31, 2025 were $14.8 million compared with $5.8 million for the first quarter ended March 31, 2024. The increase was primarily attributed to an increase in personnel-related expenses, including compensation costs from increased headcount, an increase in professional and consultant fees related to legal, accounting and consulting fees, and an increase in marketing-related costs.
- **Net Loss**: Net loss was $34.5 million, or ($0.45) per share, for the first quarter ended March 31, 2025, compared to $16.9 million, or ($0.36) per share, for the first quarter ended March 31, 2024.

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 400 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for high-risk BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk NMIBC. CG Oncology also has a Phase 2 trial, CORE-008, evaluating the safety and efficacy of cretostimogene in high-risk NMIBC. Additionally, we have initiated an Expanded Access Program for cretostimogene in North America for patients who are unresponsive to BCG and meet certain program eligibility requirements. Cretostimogene is an investigational 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; the timing and likelihood of regulatory filings and approvals for cretostimogene; the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients; and that cretostimogene has best-in-disease durability and tolerability data. 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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CG ONCOLOGY, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 41,472	$ 257,068
Marketable securities	646,962	484,930
Prepaid expenses and other current assets	12,413	11,431
Accounts receivable - other	345	781
Total current assets	701,192	754,210
Property and equipment, net	264	272
Note receivable, net	25,176	-
Operating lease right-of-use assets	1,033	221
Other assets	516	94
Total assets	$ 728,181	$ 754,797
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,731	$ 6,517
Operating lease liabilities, current portion	255	186
Accrued expenses and other current liabilities	15,656	14,665
Total current liabilities	22,642	21,368
Operating lease liabilities, net of current portion	781	52
Total liabilities	23,423	21,420
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.0001 par value per share; 700,000,000 and 700,000,000 shares authorized as of March 31, 2025 and December 31, 2024, respectively; 76,221,289 and 76,154,783 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	8	8
Additional paid-in capital	957,183	951,350
Accumulated deficit	(252,433)	(217,981)
Total stockholders' equity	704,758	733,377
Total liabilities and stockholders' equity	$ 728,181	$ 754,797

CG ONCOLOGY, INC.

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

	Three Months Ended March 31,	
	2025	2024
Revenues		
License and collaboration revenue	$ 52	$ 529
Operating expenses		
Research and development	27,467	17,210
General and administrative	14,789	5,788
Total operating expenses	42,256	22,998
Loss from operations	(42,204)	(22,469)
Other income (expense), net:		
Interest income, net	7,747	5,544
Other income (expense), net	5	(9)
Total other income, net	7,752	5,535
Net loss and comprehensive loss	$ (34,452)	$ (16,934)
Net loss per share, basic and diluted	$ (0.45)	$ (0.36)
Weighted average shares of common stock outstanding, basic and diluted	76,187,621	47,064,768