CG Oncology Announces Best-in-Disease Durability Data in BOND-003 Cohort C and Promising Early Signal in Cohort P for Cretostimogene Grenadenorepvec at the American Urological Association Annual Meeting

Apr 26, 2025

- Robust 24-month complete response rate of 42.3% by K-M for cretostimogene monotherapy in BOND-003 Cohort C –

- 58.3% of patients showed durable complete responses by K-M at 24 months –

- 97.3% of all treated patients remained free from progression to MIBC at 24 months–

- 91.6% of responders remained cystectomy-free at 24 months –

- No Grade 3 or greater treatment-related adverse events or deaths reported –

- Strong initial Cohort P data reported 90.5% high-grade recurrence-free survival at 3 and 9 months by K-M –

- Company will host a conference call and webcast at 8 a.m. EDT on Monday, April 28, 2025 -

IRVINE, Calif., April 26, 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 announced that cretostimogene grenadenorepvec monotherapy data was presented at the Practice-Changing, Paradigm-Shifting Clinical Trials in Urology Plenary Session at the 2025 American Urological Association (AUA) Annual Meeting, in Las Vegas, Nevada.

The Phase 3 BOND-003 Cohort C study is in patients with high-risk non-muscle invasive bladder cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG) treatment with carcinoma in situ (CIS) with or without Ta or T1 disease. The study reported 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 (DOR) is 28 months and is ongoing. Notably, 97.3% of patients were free from progression to muscle invasive disease at 24 months.

BOND-003 Cohort C	CR Rate, % (95% CI)	CR by K-M estimate, % (95% CI)	DOR by K-M estimate, % (95% CI)
12-month	46.4% (36.9, 56.1)[1]	50.7% (40.9, 59.8)	64.1% (52.4, 73.7)
24-month	33.7% (24.8, 43.8)[2]	42.3% (32.7, 51.6)	58.3% (46.3, 68.5)

[1] *CR rate observed in 51 out of 110 patients*

[2] *CR rate observed in 34 out of 101 evaluable patients, pending 9 ongoing CRs yet to reach 24-month assessment*

Additionally, Cohort P, which is in patients with BCG-unresponsive Ta/T1 disease without CIS, showed an estimated 90.5% (95% CI: 77.9, 100.0) high-grade recurrence-free survival at 3 and 9 months in 24 treated patients. A well-tolerated safety profile was observed, consistent with the data in Cohort C.

“We continue to see strong safety and efficacy, as well as best-in-disease durability and tolerability, with cretostimogene at the 24-month mark, in a high-risk, heavily pretreated NMIBC patient population,” said Gary D. Steinberg, M.D., Professor, Department of Urology at Rush University Medical Center. “Now, we have Cohort P data demonstrating cretostimogene also has activity and efficacy in BCG-unresponsive patients with Ta/T1 lesions. This body of evidence demonstrates the power of cretostimogene’s unique dual mechanism of action, its potential to treat different tumor types across high-risk NMIBC, positioning it as a potential breakthrough, backbone therapy in bladder cancer treatment.”

A total of 110 highly pretreated patients are efficacy evaluable in the BOND-003 Cohort C study, which makes it the largest study in this patient population to date. These patients received a median of 12 prior BCG doses, some as high as 66. Prior intervening therapy also included intravesical chemotherapy (41.1%) and systemic immunotherapy (6.3%). Despite their highly pretreated conditions, patients tolerated cretostimogene treatment well. There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. Patients who experienced TRAEs of any grade had a median resolution time of one day. No treatment-related discontinuation of cretostimogene was observed. 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria.

“The compelling efficacy, durability, freedom from progression to muscle-invasive disease, and tolerability of cretostimogene offer potential, distinct advantages over existing therapies for the treatment of high-risk BCG-unresponsive NMIBC,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “Ongoing investigations of this promising monotherapy, as well as future combinations, have the potential to address a considerable unmet need for bladder cancer patients. This suggests that, if approved, cretostimogene will represent an important advancement for people suffering with bladder cancer, and we are working diligently to bring it forward to patients.”

Investor Conference Call

CG Oncology will host a conference call and webcast at 8 a.m. EDT on Monday, April 28, 2025. Individuals can access the webcast via the link on the company's Investor Relations website https://ir.cgoncology.com. An archive will be available following the completion of the call.

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, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, its potential to have best-in-disease durability and tolerability, and that cretostimogene offers distinct advantages over existing therapies for the treatment of HR BCG-UR NMIBC. 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: additional patient data related to cretostimogene that continues to become available may be inconsistent with the data produced as of the data cutoff, and further analysis of existing data and analysis of new data may lead to conclusions different from those established as of the date hereof; 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; potential delays in the commencement, enrollment and completion of clinical trials; competitive developments with respect to current and other investigational NMIBC treatments may adversely affect the commercial opportunity of cretostimogene; 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.

Contacts:
Media
Sarah Connors
Vice President, Communications and Patient Advocacy, CG Oncology
(508) 654-2277
sarah.connors@cgoncology.com

Investor Relations
Chau Cheng
Vice President, Investor Relations, CG Oncology
(949) 342-8939
chau.cheng@cgoncology.com