CG Oncology Continues to Demonstrate Best-in-Disease Durability and Tolerability in BOND-003 Cohort C; Additional 12 Patients in Complete Response at 24 Months

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- Robust 24-month complete response (CR) rate of 41.8% observed for cretostimogene monotherapy in patients with high-risk non-muscle invasive bladder cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) treatment -
- 90% of 12-month responders remained disease free at 24 Months -
- Safety profile remains consistent -

IRVINE, Calif., Sept. 05, 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 updated data on BOND-003 Cohort C showing 12 additional patients with high risk non-muscle invasive bladder cancer (HR NMIBC) were in complete response (CR) at 24 months. The robust 24-month complete response landmark rate of 41.8% (CR rate observed in 46 out of 110 patients) for cretostimogene monotherapy reaffirms the best-in-disease durability that the Company announced at the American Urological Association Annual Meeting in April 2025. Cretostimogene's safety profile also remains consistent with no grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. Trinity J. Bivalacqua, MD, PhD, Urologic Oncology at Penn Medicine, and Co-Director, Genitourinary Cancer Service Line, Abramson Cancer Center, will present these updated data tomorrow, September 6, 2025, at the New England Section of the American Urological Association's 94th annual meeting in Boston, Massachusetts.

"Based on the latest data cut, I remain very encouraged that if approved, cretostimogene will represent an important, bladder-sparing advancement in the management of high risk non-muscle invasive bladder cancer in patients who have disease that is unresponsive to BCG," said Trinity J. Bivalacqua, MD, PhD. "In my clinical experience, bladder cancer patients are seeking treatment options that offer durable and sustained results. The latest data from the BOND-003 Cohort C study demonstrates that if a patient is a responder at 12 months, there is a 90 percent chance they will remain in response at 24 months. This is unprecedented in the high-risk, heavily pretreated NMIBC patient population and very meaningful for those battling this difficult disease."

"The data from our Phase 3 BOND-003 Cohort C registrational trial underscores cretostimogene's potential to become a breakthrough backbone treatment for bladder cancer patients," said Ambaw Bellete, President & Chief Operating Officer at CG Oncology. "We are eager to bring this innovative treatment to a broad range of NMIBC patients, and we are making great strides towards that goal as we prepare to initiate our BLA submission for cretostimogene in our initial indication for the treatment of patients with HR NMIBC unresponsive to BCG in the fourth quarter of this year."

The Phase 3 BOND-003 Cohort C study is in patients with high-risk 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% CR at any time and 41.8% at 24 months with 46 confirmed CRs as of the cutoff date of June 23, 2025. The estimated 12- and 24-month duration of response (DOR) rates are 64.1% and 58.3%, respectively. Median DOR is 28 months and is ongoing. Notably, 96.6% of patients were free from progression to muscle invasive disease at 24 months.

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 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, and 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.

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, as supplemented in Part II, Item 1A, "Risk Factors" of our quarterly report on

Form 10-Q for the quarter ended June 30, 2025, 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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