CG Oncology Reports Positive First Results from CORE-008 Cohort CX Phase 2 Trial Evaluating Intravesical Combination Therapy in High-Risk BCG-Exposed and BCG-Unresponsive Patients

May 15, 2026

- High CR rates at any time observed in the CIS-containing population with 85.7% and 92.3% in the ITT population and Efficacy Evaluable population, respectively

- High-Grade - EFS in the overall intention-to-treat population was 96.0% at 3 months and 89.5% at 6 months

- Efficacy was comparable across concurrent and sequential treatment arms and across both BCG-exposed and BCG-Unresponsive populations

DALLAS, May 15, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced positive first results from CORE-008 Cohort CX, a Phase 2 study evaluating intravesical cretostimogene grenadenorepvec in combination with gemcitabine sequential versus concurrent treatment schedules in patients with high-risk (HR) non-muscle invasive bladder cancer (NMIBC). This trial includes HR NMIBC patients who are either BCG-exposed or BCG-unresponsive. The data, which demonstrate encouraging high-grade event-free survival (HG-EFS), high complete response (CR) rates and a well-tolerated safety profile, will be presented tomorrow at the Society of Urologic Oncology (SUO) Session at the 2026 American Urological Association (AUA) Annual Meeting in Washington, D.C.

“Cohort CX was designed to assess whether combining cretostimogene with gemcitabine can further extend the strong clinical profile we have established with cretostimogene monotherapy,” said Vijay Kasturi, Chief Medical Officer of CG Oncology. “As the first prospective intravesical-only combination study of its kind, these early data demonstrate robust clinical activity across both treatment schedules, a favorable safety profile, and comparable efficacy. Importantly, the results reinforce the strategic potential of scalable intravesical-only combination regimens in high-risk NMIBC. We look forward to sharing durability data later this year.”

Efficacy and Safety Analysis: As of the March 13, 2026, data cut off, the overall HG-EFS was 96.0% at 3 months and 89.5% at 6 months, with a median follow-up of 6.6 months, in the overall intent-to-treat (ITT) population. There were no statistically significant differences in HG-EFS across concurrent and sequential treatment arms. High complete response (CR) rates at any time were observed in the CIS-containing population with 85.7% (24/28) (95% CI, 67.3% – 96.0%) and 92.3% (24/26) (95% CI, 74.9% - 99.1%) in the ITT and Efficacy Evaluable population, respectively. Furthermore, complete response rates were maintained across the treatment arms. A favorable safety and tolerability profile was observed with no Grade 3 or greater treatment-related adverse events (TRAEs) and no deaths reported. The majority of patients were male (78.2%), white (92.7%), and over 65 years of age (81.8%), with the cohort well-balanced across concurrent and sequential treatment arms. Out of the overall population, 65.6% of patients were BCG-exposed and 34.5% were BCG-unresponsive. More than 80% of patients were treated in community practices.

“In Cohort CX, we observed consistent responses to the combination of cretostimogene and gemcitabine across both BCG-exposed and BCG-unresponsive populations,” said Trinity Bivalacqua, M.D., Ph.D., Professor of Urology at the University of Pennsylvania and lead investigator of CORE-008 Cohort CX. “These findings highlight the feasibility and encouraging clinical profile of this intravesical oncolytic immunotherapy combined with chemotherapy as a bladder-sparing approach that can be readily adopted in everyday practice. At a time when urologists face ongoing therapeutic constraints and supply challenges, expanding the intravesical treatment armamentarium has the potential to meaningfully improve care for patients across a wide range of NMIBC disease states.”

About CORE-008
CORE-008 is a randomized, Phase 2, multi-arm, multi-cohort clinical trial designed to evaluate the efficacy and safety of cretostimogene grenadenorepvec in a broad population of patients with high-risk non-muscle invasive bladder cancer (HR NMIBC), including BCG-naïve, BCG-exposed, and BCG-unresponsive disease. Cohort CX of CORE-008 evaluates the combination of intravesical cretostimogene with gemcitabine in patients with BCG-exposed or BCG-unresponsive HR NMIBC. The primary endpoint of Cohort CX is high-grade event-free survival, defined as high-grade recurrence or persistence, progression to T1 disease, progression to T2 or higher disease, or death from any cause.

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 NMIBC patients, the strategic potential of combining cretostimogene with gemcitabine in high-risk NMIBC, that the combination of cretostimogene with gemcitabine will have robust clinical activity and a favorable safety profile, and that the combination of cretostimogene with gemcitabine will have the potential to meaningfully improve care for patients. 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, PIVOT-006, and CORE-008 cohort CX 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.

Contacts:

Media
Sarah Connors
Vice President, Communications and Patient Advocacy, CG Oncology
sarah.connors@cgoncology.com

Investor Relations
Megan Knight
Vice President, Investor Relations, CG Oncology
megan.knight@cgoncology.com