CG Oncology Announces Publication of Pivotal Phase 3 BOND-003 Cohort C Study Results in The Lancet Oncology

Jul 27, 2026

Data reinforce durable responses, bladder preservation, low rate of disease progression, and favorable safety and tolerability in patients with high-risk, BCG-unresponsive non-muscle invasive bladder cancer

DALLAS, July 27, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced the publication of results from the pivotal Phase 3 BOND-003 Cohort C trial evaluating cretostimogene grenadenorepvec monotherapy in patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without Ta/T1 disease, in *The Lancet Oncology.*

"Patients with BCG-unresponsive NMIBC often face the difficult decision between pursuing additional bladder-sparing therapies or undergoing a severe, life-altering cystectomy," said Mark D. Tyson II, M.D., M.P.H., Mayo Clinic, and lead author of the publication. "The results from BOND-003 represent a potential shift in this treatment paradigm, underpinned by encouraging durability of response and bladder preservation outcomes. With a clinically meaningful median duration of response of 27.9 months, possibly among the longer duration of responses seen in this setting, paired with approximately 89% of patients maintaining their bladders at 12 months and 81% at 24 months, we are seeing evidence of sustained bladder preservation without compromising the window for further therapeutic options, if needed."

Dr. Tyson continued, "These results are particularly encouraging given BOND-003 enrolled a heavily pretreated population representative of the patients that clinicians often encounter in real-world practice. Specifically, we observed meaningful responses in patients who had already received other therapies, including intravesical gemcitabine–docetaxel or systemic pembrolizumab, underscoring cretostimogene's activity across a clinically diverse and difficult-to-treat patient population. If approved by the FDA, cretostimogene may represent an important, bladder-sparing, advancement in the bladder cancer treatment paradigm, and meaningfully improve patient outcomes."

BOND-003 Cohort C met its primary endpoint with statistical significance, exceeding historic and contemporary clinical benchmarks. Key findings and observations reported in the publication include:

- **Robust complete response (CR) rates and durable responses in patients with high-risk BCG-unresponsive NMIBC:**
  - 75.5% (95% CI 66.3–83.2) achieved a CR at any time, after receiving treatment with cretostimogene as monotherapy.
  - 12- and 24-month duration of response (DOR) was 64.2% (95% CI 52.2–73.8) and 60.1% (95% CI 48.2–70.0), respectively.
  - Median DOR is at least 27.9 months and is ongoing, with approximately 90% of patients in response at 12 months maintaining durable responses at 24 months, and one patient disease-free beyond 51 months.
- **Favorable safety and tolerability profile:** No Grade 3 or greater treatment-related adverse events or treatment-related discontinuations or deaths reported. The median time to resolution of related adverse events was 1 day (IQR 0–7). The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria.
- **Clinically meaningful progression-free survival:** 96.6% of patients were free from progression to muscle invasive bladder cancer at 48 weeks and 96 weeks.
- **Practical, office-based administration:** Cretostimogene does not require prophylactic medication (e.g., anticholinergics), operating room time, additional cystoscopy, or anesthesia-dosing and aligns with existing AUA/SUNA intravesical administration policy, supporting ease of integration into both academic and community urology practice settings.

"The publication of the BOND-003 Cohort C results in *The Lancet Oncology* represents an important milestone for CG Oncology and validates the strength of the clinical evidence supporting cretostimogene," said Vijay Kasturi, M.D., Chief Medical Officer of CG Oncology. "The BOND-003 Cohort C data demonstrate cretostimogene's favorable efficacy and best-in-disease durability. Importantly, we also observed a very low rate of progression to muscle-invasive bladder cancer, with only 3.4% of patients progressing during the study. These data underscore cretostimogene's potential to become a foundational monotherapy for NMIBC and support our ongoing effort to explore its role across multiple disease settings, including adjuvant and combination approaches, aimed at addressing the needs of broader bladder cancer patient populations."

The full manuscript, titled "Intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive, non-muscle

invasive bladder cancer with carcinoma in situ (BOND-003 Cohort C): a single-arm, phase 3 trial", is available here: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(26)00194-4/abstract

About the BOND-003 Phase 3 Trial
BOND-003 (NCT04452591) is a single-arm, Phase 3, monotherapy clinical trial for the treatment of patients with high-risk BCG-unresponsive NMIBC with carcinoma in-situ (CIS) with or without Ta or T1 papillary tumors. The fully enrolled global trial with a total of 112 in North America, Australia, and the Asia-Pacific region. The primary endpoint of the trial is CR at any time, with DOR measured as a secondary endpoint. The highly pre-treated trial population includes patients with prior intravesical chemotherapy and systemic immunotherapy.

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. Cretostimogene has received FDA Fast Track and Breakthrough Therapy designations. 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, its potential to have best-in-disease durability and tolerability, cretostimogene's potential to become a foundational therapy for NMIBC, that cretostimogene may represent an important, bladder-sparing, advancement in bladder cancer treatment, that cretostimogene may meaningfully improve patient outcomes, and that cretostimogene offers distinct advantages over existing therapies for the treatment of high-risk, BCG-unresponsive 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: 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.

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