CG Oncology to Present New Data on Cretostimogene Grenadenorepvec at the Society of Urologic Oncology 27th Annual Meeting

Nov 25, 2026

- Late-breaking podium presentations of Phase 3 PIVOT-006 and CORE-008 Cohort CX data, in addition to a BOND-003 Cohort P poster, further support cretostimogene's potential as a backbone therapy across a broad range of NMIBC patients

- Late Breaking presentation of Phase 3 PIVOT-006 results will include recurrence-free survival at 12 months, analyses by stratification factors, and safety data

DALLAS, Nov. 25, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced that new data from its cretostimogene grenadenorepvec clinical development program will be presented at the Society of Urologic Oncology 27th Annual Meeting, taking place December 1-4, 2026, in San Diego, California.

The presentations will include two late-breaking podium presentations featuring results from PIVOT-006, the Phase 3 randomized controlled trial evaluating adjuvant intravesical cretostimogene in patients with intermediate-risk and high-grade Ta ≤3 cm non-muscle invasive bladder cancer (NMIBC), and CORE-008 Cohort CX evaluating cretostimogene in combination with gemcitabine in patients with BCG-unresponsive or high-risk, BCG-exposed NMIBC. The PIVOT-006 presentation will build upon previously announced topline results demonstrating a 68% reduction in the risk of recurrence (HR=0.32; 95% CI: 0.23, 0.45; p<0.0001), with analyses of recurrence-free survival (RFS) at 12 months and RFS by the stratification factors which include tumor grade (low-grade and high-grade) and single dose post-operative chemotherapy. Updated 12-month results from BOND-003 Cohort P in patients with high-risk, BCG-unresponsive papillary-only NMIBC will also be presented in a poster.

"The data being presented at SUO reflect the breadth of our clinical development program and our ambition to establish cretostimogene as a potential backbone therapy across the NMIBC disease spectrum. Building on our recent announcement that PIVOT-006 demonstrated a significant recurrence benefit in intermediate-risk NMIBC, we look forward to sharing a more detailed analysis of these pivotal Phase 3 results at SUO. Together with updated findings from BOND-003 and CORE-008, these presentations underscore our commitment to advancing bladder-sparing therapies that may meaningfully improve outcomes for patients," said Arthur Kuan, Chairman, President and Chief Executive Officer of CG Oncology.

Details of the late-breaking presentation and posters are as follows:

Late-Breaking Podium Presentations

- ***Title:*** *Topline Results From PIVOT-006: A Phase 3, Randomized Controlled Study of Adjuvant Intravesical Cretostimogene Grenadenorepvec Versus Surveillance for Intermediate-Risk Non-Muscle Invasive Bladder Cancer*
  Presenter: Max Kates, M.D., Professor of Urology and Oncology and Director of the Bladder Cancer Multidisciplinary Clinic at the Johns Hopkins Brady Urological Institute
  Session: State of the Art Session III - Stop the Presses: Late-Breaking Abstracts in Urologic Oncology.
  Date & Time: December 2, 2026, from 4:16-4:23 p.m. PT. The late-breaking session is scheduled for 4:00-5:00 p.m. PT on December 2, 2026.

- ***Title:*** *Sustained One-Year Responses With Intravesical Cretostimogene Grenadenorepvec With Gemcitabine in High-Risk BCG-Exposed or BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (CORE-008 Cohort Cx)*
  Presenter: Trinity J. Bivalacqua, M.D., Ph.D.
  Session: Late-Breaking Abstracts Bladder Cancer Session II: Saving the Bladder in High-Risk NMIBC
  Date & Time: December 4, 2026, from 3:45-3:50 p.m. PT

Poster Presentation

- **Title:** *Updated Results From BOND-003 Cohort P: A Multi-National, Single-Arm Study of Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk BCG-Unresponsive NMIBC With High-Grade Ta/T1 Without CIS*
  Presenter: Mark D. Tyson, M.D., Urologic Oncologist at Mayo Clinic, Scottsdale, AZ
  Poster Number: 323

Date & Time: December 4, 2026, from 1:15-2:15 p.m. PT

The SUO meeting will take place at the Hilton San Diego Bayfront. To view the full SUO program schedule you may visit: https://suonet.org/events/annual-meeting/program-schedule

About PIVOT-006 Phase 3 Clinical Trial
PIVOT-006 is one of the largest randomized registrational Phase 3 studies conducted in intermediate-risk NMIBC, and enrolled 367 patients across ~90 sites in the United States and Canada. Enrolled patients had the broadest range of disease characteristics specified in AUA/SUO guidelines at the time of study start including recurrent low-grade (LG) Ta < 12mo, solitary LG Ta > 3cm, LG Ta multifocal, solitary HG Ta ≤ 3cm and LG T1. The study compares adjuvant intravesical cretostimogene grenadenorepvec versus surveillance following complete tumor resection, reflecting real-world clinical practice in this patient population.

About BOND-003 Cohort P
BOND-003 is a Phase 3, single-arm clinical trial evaluating intravesical cretostimogene grenadenorepvec in patients with high-risk BCG-unresponsive NMIBC. Cohort P is evaluating cretostimogene in patients with high-grade Ta/T1 papillary-only disease without carcinoma in situ (CIS). The study is assessing the efficacy and safety of cretostimogene in this patient population, including the durability of disease control and its potential to help patients avoid radical cystectomy.

About CORE-008 Cohort CX
CORE-008 is a multi-cohort clinical trial evaluating the safety and efficacy of cretostimogene grenadenorepvec in patients with high-risk NMIBC across different disease settings and treatment combinations. Cohort CX is evaluating intravesical cretostimogene in combination with gemcitabine in patients with high-risk BCG-exposed or BCG-unresponsive NMIBC. The cohort is designed to assess the safety and efficacy of the combination, including the durability of response.

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 700 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk and high-grade Ta ≤ 3cm NMIBC. Cretostimogene has received FDA Fast Track and Breakthrough Therapy designations for BCG-unresponsive NMIBC. CG Oncology also has a multi-cohort trial, CORE-008, evaluating the safety and efficacy of cretostimogene in BCG-exposed high-risk, BCG-naïve high-risk, and BCG-unresponsive NMIBC. Additionally, we have 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 the anticipated presentation of clinical data from PIVOT-006, BOND-003 and CORE-008; and the potential safety, efficacy and therapeutic benefits of cretostimogene, including its potential as a backbone therapy across the NMIBC disease spectrum. 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: topline data is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA may not agree with our interpretation of such results; potential delays in the commencement, enrollment and completion of clinical trials; potential delays in the preparation, submission, acceptance, completion or review of our current and planned BLAs; the risk that regulatory authorities may require additional data or studies, may not approve cretostimogene, or may grant a narrower indication or label than anticipated; uncertainties regarding the timing and scope of any commercial launch and our ability to achieve anticipated patient access, market acceptance and therapeutic benefits; the risk that the target patient population size may be smaller than initially anticipated; 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 most recent annual report on Form 10-K and other filings that we make with the SEC from time to time. 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