PIVOT-006 Phase 3 Registrational Trial Demonstrates Unprecedented Improvement in Recurrence-Free Survival (RFS) for Intermediate-Risk and High-Grade Ta Non-Muscle Invasive Bladder Cancer (NMIBC)

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– Cretostimogene reduced the risk of recurrence by 68%, demonstrating a statistically significant and clinically meaningful benefit with a hazard ratio of 0.32 (95% CI: 0.23, 0.45; p<0.0001)

– Compelling safety and tolerability results, no Grade 3 or higher TRAEs and no treatment-related discontinuations

– PIVOT-006 topline results to be presented as a late-breaking podium presentation at the Society of Urologic Oncology Annual Meeting on December 2, 2026

– PIVOT-006 data will support a second BLA submission in intermediate-risk and high-grade Ta NMIBC anticipated in Q2 2027

– Based on FDA feedback, initial BLA submission in BCG-unresponsive NMIBC to be broadened to include both CIS and high-grade papillary-only disease; completion anticipated in March 2027

DALLAS, Nov. 16, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced positive topline results from PIVOT-006, its Phase 3 registrational trial evaluating adjuvant intravesical cretostimogene grenadenorepvec in patients with intermediate-risk and high-grade Ta ≤3 cm NMIBC, following complete tumor resection. There are currently no U.S. FDA approved adjuvant treatment options in this population of approximately 50,000 patients. Together with the Company's data in high-risk BCG-unresponsive NMIBC, the PIVOT-006 results have the potential to significantly broaden the patient populations that could benefit from cretostimogene if approved.

PIVOT-006 achieved its primary endpoint, demonstrating statistically significant and clinically meaningful improvements versus the control arm. Cretostimogene resulted in a 68% reduction in the risk of recurrence compared with the control arm, with a hazard ratio of 0.32 (95% CI: 0.23, 0.45; p<0.0001). The median follow-up was 17 months as of October 26, 2026. Cretostimogene was generally well tolerated, with safety results consistent with those reported in previous studies. There were no Grade 3 or greater treatment-related adverse events (TRAEs), and no treatment-related discontinuations.

"The unparalleled PIVOT-006 results represent a defining milestone for CG Oncology and position cretostimogene as the first and only therapeutic candidate to demonstrate a significant recurrence benefit in a pivotal Phase 3 trial in intermediate-risk and HG Ta NMIBC. We are working expeditiously to complete our BLA filing in intermediate-risk and HG Ta NMIBC in the second quarter of 2027," said Arthur Kuan, Chairman, President and Chief Executive Officer of CG Oncology. "Based on FDA feedback, we plan to broaden our initial BLA submission in BCG-unresponsive NMIBC, which was focused on patients with CIS with or without papillary tumors, to also include patients with high-grade papillary-only disease. Together, these populations represent the full range of BCG-unresponsive patients, and our goal is a label that reflects that. To incorporate the additional data, we now expect to complete the submission before the end of March 2027. All BLA-enabling manufacturing activities supporting both regulatory filings have been completed. Ultimately, this strategy reflects our commitment to meaningfully improve the lives of as many bladder cancer patients as possible."

"Today's results highlight our differentiated clinical approach, aimed at exploring cretostimogene across the broad NMIBC spectrum and build upon our robust body of clinical evidence including what we believe to be the best-in-disease safety and tolerability data reported," said Vijay Kasturi, M.D., Chief Medical Officer of CG Oncology. "For patients with intermediate-risk and high-grade Ta NMIBC, reducing recurrence is a meaningful clinical objective because recurrence can bring additional invasive procedures and continued disease burden. The significant improvement in recurrence-free survival observed in PIVOT-006 across both high-grade and low-grade patients underscores the promise of cretostimogene as an important potential new treatment option following tumor resection. These data give us the opportunity to change clinical practice and help more people remain cancer-free longer while reducing the burden of their disease."

About PIVOT-006 Phase 3 Clinical Trial
PIVOT-006 is one of the largest randomized 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 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 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 significant improvement in recurrence-free survival observed in the PIVOT-006 registrational trial, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, the planned timelines of our BLA submissions and their respective indications, our goal of securing the broadest possible label and including the totality of the BCG-unresponsive population at launch, cretostimogene's potential as a backbone immunotherapy across the NMIBC spectrum, the potential of PIVOT-006 results to change clinical practice and broaden the patient populations that could benefit from cretostimogene, and the expected patient population size that could benefit from cretostimogene, if approved. 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.

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