CG Oncology Provides Updated Timeline for PIVOT-006 Phase 3 Topline Data in Intermediate-Risk NMIBC

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- PIVOT-006 Phase 3 topline data evaluating cretostimogene monotherapy for intermediate-risk NMIBC now expected in 1H 2026, nearly one year ahead of schedule

- First randomized registrational trial to evaluate an investigational therapy in intermediate-risk NMIBC

IRVINE, Calif., Jan. 09, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced an expedited timeline for the topline data readout now expected in the first half of 2026 for the Phase 3 PIVOT-006 clinical trial comparing adjuvant intravesical cretostimogene grenadenorepvec versus surveillance in patients with intermediate-risk non-muscle invasive bladder cancer (IR NMIBC). PIVOT-006 is the first Phase 3 randomized trial in this patient population, encompassing the broadest range of patient types per AUA/SUO Guidelines including HG Ta solitary lesions < 3cm.

"We are thrilled to announce that we now expect PIVOT-006 topline Phase 3 data in the first half of 2026, which is nearly one year ahead of schedule thanks to the unprecedented early completion of enrollment. Our goal is to bring forward a potential indication in adjuvant IR NMIBC, for which there are currently no U.S. FDA approved options. Broad participation across academic and community sites supports the real-world relevance of this trial, and the rapid enrollment underscores the immense unmet need that exists for intermediate-risk NMIBC patients," said Arthur Kuan, Chairman & Chief Executive Officer, CG Oncology. "The IR population is estimated to be greater than fifty thousand patients in the US alone, and we look forward to broadening our potential reach to individuals living with IR NMIBC."

PIVOT-006 Topline Data Expected in 1H 2026
CG Oncology now plans to share topline data from the Phase 3, randomized, open-label PIVOT-006 registrational study in the first half of 2026. This expedited timeline is due to the rapid study enrollment across over 90 sites. The PIVOT-006 study compares adjuvant intravesical cretostimogene grenadenorepvec versus surveillance following bladder tumor removal in more than 360 patients with intermediate-risk non-muscle invasive bladder cancer (IR NMIBC). PIVOT-006 is the first Phase 3 randomized trial in this patient population, encompassing the broadest range of patient types per AUA/SUO Guidelines including HG Ta solitary lesions < 3cm.

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 anticipated timeline of topline data of the PIVOT-006 study, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, cretostimogene's potential as a backbone immunotherapy across the NMIBC spectrum, the IR patient population is estimated to be greater than fifty thousand patients in the United States, and that we may broaden our potential market reach to patient living with IR 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 and PIVOT-006 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, as supplemented by "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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