Groundbreaking Cretostimogene Grenadenorepvec Monotherapy Data Demonstrates Sustained, Durable Complete Responses in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

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– 74.5% of patients achieved a complete response at any time –

– Median duration of response is greater than 27 months and not reached –

– Latest data update continued to show favorable safety and tolerability results –

– Company hosting virtual investor event with lead investigator at 8 am EST today –

IRVINE, Calif., Dec. 05, 2024 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON), a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients with bladder cancer, today announced topline data from the Phase 3 BOND-003 trial in patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG) demonstrating 74.5% of patients (82 out of 110, 95% CI, 65.4% - 82.4%) achieved a complete response (CR) at any time, after receiving treatment with cretostimogene as a single agent. The median duration of response (DOR) has not been reached but exceeds 27 months as of the data cutoff of September 30, 2024. These data will be presented today as a Late-Breaking Abstract at the Society of Urologic Oncology (SUO) 25th Annual Meeting. Additionally, the company is hosting a virtual investor event today at 8 am EST and details to join are included below.

“There continues to be a significant need for new treatment options for patients with bladder cancer,” said Gary D. Steinberg, M.D., Professor, Department of Urology at Rush University Medical Center. “Therefore, I am very encouraged by the latest data from the BOND-003 study, which demonstrates cretostimogene’s compelling efficacy as well as its potential to induce a best-in-class durable response in NMIBC patients, with 63.5% of patients remaining in response at 12 months or greater and 56.6% of patients remaining in response at 24 months or greater, by K-M estimate. Additionally, 97.3% of patients were free from progression to Muscle Invasive Bladder Cancer (MIBC) at 12 months. If approved by the FDA, cretostimogene may represent an important, bladder-sparing, advancement in the bladder cancer treatment paradigm, and meaningfully improve patient outcomes.”

There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. No treatment-related discontinuation of cretostimogene was observed. 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria.

“The BOND-003 monotherapy data underscores our novel investigational oncolytic immunotherapy’s unique product profile, including its dual mechanism of action, which we believe differentiates it from current and investigational NMIBC treatments,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “Based upon the latest data, we are confident that cretostimogene is well positioned to address an unmet need for patients as a potential backbone bladder-sparing therapeutic if approved by the FDA.”

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 patients is currently ongoing in North America 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.

Cretostimogene monotherapy received FDA Fast Track and Breakthrough Therapy Designations in BCG-Unresponsive, high-risk NMIBC patients with CIS in December 2023. On May 3, 2024, CG Oncology presented preliminary data from the Phase 3 BOND-003 trial at the 2024 American Urological Association Annual Meeting.

Investor Conference Call
CG Oncology will host a conference call and live webcast at 8 am EST today, December 5, 2024. Individuals interested in listening to the live conference call may do so by using the webcast link in the “Investor Relations" section of the company's website at https://ir.cgoncology.com. A webcast replay will be available in the investor relations section on the company's website following the completion of the call.

About Bladder Cancer
More than 83,000 people are estimated to be diagnosed with bladder cancer in 2024. NMIBC is the most common form of bladder cancer, representing approximately 75% of newly diagnosed cases. Bladder cancer is the sixth most common form of cancer in the United States, and men account for three quarters of newly diagnosed cases.

About Cretostimogene Grenadenorepvec
Cretostimogene grenadenorepvec is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 250 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 and intermediate-risk NMIBC patients and its potential to have a best-in-class durable response and meaningfully improve patient outcomes. 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: additional patient data related to cretostimogene that continues to become available may be inconsistent with the data produced as of the data cutoff, and further analysis of existing data and analysis of new data may lead to conclusions different from those established as of the date hereof; 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; potential delays in the commencement, enrollment and completion of clinical trials; competitive developments with respect to current and other investigational NMIBC treatments may adversely affect the commercial opportunity of cretostimogene; 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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