Cretostimogene Grenadenorepvec Data Continues to Demonstrate Best-in-Class Durability of Response as well as Consistent and Compelling Safety and Efficacy

Mar 24, 2025

– Latest BOND-003 data show 75.5% of patients achieved a complete response at any time –
– Median duration of response exceeds 28 months and is ongoing –
– No close contact precautions needed post cretostimogene treatment –

IRVINE, Calif., March 24, 2025 (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 that 83 out of 110 patients (75.5%) achieved a complete response (CR) at any time in a Phase 3 study of cretostimogene monotherapy for high-risk BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ (CIS). As of the data cutoff of January 20, 2025, 46% of patients were in CR at 12 months, with 30 confirmed responses at 24 months, with the data continuing to mature. The median duration of response (DoR) has not been reached but exceeds 28 months. These data from BOND-003 Cohort C were presented today as a late-breaking abstract at the 40th Annual European Association of Urology (EAU) Congress taking place in Madrid, Spain.

"Cretostimogene's strong safety and efficacy profile, combined with its best-in-class durability, address an unmet need for my non-muscle invasive bladder cancer patients," said Trinity J. Bivalacqua, M.D., Professor of Urology and Oncology at the Perelman Center for Advanced Medicine, University of Pennsylvania. "Now with the new translational data indicating that post-treatment close contact precautions are unnecessary, I am confident that cretostimogene will represent a breakthrough in bladder cancer treatment, if approved by the FDA."

Translational data shared at the EAU Congress showed the level of cretostimogene peaked immediately after instillation, which was sustained locally for 4-5 days. Furthermore, intravesical delivery of cretostimogene reduces anti-drug antibody neutralization, thereby preserving therapeutic efficacy. There was no systemic exposure, with cretostimogene levels remaining below the limit of detection, providing evidence that post cretostimogene treatment close contact precautions are not needed. This information supports the current dosing schedule.

There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. Patients who experienced TRAEs of any grade had a median resolution time of one day. 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.

"We are highly encouraged by the latest BOND-003 results, the largest study to date in BCG-unresponsive NMIBC with CIS patients, and cretostimogene's potential to significantly impact the future of bladder cancer care," said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. "We are grateful to the patients and providers who participated in our study, advancing research and offering hope to those seeking bladder-sparing options."

About Cretostimogene Grenadenorepvec

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy being evaluated in BOND-003, a Phase 3 clinical trial for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guérin (BCG) therapy. Cretostimogene is also being evaluated in a Phase 3 monotherapy clinical trial (PIVOT-006) in patients with intermediate-risk NMIBC. In addition, cretostimogene is being evaluated in an investigator-sponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer.

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy 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.

Contacts:
Media

Sarah Connors
Vice President, Communications and Patient Advocacy, CG Oncology
(508) 654-2277
sarah.connors@cgoncology.com

Investor Relations
Chau Cheng
Vice President, Investor Relations, CG Oncology
(949) 342-8939
chau.cheng@cgoncology.com