Cretostimogene Monotherapy Demonstrated 75.2% Complete Response Rate in High-Risk, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

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- Phase 3 BOND-003 study results showed sustained, durable complete responses over 12 months with novel investigational oncolytic immunotherapy -

- Company will hold an investor conference call today at 4:30pm EDT -

IRVINE, Calif., May 03, 2024 (GLOBE NEWSWIRE) -- CG Oncology, Inc. today announced that data from the Phase 3 BOND-003 study evaluating the efficacy and safety of cretostimogene monotherapy in patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG), showed that 75.2% of patients (79 out of 105 [95% confidence interval (CI), 65-83]) achieved a complete response (CR) at any time, as of the cutoff date of April 1, 2024. These data were featured today at the Paradigm-Shifting, Practice-Changing Clinical Trials in Urology Plenary Session as an oral presentation (Abstract #24-11358) by Dr. Mark D. Tyson, Urologic Oncologist at Mayo Clinic, at the 2024 American Urological Association (AUA) Annual Meeting, in San Antonio, TX. In addition, cretostimogene has shown durable responses over time with twenty-nine patients maintaining a complete response for 12 months or more, pending evaluation and assessment of ongoing responses in twenty-two patients as of the data cutoff. Median duration of response (DOR) was not reached. 92.4% cystectomy-free survival was observed and none of the patients with a complete response had undergone radical cystectomy or showed nodal or metastatic progression.

Cretostimogene is an investigational oncolytic immunotherapy which has shown selective oncolysis and potent anti-tumor immune response, and is being evaluated in BOND-003 (NCT04452591), 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 study is CR at any time, with DOR measured as a secondary endpoint. The highly pre-treated study population includes patients with prior intravesical chemotherapy and systemic immunotherapy.

There were no Grade 3 or higher treatment-related adverse events (TRAEs) or deaths reported, and two patients (1.8%) had serious TRAEs (Grade 2). No treatment-related discontinuation of cretostimogene was observed. 94.5% of patients completed all expected treatments. TRAEs occurred in 70 patients (62.5%). The most common TRAEs (≥10%) were bladder spasm, pollakiuria, dysuria, micturition urgency, and hematuria, as of the safety cutoff date of January 31, 2024.

“The positive 12-month BOND-003 data presented at AUA 2024, with a notable duration of response, reinforces cretostimogene monotherapy as a potential backbone therapy in the NMIBC treatment landscape for BCG-unresponsive patients. This innovative immunotherapy candidate may, if approved, emerge as a favored option for patients over the surgical extraction of their bladder, as they face limited options,” said Gary D. Steinberg, M.D., Professor, Department of Urology at Rush University Medical Center. “Cretostimogene reported remarkable interim efficacy results, with over half of the patients experiencing complete responses upon repeat induction. There continues to be a need for new options for patients with bladder cancer.”

“We’re thrilled to present today’s updated data which reinforces cretostimogene’s potential as a bladder-sparing therapeutic that could materially improve both patient outcomes and quality of life,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “Importantly, with topline data expected from BOND-003 by the end of 2024, we look forward to a regulatory approval submission.”

Last December, the U.S. Food and Drug Administration (FDA) granted both Fast Track Designation and Breakthrough Therapy Designation for cretostimogene in high-risk BCG-unresponsive NMIBC with carcinoma in-situ with or without Ta or T1 papillary tumors.

Investor Conference Call

CG Oncology will host a conference call and live webcast at 4:30pm EDT today on May 3, 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 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 Guerin (BCG) therapy. Cretostimogene was previously evaluated in a Phase 2 clinical trial (CORE-001) in combination with pembrolizumab in the same indication and is also being evaluated in a Phase 3 monotherapy clinical trial (PIVOT-006) in intermediate-risk NMIBC patients. In addition, cretostimogene is being evaluated in an investigator-sponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer.

About the BOND-003 Clinical Study

BOND-003 (NCT04452591) is a single-arm, open-label, Phase 3 clinical trial evaluating cretostimogene as monotherapy in patients with high-risk NMIBC unresponsive to BCG therapy. The study fully enrolled 112 evaluable patients with BCG-unresponsive NMIBC across North America and the Asia-Pacific region.

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 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 the expected timing of final data for the BOND-003 trial. 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, data readout and completion of clinical trials, including the BOND-003 trial; 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 SEC, including under the heading “Risk Factors” in our annual report on Form 10-K and any subsequent filings with the SEC. 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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