CG Oncology Announces Nature Medicine Publication of Phase 1b Study Results Evaluating Cretostimogene Grenadenorepvec in Combination with Nivolumab in Muscle-Invasive Bladder Cancer

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– Phase 1b study results were published simultaneously in *Nature Medicine* and presented at the Society for Immunotherapy of Cancer 2024 –

– Encouraging data adds to the body of evidence supporting potential use of cretostimogene as a backbone bladder-sparing therapeutic for bladder cancer –

IRVINE, Calif., Nov. 11, 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 the publication in *Nature Medicine* of Phase 1b investigator-sponsored study results evaluating intravesical cretostimogene grenadenorepvec in combination with Bristol Myers Squibb's immune checkpoint inhibitor nivolumab, in muscle-invasive bladder cancer (MIBC). The publication is now available online and will be in a future print edition of *Nature Medicine*. The results were also presented at the Society for Immunotherapy of Cancer (SITC) 2024 by Dr. Roger Li, M.D., urologic oncologist at Moffitt Cancer Center.

This is the second publication in *Nature Medicine* evaluating the safety and efficacy of cretostimogene grenadenorepvec this year. In June 2024, *Nature Medicine* published the final results from CORE-001, a phase 2 study of cretostimogene grenadenorepvec in combination with another checkpoint inhibitor, pembrolizumab, in high-risk Bacillus Calmette Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

"The recent *Nature Medicine* publications underscore cretostimogene's compelling safety profile and provide preliminary evidence supporting the potential use as a combination therapy for patients with different types of bladder cancer," said Vijay Kasturi, MD, Chief Medical Officer, CG Oncology. "Cretostimogene's dual mechanism of action positions it to potentially work well as either a monotherapy or in combination because it selectively replicates and destroys cancer cells while simultaneously amplifying the immune response against bladder tumors. Cretostimogene targets bladder cancer cells, without harming normal cells in the bladder. We are encouraged by cretostimogene's strong body of clinical evidence to date, and we look forward to sharing topline results from our BOND-003 registrational study in High-Risk Non-Muscle Invasive Bladder Cancer later this year."

About the Phase 1b Study
The Phase 1b study examined the safety and efficacy of combining cretostimogene grenadenorepvec with nivolumab in patients with MIBC who were ineligible for cisplatin chemotherapy. Of the 21 patients enrolled and treated, there were no dose-limiting toxicity and no grade 3 or higher treatment-related adverse events (TRAE). Early indications of efficacy for the combination treatment include a pathologic complete response rate of 42.1%, which is significantly higher than what has been reported in the literature with nivolumab monotherapy, and 1-year recurrence free survival of 70.4%. Together, these results highlight the potential of cretostimogene grenadenorepvec in a combination for cisplatin-ineligible patients with MIBC.

In December 2023, the Food and Drug Administration granted Fast Track and Breakthrough Therapy Designations for cretostimogene in the same patient population supported by data from the Phase 3 BOND-003 trial. Data to-date shows a 75.2% complete response rate at any time with durable responses sustained over 12 months. Topline data from BOND-003 is expected by the end of 2024.

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 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 in combination with nivolumab in MIBC, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients; and the anticipated timing of BOND-003 topline data. 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 in combination with nivolumab 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; 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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