CG Oncology Initiates Expanded Access Program for Cretostimogene Grenadenorepvec

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- First Patient Dosed in Expanded Access Program and Enrollment Ongoing -

IRVINE, Calif., June 18, 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 that it has initiated an Expanded Access Program (EAP) for cretostimogene grenadenorepvec in the U.S. for patients with Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette-Guerin (BCG) and meet certain program eligibility criteria. The first patient has been dosed in the EAP and enrollment in the study is ongoing.

“Bladder cancer is a highly recurrent disease with few treatment options available to patients,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “This program reflects our commitment to patients afflicted with NMIBC and our desire to ensure that they have efficient access to cretostimogene, our novel oncolytic immunotherapy candidate.”

"Navigating NMIBC can be a journey filled with uncertainties, especially given how frequently bladder cancer recurs," said Andrea Maddox-Smith, CEO of the Bladder Cancer Advocacy Network (BCAN). "At BCAN, patients are at the forefront of everything we do. Despite the progress being made to find new treatments, there are times when patients have exhausted all approved treatment options, and they are not eligible for a traditional clinical trial. Expanded Access Programs represent tremendous hope for these patients and their families, by allowing them access to investigational drugs that they would not otherwise have available to them."

About Expanded Access to Cretostimogene Grenadenorepvec

EAP programs are intended to serve as a potential pathway for a patient with a serious or immediately life-threatening disease or condition, to gain access to an investigational medical treatment outside of clinical trials before it is approved by the U.S. Food and Drug Administration (FDA), when no comparable or satisfactory alternative therapy options are available. Healthcare providers and bladder cancer patients who are interested to learn more about CG Oncology’s EAP including eligibility criteria may visit www.clinicaltrials.gov, NCT06443944, or contact EAP@cgoncology.com.

To learn more about CG Oncology’s clinical studies please visit the CG Oncology website at www.cgoncology.com.

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 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.

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 access to cretostimogene through the Company’s Expanded Access Program (EAP) for certain patients with NMIBC; the anticipated timing of BOND-003 final data; and the Company’s expectations on a regulatory approval submission. 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 pembrolizumab 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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