CG Oncology Announces First Patient Dosed in PIVOT-006 Phase 3 Clinical Trial of Cretostimogene in Intermediate-risk Non-Muscle Invasive Bladder Cancer

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- PIVOT-006 Phase 3 open-label trial of adjuvant cretostimogene is CG Oncology's earliest disease stage clinical trial for patients with Non-Muscle Invasive Bladder Cancer (NMIBC) -

- Primary endpoint of PIVOT-006 Phase 3 clinical trial is overall recurrence-free survival (RFS), with secondary endpoints including RFS at 12 and 24 months and progression-free survival (PFS) -

IRVINE, Calif., Feb. 27, 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 afflicted with bladder cancer, today announced the first patient has been dosed in the PIVOT-006 Phase 3 clinical trial of cretostimogene for the treatment of patients with intermediate-risk NMIBC following transurethral resection of the bladder tumor (TURBT).

"The dosing of the first patient in our PIVOT-006 trial advances cretostimogene earlier in the treatment paradigm for NMIBC patients who face limited treatment options, frequent disease recurrence and repetitive surgery," said Arthur Kuan, Chairman and Chief Executive Officer, CG Oncology. "Intermediate-risk NMIBC patients face a difficult combination of disease characterized by tumor recurrence and a shortage of BCG therapy which is often reserved for use only in high-risk patients, limiting treatment options for intermediate-risk patients. Our goal with the PIVOT-006 trial is to advance cretostimogene as a potential backbone oncolytic immunotherapy."

PIVOT-006 is a Phase 3, open-label, two-arm trial enrolling up to 426 intermediate-risk NMIBC patients, one arm to be administered cretostimogene following the standard of care TURBT with the second arm receiving the standard of care TURBT only. The initial induction course is six weekly doses of cretostimogene containing $1x10^{12}$ VPs per milliliter. Patients who are recurrence free at month three will receive a maintenance course involving three weekly cretostimogene doses administered at the same dose, in months 3 and 6, followed by single weekly doses in months 9 and 12. The primary endpoint of this trial is overall RFS, with secondary endpoints including RFS at 12 and 24 months and PFS.

"I am excited to see the PIVOT-006 study get underway in the intermediate-risk NMIBC population with cretostimogene, a highly selective oncolytic immunotherapy," said Neal D. Shore, MD, FACS, the Medical Director for the Carolina Urologic Research Center in Myrtle Beach, South Carolina. "Novel treatment options and clinical trials are essential in NMIBC, particularly in this group of underserved patients who undergo considerable follow up and have limited intravesical therapeutic options. Cretostimogene is a novel therapy which has the potential to be a paradigm shift in how we might manage the ongoing burden of this highly recurrent aspect of bladder cancer."

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 BCG-unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC). Cretostimogene is also being evaluated in a Phase 2 clinical trial (CORE-001) in combination with pembrolizumab in the same indication and 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 PIVOT-006 Clinical Study

PIVOT-006 (NCT06111235) is a Phase 3, open-label, two-arm monotherapy study enrolling 426 patients and evaluating adjuvant cretostimogene in intermediate-risk NMIBC patients following transurethral resection of the bladder tumor (TURBT). The primary endpoint of PIVOT-006 is overall recurrence-free survival (RFS), with secondary endpoints including RFS at 12 and 24 months and progression-free survival.

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 intermediate-risk NMIBC patients and other disease states. 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: potential delays in the commencement, enrollment and completion of clinical trials, including enrollment in the PIVOT-006 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; unfavorable results from clinical trials; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; regulatory developments in the United States and foreign countries; and other risks described in our filings with the SEC, including under the heading "Risk Factors" in the final prospectus dated January 24, 2024 we filed with the SEC 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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