Cretostimogene Grenadenorepvec Monotherapy First Results Show 75.7% Complete Response Rate at Any Time in Patients With High-Risk BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer

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IRVINE, Calif.–(BUSINESS WIRE)– CG Oncology, Inc. today announced that Phase 3 monotherapy data from the BOND-003 clinical trial evaluating the efficacy and safety of cretostimogene grenadenorepvec in patients with high-risk NonMuscle Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette-Guerin (BCG), showed that 75.7% of evaluable patients achieved a complete response (CR) at any time, as of the cutoff date of October 5, 2023. These data will be featured today in a Late-Breaking Oral Podium Presentation (Abstract #LBA3396) by Mark D. Tyson, M.D., urologic oncologist at Mayo Clinic, at the 24 Annual Meeting of the Society of Urological Oncology (SUO) taking place November 28 – December 1, 2023 in Washington, DC.

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy 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 with or without Ta/T1 disease. The fully-enrolled trial of 116 patients with BCGunresponsive NMIBC is taking place across North America and the Asia-Pacific region. The primary endpoint of the study is CR at any time, with duration of response measured as a secondary endpoint.

“The positive BOND-003 interim results demonstrate the impact of cretostimogene in BCG-unresponsive disease patients as a promising new monotherapy which may lead to profoundly meaningful non-surgical outcomes for those with recurrent bladder cancer,” said Trinity J. Bivalacqua, M.D., Ph.D., Professor of Urology and Oncology at the Perelman Center for Advanced Medicine, University of Pennsylvania. “NMIBC has been a difficult disease to treat, and patients have often had no options except surgical removal of the bladder.”

Summary of BOND-003 Data:

Interim data for BOND-003 showed anti-tumor activity of cretostimogene grenadenorepvec as monotherapy in patients with high-risk BCG-unresponsive NMIBC.

- Based on a preliminary data cutoff on October 5, 2023, 66 patients were evaluable for efficacy with a minimum of 3-month follow up.
- 75.7% of patients evaluable for efficacy (n=50/66) have achieved CR at any time. The 3and 6-month landmark CR rates were 68.2% (n=45/66) and 63.6% (n=42/66), respectively.
- The adverse events observed following dosing of cretostimogene grenadenorepvec as monotherapy were consistent with that observed in prior studies, as the treatment has generally been well tolerated. The most common treatment-related adverse events (AEs) reported included transient grade 1-2 local genitourinary symptoms. No grade 3 or higher AEs related to cretostimogene grenadenorepvec were observed and there were no treatment discontinuations due to AEs.

“We are thrilled to present this data at SUO, and we look forward to further discussions with the FDA on advancing cretostimogene grenadenorepvec as a potential new therapy for bladder cancer patients at significant risk of disease recurrence and progression,” said Arthur Kuan, Chief Executive Officer, CG Oncology. “Our goal is to transform the treatment landscape for patients with bladder cancer, and these results reinforce our commitment to developing bladdersparing therapeutics to improve patient outcomes and quality of life.”

About Cretostimogene Grenadenorepvec

Cretostimogene grenadenorepvec 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. Cretostimogene grenadenorepvec is also being evaluated in a Phase 2 clinical trial (CORE-001) in combination with pembrolizumab in the same indication. In addition, cretostimogene grenadenorepvec is being evaluated in an investigatorsponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer.

About Bladder Cancer

More than 82,000 people are estimated to be diagnosed with bladder cancer in 2023. 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.

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