CG Oncology Receives Both FDA Fast Track and Breakthrough Therapy Designation for Cretostimogene Grenadenorepvec in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

Dec 05, 2023

Both Fast Track and Breakthrough Therapy Designation intended to accelerate path to U.S. FDA submission

Recent Phase 3 monotherapy first results demonstrated complete response rate of 75.7% at any time

IRVINE, Calif. (BUSINESSWIRE)– CG Oncology, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted both Fast Track Designation and Breakthrough Therapy Designation for cretostimogene grenadenorepvec in high-risk Bacillus Calmette-Guérin (BCG)-unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) with carcinoma in situ with or without Ta or T1 (papillary) tumors.

“Receiving both FDA Fast Track and Breakthrough Therapy Designation is an important milestone in the development of cretostimogene grenadenorepvec and for patients with bladder cancer who urgently need more therapeutic options,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “We are encouraged by this momentum following our recent announcement of first results from our Phase 3 BOND-003 study for patients with high-risk BCG-unresponsive NMIBC. CG Oncology looks forward to working with the FDA to advance cretostimogene grenadenorepvec as a potential backbone therapy in bladder cancer. We would like to thank the patients, caregivers, investigators and their staff who have participated in the clinical trials.”

The FDA decision is informed by the results of CG Oncology’s clinical trials, which showed that patients treated with cretostimogene grenadenorepvec demonstrated clinical benefit based on complete response rates and has been generally well tolerated.

More than 82,000 people are estimated to be diagnosed with bladder cancer this year. NMIBC is the most common form of bladder cancer, representing approximately 75% of newly-diagnosed cases. Four times more men are diagnosed with bladder cancer than women, and it is the sixth most common type of cancer in the United States.

“The Bladder Cancer Advocacy Network (BCAN) is grateful for the expedited review of this potential treatment option for bladder cancer patients with high-risk BCG-unresponsive NMIBC. What patients and their loved ones desperately need are more and better ways to treat their disease,” said Andrea Maddox-Smith, Chief Executive Officer of BCAN. “We appreciate the urgency demonstrated by the FDA in recognizing the potential of this therapy.”

Cretostimogene grenadenorepvec is in active clinical studies in bladder cancer. Results from an interim analysis of the BOND-003 Phase 3 trial of cretostimogene grenadenorepvec monotherapy for patients with high-risk BCG-unresponsive NMIBC were presented on November 30, 2023, at the 24th Annual Meeting of the Society of Urological Oncology (SUO). The data showed that patients treated with cretostimogene grenadenorepvec had a complete response rate of 75.7% at any time, and was generally well tolerated with no Grade 3 or higher treatment-related adverse events observed. The interim results were based on 66 patients evaluable for efficacy, with an efficacy data cutoff of October 5, 2023.

The FDA’s Fast Track program is intended to facilitate the development and expedite the review of new drugs and biologics designed to treat serious conditions with unmet medical needs. The FDA’s Breakthrough Therapy designation is a process designed to expedite the development and regulatory review of drugs or biologics that are intended to treat serious conditions where preliminary clinical evidence indicating that the drug or biologic may demonstrate substantial improvement on at least one clinically significant endpoint over available therapy.

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 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, Phase 3, monotherapy study evaluating cretostimogene grenadenorepvec in patients with high-risk NMIBC unresponsive to BCG. The primary endpoint of the study is complete response (CR) at any time. In a preplanned preliminary analysis, it was reported that patients had a CR rate of 75.7% at any time with no Grade 3 or higher treatment-related adverse events observed. The most common treatment-related adverse events reported include transient grade 1-2 local genitourinary symptoms. No grade 3 or higher adverse events related to cretostimogene grenadenorepvec were observed.

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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