CG Oncology to Unveil Encouraging Results on Cretostimogene in Combination with Pembrolizumab at ASCO 2024

Apr 24, 2024

- Final results of CORE-001 Phase 2 trial of cretostimogene in combination with pembrolizumab for the treatment of BCG-unresponsive NMIBC -

IRVINE, Calif., April 24, 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 an abstract with final results of CORE-001, its Phase 2 trial of cretostimogene in combination with pembrolizumab, will be presented at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting, which will take place from May 31-June 4, 2024, at McCormick Place Convention Center, in Chicago, IL.

“We are delighted to be sharing the final results from our CORE-001 Phase 2 trial at ASCO, in line with the guidance we previously gave of providing additional CORE-001 durability data in 1H 2024,” said Vijay Kasturi, M.D., Chief Medical Officer, CG Oncology. “In anticipation of sharing the final results from this trial, we would like to extend our heartfelt thanks to the investigators and patients who contributed to the trial’s success.”

Details of the abstract are as follows:

Final results of CORE-001 trial of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in Patients with BCG-Unresponsive, Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ
Abstract Number: 4601
Session & Primary Track: Poster Session, Genitourinary Cancer - Kidney and Bladder
Presenter: Roger Li, M.D., lead study investigator and Urologic Oncologist at Moffitt Cancer Center
Presentation Date & Time: June 2, 2024, 9:00-10:00am Central Daylight Time
Location: McCormick Place Convention Center, Hall A

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 was previously evaluated in a Phase 2 clinical trial (CORE-001) in combination with pembrolizumab in the same indication and 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.

About the CORE-001 Study

CORE-001 was a Phase 2 single-arm, open-label clinical trial of cretostimogene administered in 35 patients with high-risk, BCG-unresponsive NMIBC that have carcinoma in situ-containing tumors, in combination with pembrolizumab, following disease resection. CORE-001 was conducted pursuant to a clinical collaboration and supply agreement with Merck (known as MSD outside the United States and Canada).

More information about the study, CORE-001 (NCT04387461), along with other studies sponsored by CG Oncology, can be found at www.clinicaltrials.gov or www.cgoncology.com.

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 pembrolizumab for high-risk NMIBC patients and the importance of the data as they relate to addressing bladder cancer. 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: reported topline data is based on preliminary analysis of key efficacy and safety data is subject to more audit and verification procedures that could result in material changes in the final data; 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 date hereof, 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; and other risks described in our filings with the SEC, including under the heading “Risk Factors” in our annual report on Form 10-K 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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