CG Oncology to Present Results on Cretostimogene at the AUA 2024 Annual Meeting

Mar 28, 2024

- New 12-month data from the Phase 3 BOND-003 trial to be featured in an oral presentation in the Paradigm-shifting, Practice-changing Clinical Trials in Urology plenary session -

IRVINE, Calif., March 28, 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 three abstracts highlighting cretostimogene will be presented at the American Urological Association (AUA) Annual Meeting, taking place at Henry B. González Convention Center in San Antonio, TX from May 3-6, 2024. CG Oncology is exhibiting at the AUA meeting at booth #100.

“We are excited to share encouraging 12-month Phase 3 monotherapy results from the BOND-003 study at AUA 2024,” said Ambaw Bellete, President and Chief Operating Officer, CG Oncology. “Our presence reinforces our commitment to improving outcomes for patients diagnosed with bladder cancer across the disease spectrum.”

Details of the oral presentations are as follows:

Pivotal Results from BOND-003: A Phase 3, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High Risk, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ
Abstract Number: 24-11358
Session: Paradigm-shifting, Practice-changing Clinical Trials in Urology
Presenter: Mark D. Tyson, M.D., Urologic Oncologist at Mayo Clinic, Scottsdale, AZ
Presentation Date & Time: May 3, 2024, 10:23-10:31am Central Daylight Time
Location: Henry B. González Convention Center, Stars at Night Ballroom

PIVOT-006: A Phase 3, Randomized Study of Adjuvant Intravesical Cretostimogene Grenadenorepvec versus Surveillance for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer Following Transurethral Resection of Bladder Tumor
Session: Clinical Trials in Progress, Bladder Cancer
Presenter: Robert Svatek, M.D., Urologic Oncologist at University of Texas Health Science Center, San Antonio, TX
Presentation Date & Time: May 5, 2024, 10:24-11:32am Central Daylight Time
Location: Henry B. González Convention Center, Learning Lab

BOND-003- Cohort P: A Multi-national, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High Risk, Papillary Only, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer
Session: Clinical Trials in Progress, Bladder Cancer
Presenter: Mark D. Tyson, M.D., Urologic Oncologist at Mayo Clinic, Scottsdale, AZ
Presentation Date & Time: May 5, 2024, 10:56-11:04am Central Daylight Time
Location: Henry B. González Convention Center, Learning Lab

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 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 BOND-003 Clinical Study

BOND-003 (NCT04452591) is a single-arm, open-label, Phase 3 clinical trial evaluating cretostimogene as monotherapy in patients with high-risk NMIBC unresponsive to BCG therapy. The study has enrolled 115 patients with BCG-unresponsive NMIBC across North America and the Asia-Pacific region.

About the PIVOT-006 Clinical Study

PIVOT-006 (NCT06111235) is a randomized, open-label, Phase 3 clinical trial enrolling 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 high-risk and intermediate-risk NMIBC patients. 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: interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data becomes available; potential delays in the commencement, enrollment and completion of clinical trials, including the BOND-003 and PIVOT-006 trials; 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; 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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