CG Oncology Completes Enrollment in PIVOT-006

Sep 03, 2025

– Rapid enrollment underscores high unmet need in intermediate-risk non-muscle invasive bladder cancer (NMIBC) –
– One of the largest randomized phase 3 studies in this patient population will encompass broadest range of patient types per AUA/SUO Guidelines –

IRVINE, Calif., Sept. 03, 2025 (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 it has completed enrollment in its Phase 3, randomized, open-label PIVOT-006 study comparing adjuvant intravesical cretostimogene grenadenorepvec versus surveillance following bladder tumor removal in patients with intermediate-risk non-muscle invasive bladder cancer (IR NMIBC).

“Intermediate-risk NMIBC presents a significant clinical challenge, with recurrence rates reaching up to 70% and few durable treatment options available to patients,” said Robert Svatek, M.D., MSCI, urologic oncologist at the Mays Cancer Center at UT Health San Antonio MD Anderson Cancer Center and global Principal Investigator for PIVOT-006. “Although it carries a lower risk of progression than high-risk disease, the relentless cycle of procedures and surveillance can diminish patients’ quality of life. There is growing enthusiasm within the urology community about the potential of cretostimogene in both intermediate- and high-risk NMIBC, underscored by the rapid enrollment of over 360 patients into the PIVOT-006 study across 90 plus sites. This unique therapy introduces a novel treatment paradigm—selectively lysing tumor cells while simultaneously activating a robust anti-cancer immune response.”

“At CG Oncology, we remain steadfast in our mission to transform the treatment landscape for individuals living with bladder cancer,” said Vijay Kasturi, MD, Chief Medical Officer at CG Oncology. “Our clinical trial program is purposefully designed to address the full spectrum of disease stages and tumor types, with a particular focus on areas of high unmet need. We are especially encouraged by the strong interest and rapid enrollment, nearly a year ahead of schedule, in PIVOT-006 which highlights the urgent need for new treatment options in the intermediate-risk NMIBC population. This momentum reinforces our path toward a potential indication in adjuvant IR NMIBC, for which there are no U.S. FDA approved options. We are deeply grateful to the SUO-CTC for their support, to all participating trial sites for their dedication, and most importantly, to the patients who make this research possible.”

About PIVOT-006
PIVOT-006 is a Phase 3, randomized, open-label trial in intermediate-risk NMIBC comparing adjuvant intravesical cretostimogene grenadenorepvec to surveillance after bladder tumor removal. All participants undergo standard tumor removal, then are randomized to either receive cretostimogene instillations (weekly for 6 weeks, then weekly for 3 weeks every 3 months for one year) or surveillance. Control patients may switch to treatment if they relapse. To learn more about the study including eligibility requirements please visit: https://pivot006.com/.

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 400 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for high-risk BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk NMIBC. CG Oncology also has a Phase 2 trial, CORE-008, evaluating the safety and efficacy of cretostimogene in high-risk NMIBC. Additionally, we have initiated an Expanded Access Program for cretostimogene in North America for patients who are unresponsive to BCG and meet certain program eligibility requirements. Cretostimogene is an investigational candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

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, statements regarding our anticipated cash runway, future results of operations and financial position; the anticipated timing and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene, including anticipated next milestones in our development pipeline; the timing and likelihood of regulatory filings and approvals for cretostimogene; and 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; we may use our capital resources sooner than expected and they may be insufficient to allow us to achieve our anticipated milestones; 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 Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our annual report on Form 10-K and other filings that we make with the SEC from time to time (which are available at http://www.sec.gov). 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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