New Cretostimogene Grenadenorepvec Data Highlight its Potential to Become the Backbone Therapy for High-Risk Non-Muscle Invasive Bladder Cancer

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- *Cretostimogene demonstrated HG-EFS at 3- 6- and 9-months of 95.7%, 84.6% and 80.4%, respectively, in HR BCG UR Ta/T1 Disease in BOND-003 Cohort P*
- *CORE-008 Cohort A Data in HR BCG-Naïve NMIBC demonstrates 88% CR and favorable safety with optimized administration*
- *Robust clinical pipeline that spans multiple late-stage studies across intermediate- and high-risk NMIBC*

IRVINE, Calif., Dec. 05, 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 topline data from BOND-003 Cohort P and first results from CORE-008 Cohort A which demonstrated promising efficacy, safety and tolerability. These data will be presented today as Late-Breaking Abstracts at the Society of Urologic Oncology (SUO) 26th Annual Meeting.

“For people living with bladder cancer, the need for primary treatment of newly diagnosed NMIBC and a durable, bladder-sparing option for those with BCG unresponsive disease is urgent. New data from BOND-003 Cohort P and CORE-008 Cohort A add to a growing body of evidence demonstrating cretostimogene’s potential to become a backbone treatment across the NMIBC spectrum, if approved. The topline efficacy, safety, and tolerability announced today are consistent with what we previously observed with the pivotal Phase 3 monotherapy data, but in an even more prevalent NMIBC population, notably BCG-UR papillary-only,” said Trinity J. Bivalacqua, M.D., Ph.D., Urologic Oncologist at University of Pennsylvania.

“We are delighted to share new and more mature data in different sub-groups, underscoring our commitment to address the broadest range of NMIBC patients. This sets us up for the future expansion and long-term success of cretostimogene. With its best-in-disease profile and dual MOA, we are confident that cretostimogene will continue to demonstrate differentiated data from current and investigational NMIBC therapies,” said Ambaw Bellete, President & Chief Operating Officer at CG Oncology.

TOPLINE BOND-003 COHORT P RESULTS
Results from the BOND-003 Cohort P clinical trial of cretostimogene monotherapy in patients with BCG-UR papillary-only NMIBC demonstrate encouraging HG-EFS and a consistent, well-tolerated safety profile. The study’s primary endpoint is High-Grade Event-Free Survival (HG-EFS). As of the September 1, 2025, data cut-off, in 51 efficacy evaluable patients, Kaplan-Meier estimates of HG-EFS at 3- 6- and 9-months are 95.7% (95% CI 83.8 – 98.9), 84.6% (95% CI 68.6 – 92.9%) and 80.4% (95% CI 62.3-90.4%), respectively.

A favorable safety and tolerability profile was observed with no Grade 3 or greater treatment-related adverse events (TRAEs) and no deaths reported. To date, no patients have undergone a radical cystectomy or progressed to MIBC. No treatment-related discontinuation of cretostimogene was observed. There were no missed doses, or dose delays due to TRAE. The most common TRAEs (≥10%) were bladder spasms, dysuria, pollakiuria, and hematuria.

The study has completed enrollment with 56 patients receiving cretostimogene across 35 clinical sites in the United States and Japan.

CORE-008 Cohort A Results
The first results from CORE-008 Cohort A demonstrate that cretostimogene monotherapy has promising clinical efficacy, tolerability, and safety in patients with high-risk, BCG-naïve NMIBC with CIS, compared with outcomes observed in historical BCG-naive trials. The primary endpoint is Complete Response (CR) at any time. As of the September 1, 2025, data cut off, the overall CR rate at any time in evaluable patients is 83.7% (41/49) (95% CI 70.3-92.7%) with the original administration achieving a 79.2% CR rate (57.8, 92.9) in 19 out of 24 patients as compared with the optimized administration which resulted in an 88.0% CR rate (68.8, 97.5) in 22 out of 25 patients.

The safety and tolerability profile is consistent with prior clinical trials of cretostimogene. The most common adverse events are low grade and localized to the bladder. There are no related serious adverse events (SAEs), Grade 3+ adverse events or treatment-related discontinuations. No patients progressed to MIBC or metastatic disease.

CORE-008 Cohort A	**CR Rate, % (95% CI)**	**Safety (n=54)**	
		Any Grade	Grade ≥ 3
Original Administration (five-step)	79.2% (57.8, 92.9)[1]	16 (59.3%)[1]	0 (0%)
Optimized Administration (two-step)	88.0% (68.8, 97.5)[2]	13 (48.1%)	0 (0%)
Overall	83.7%	29 (53.7%)	0 (0%)

[1] *CR rate in 19 out of* 24 patients; safety in 27 patients

[2] CR rate in 22 out of 25 patients; safety in 27 patients

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, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, cretostimogene's potential as a backbone immunotherapy across the NMIBC spectrum, and that cretostimogene results support optimized administration from a five-step process to a two-step process. 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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