Delaware Superior Court Jury Issues Unanimous Verdict that CG Oncology Owes No Future Royalties or Other Payments to ANI Pharmaceuticals

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IRVINE, Calif., July 29, 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 a jury in the Superior Court of the State of Delaware (the "Court") unanimously found in favor of CG Oncology on all claims in a March 2024 lawsuit brought by ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) ("ANI"). The jury unanimously rejected all of ANI Pharmaceuticals' claims for unjust enrichment damages after Judge Sheldon K. Rennie, on July 16, 2025, had ruled in favor of CG Oncology that, as a matter of law, ANI Pharmaceuticals was not entitled to any royalties on future sales of cretostimogene grenadenorepvec. At present CG Oncology has not been advised as to whether ANI Pharmaceuticals will appeal any aspect of the decisions. As a result of today's decision CG Oncology will not owe ANI Pharmaceuticals a future royalty of 5% on commercial sales of cretostimogene and there are no further payments due to ANI Pharmaceuticals for damages. Cretostimogene is CG Oncology's investigational, intravesically delivered oncolytic immunotherapy in development for bladder cancer.

"CG Oncology thanks both Judge Rennie and the jury for their thoughtful evaluation and decisions in the case which represent a major victory for bladder cancer patients who could benefit from cretostimogene," said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology. "The decisions allow CG Oncology to continue to focus our resources and energy on delivering on our mission to bring forward innovative immunotherapies that help bladder cancer patients live with dignity and have an enhanced quality of life."

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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