UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 16, 2026

CG Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41925**	**37-1611499**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3000 Pegasus Park Drive **Suite 1640** **Dallas, Texas**	**75247**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (949) 409-3700

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	CGON	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On November 16, 2026, CG Oncology, Inc. (the "***Company***") issued a press release entitled "PIVOT-006 Phase 3 Registrational Trial Demonstrates Unprecedented Improvement in Recurrence-Free Survival (RFS) for Intermediate-Risk and High-Grade Ta Non-Muscle Invasive Bladder Cancer (NMIBC)." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On November 16, 2026, the Company posted an updated corporate presentation on the Company's website. A copy of this presentation is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. Investors may also access the presentation by visiting the "Investor Relations" section of the Company's website at www.cgoncology.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission (the "***SEC***") made by the Company, regardless of any general incorporation language in such filing.

By furnishing the information in this Item 7.01, including Exhibits 99.1 and 99.2, the Company makes no admission as to the materiality of Item 7.01 in this report. The information contained in the corporate presentation is summary information that is intended to be considered in the context of the Company's filings with the SEC and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Item 7.01, including Exhibits 99.1 and 99.2, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating its website or through other public disclosure.

Item 8.01 Other Events.

On November 16, 2026, the Company announced topline data for its Phase 3 PIVOT-006 registrational trial evaluating adjuvant intravesical cretostimogene in patients with intermediate-risk and high-grade Ta ≤3 cm non-muscle invasive bladder cancer ("***NMIBC***") following complete tumor resection. There are currently no U.S. Food and Drug Administration ("***FDA***") approved adjuvant treatment options in this population of approximately 50,000 patients.

PIVOT-006 achieved its primary endpoint, demonstrating statistically significant and clinically meaningful improvements versus the control arm. Cretostimogene resulted in a 68% reduction in the risk of recurrence compared with the control arm, demonstrating a hazard ratio of 0.32 (95% CI: 0.23, 0.45; $p<0.0001$). The median follow-up was 17 months as of the October 26, 2026. Cretostimogene was generally well tolerated, with safety results consistent with those reported in previous studies. There were no Grade 3 or greater treatment-related adverse events ("***TRAEs***"), and no treatment-related discontinuations.

Additionally, the Company announced updated timing for the submission and completion of its current and planned biologics license applications ("***BLAs***") with the FDA. The Company anticipates completing the submission of its BLA for the use of cretostimogene to treat patients with BCG-unresponsive NMIBC with carcinoma in situ ("***CIS***") with or without papillary tumors, which will now also include BCG-unresponsive high-grade papillary-only disease (without CIS), in March 2027. The Company also plans to submit a BLA for the use of cretostimogene in intermediate-risk and high-grade Ta NMIBC in the second quarter of 2027.

Forward Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the Company's current beliefs and expectations and include, but are not limited to: the significant improvement in recurrence-free survival observed in the PIVOT-006 registrational trial, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, the planned timelines of the Company's BLA submissions and their respective indications, the Company's goal of securing the broadest possible label and including the totality of the BCG-unresponsive population at launch, cretostimogene's potential as a backbone immunotherapy across the NMIBC spectrum, the potential of PIVOT-006 results to change clinical practice and broaden the patient populations that could benefit from cretostimogene, and the expected patient population size that could benefit from cretostimogene, if approved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: topline data is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA may not agree with the Company's interpretation of such results; potential delays in the commencement, enrollment and completion of clinical trials; potential delays in the preparation, submission, acceptance, completion or review of the Company's current and planned BLAs; the risk that regulatory authorities may require additional data or studies, may not approve cretostimogene, or may grant a narrower indication or label than anticipated; uncertainties regarding the timing and scope of any commercial launch and the Company's ability to achieve anticipated patient access, market acceptance and therapeutic benefits; the risk that the target patient population size may be smaller than initially anticipated; the Company may use its capital resources sooner than expected and they may be insufficient to allow us to achieve the Company's anticipated milestones; the Company's 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 the Company's filings with the SEC, including under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K and other filings that the Company makes with the SEC from time to time. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated November 16, 2026
99.2	Corporate Presentation, dated November 16, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CG Oncology, Inc.

Date: November 16, 2026

By: /s/ Josh Patterson
Name: Josh Patterson
Title: General Counsel and Chief Compliance Officer

PIVOT-006 Phase 3 Registrational Trial Demonstrates Unprecedented Improvement in Recurrence-Free Survival (RFS) for Intermediate-Risk and High-Grade Ta Non-Muscle Invasive Bladder Cancer (NMIBC)

- *Cretostimogene reduced the risk of recurrence by 68%, demonstrating a statistically significant and clinically meaningful benefit with a hazard ratio of 0.32 (95% CI: 0.23, 0.45; p<0.0001)*

- *Compelling safety and tolerability results, no Grade 3 or higher TRAEs and no treatment-related discontinuations*

- *PIVOT-006 topline results to be presented as a late-breaking podium presentation at the Society of Urologic Oncology Annual Meeting on December 2, 2026*

- *PIVOT-006 data will support a second BLA submission in intermediate-risk and high-grade Ta NMIBC anticipated in Q2 2027*

- *Based on FDA feedback, initial BLA submission in BCG-unresponsive NMIBC to be broadened to include both CIS and high-grade papillary-only disease; completion anticipated in March 2027*

Dallas, TX, November 16, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today announced positive topline results from PIVOT-006, its Phase 3 registrational trial evaluating adjuvant intravesical cretostimogene grenadenorepvec in patients with intermediate-risk and high-grade Ta ≤3 cm NMIBC, following complete tumor resection. There are currently no U.S. FDA approved adjuvant treatment options in this population of approximately 50,000 patients. Together with the Company's data in high-risk BCG-unresponsive NMIBC, the PIVOT-006 results have the potential to significantly broaden the patient populations that could benefit from cretostimogene if approved.

PIVOT-006 achieved its primary endpoint, demonstrating statistically significant and clinically meaningful improvements versus the control arm. Cretostimogene resulted in a 68% reduction in the risk of recurrence compared with the control arm, with a hazard ratio of 0.32 (95% CI: 0.23, 0.45; $p<0.0001$). The median follow-up was 17 months as of October 26, 2026. Cretostimogene was generally well tolerated, with safety results consistent with those reported in previous studies. There were no Grade 3 or greater treatment-related adverse events (TRAEs), and no treatment-related discontinuations.

“The unparalleled PIVOT-006 results represent a defining milestone for CG Oncology and position cretostimogene as the first and only therapeutic candidate to demonstrate a significant recurrence benefit in a pivotal Phase 3 trial in intermediate-risk and HG Ta NMIBC. We are working expeditiously to complete our BLA filing in intermediate-risk and HG Ta NMIBC in the second quarter of 2027,” said Arthur Kuan, Chairman, President and Chief Executive Officer of CG Oncology. “Based on FDA feedback, we plan to broaden our initial BLA submission in BCG-unresponsive NMIBC, which was focused on patients with CIS with or without papillary tumors, to also include patients with high-grade papillary-only disease. Together, these populations represent the full range of BCG-unresponsive patients, and our goal is a label that reflects that. To incorporate the additional data, we now expect to complete the submission before the end of March 2027. All BLA-enabling manufacturing activities supporting both regulatory filings have been completed. Ultimately, this strategy reflects our commitment to meaningfully improve the lives of as many bladder cancer patients as possible.”

“Today’s results highlight our differentiated clinical approach, aimed at exploring cretostimogene across the broad NMIBC spectrum and build upon our robust body of clinical evidence including what we believe to be the best-in-disease safety and tolerability data reported,” said Vijay Kasturi, M.D., Chief Medical Officer of CG Oncology. “For patients with intermediate-risk and high-grade Ta NMIBC, reducing recurrence is a meaningful clinical objective because recurrence can bring

additional invasive procedures and continued disease burden. The significant improvement in recurrence-free survival observed in PIVOT-006 across both high-grade and low-grade patients underscores the promise of cretostimogene as an important potential new treatment option following tumor resection. These data give us the opportunity to change clinical practice and help more people remain cancer-free longer while reducing the burden of their disease."

About PIVOT-006 Phase 3 Clinical Trial

PIVOT-006 is one of the largest randomized Phase 3 studies conducted in intermediate-risk NMIBC, and enrolled 367 patients across ~90 sites in the United States and Canada. Enrolled patients had the broadest range of disease characteristics specified in AUA/SUO guidelines at the time of study start including recurrent low-grade (LG) Ta < 12mo, solitary LG Ta > 3cm, LG Ta multifocal, solitary HG Ta ≤ 3cm and LG T1. The study compares adjuvant intravesical cretostimogene grenadenorepvec versus surveillance following complete tumor resection, reflecting real-world clinical practice in this patient population.

About Cretostimogene Grenadenorepvec

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 700 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk and high-grade Ta ≤ 3cm NMIBC. Cretostimogene has received FDA Fast Track and Breakthrough Therapy designations for BCG-unresponsive NMIBC. CG Oncology also has a multi-cohort trial, CORE-008, evaluating the safety and efficacy of cretostimogene in BCG-exposed high-risk, BCG-naïve high-risk, and BCG-unresponsive 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 significant improvement in recurrence-free survival observed in the PIVOT-006 registrational trial, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients, the planned timelines of our BLA submissions and their respective indications, our goal of securing the broadest possible label and including the totality of the BCG-unresponsive population at launch, cretostimogene's potential as a backbone immunotherapy across the NMIBC spectrum, the potential of PIVOT-006 results to change clinical practice and broaden the patient populations that could benefit from cretostimogene, and the expected patient population size that could benefit from cretostimogene, if approved. 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: topline data is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA may not agree with our interpretation of such results; potential delays in the commencement,

enrollment and completion of clinical trials; potential delays in the preparation, submission, acceptance, completion or review of our current and planned BLAs; the risk that regulatory authorities may require additional data or studies, may not approve cretostimogene, or may grant a narrower indication or label than anticipated; uncertainties regarding the timing and scope of any commercial launch and our ability to achieve anticipated patient access, market acceptance and therapeutic benefits; the risk that the target patient population size may be smaller than initially anticipated; 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 most recent annual report on Form 10-K and other filings that we make with the SEC from time to time. 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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Exhibit 99.2



CG ONCOLOGY

Attacking Bladder Cancer
for a Better Tomorrow™

Disclaimer and Forward-Looking Statements

We caution you that this presentation contains forward-looking statements about us and our industry. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene and any future product candidates, the timing and likelihood of regulatory filings and approvals for cretostimogene and any future product candidates, our ability to commercialize cretostimogene and any future product candidates, if approved, the potential that cretostimogine may be a best-in-disease product, if approved, the pricing and reimbursement of cretostimogene and any future product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and potential to enter into any future strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions.

The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in our business, including, without limitation: we currently depend entirely on the success of cretostimogene, which is our only product candidate and is based on a novel approach to the treatment of cancer; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; results from earlier clinical trials and preclinical studies not necessarily being predictive of future results; unfavorable results from clinical trials; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; preliminary or interim data results 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 more patient data become available; our dependence on third parties in connection with manufacturing, shipping and clinical and preclinical testing; regulatory developments in the United States and foreign countries; our ability to obtain, maintain and enforce intellectual property protection for cretostimogene; we may use our capital resources sooner than we expect; we face significant competition who may develop products which are more effective, safer, or less expensive than our product candidate; and other risks described in our filings with the SEC, including under the heading “Risk Factors” in our annual report on Form 10-K, our quarterly Form 10-Q 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 of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. 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.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

This presentation concerns products that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. It is currently limited by federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

Cretostimogene grenadenorepvec is an investigational engineered oncolytic immunotherapy (OIT). It is an investigational drug and is not approved by any regulatory agency. Its safety and efficacy has not been established. In BCG-unresponsive, Non-Muscle Invasive Bladder Cancer (NMIBC), cretostimogene has shown clinical benefit and has been generally well-tolerated as both a monotherapy and in combination with other therapies in clinical trials.

Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this presentation appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights to these trademarks and tradenames.

The Promise of Cretostimogene

Potential Best-in-Disease Durability and Efficacy Results

BOND-003 Cohort C (BCG UR CIS only)[1]:

76% CR anytime
46.4% (12-mo)
41.8% (24-mo)

BOND-003 Cohort P (BCG UR Papillary only)[2]

95.7% (3-mo) HG-EFS
84.6% (6-mo)
80.4% (9-mo)

CORE-008 Cohort A (BCG Naïve HR CIS)[2]

88% CR anytime

PIVOT-006 (Intermediate-Risk + HG Ta)[3]

68% improvement in RFS with hazard ratio **0.32 (p<0.0001)**

Potential Best-in-Disease Safety/Tolerability Results[4]

- Favorable safety & tolerable profile
- **0 Grade ≥ 3 TRAEs** or deaths reported
- Most AEs were Grade 1-2

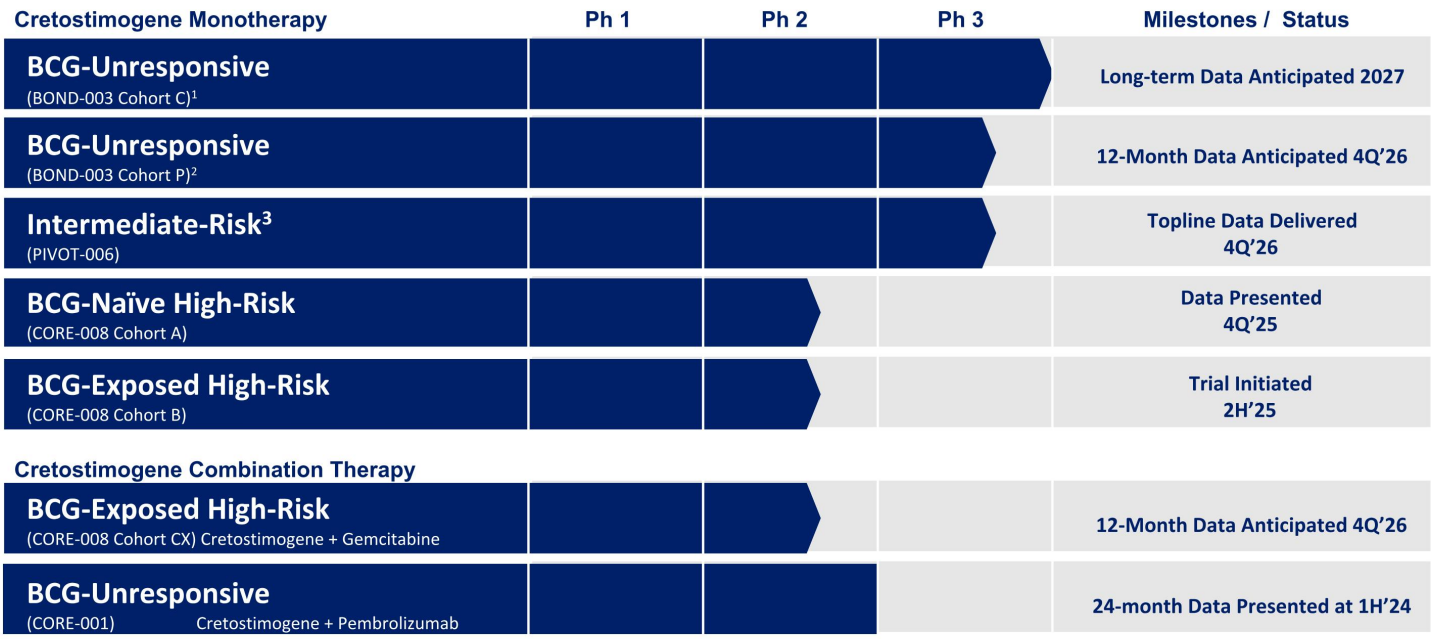
Regulatory Status & Commercial Readiness

- Breakthrough Therapy & Fast Track designations
- Current capacity: 40-50k vials/year; 10x scale-up process to support future indications underway
- Commercial prep activities ongoing - MSLs/HSDs, site / payor engagement
- Administered like BCG, seamlessly integrating into established clinical workflows without re-training
- Physicians in top key accounts treat >70% of NMIBC patients by volume

Dual MOA designed to selectively drive tumor killing & trigger durable anti-tumor immune response resulting in potential for best-in-disease profile across a broad range of NMIBC patients

TRAEs = Treatment-related adverse events; HR = high-risk; NMIBC = Non-muscle invasive bladder cancer; MSL = Medical science liaison; HSD = Health system directors; MOA = Mechanism of action. 1. Ph 3 registrational study in HR BCG-unresponsive NMIBC CIS 2. Data presented at SUO Annual Meeting Dec. 2025, data as of September 1, 2025 3. From PIVOT-006 topline data announced Nov. 2026. 4. Observed in clinical trials of cretostimogene including BOND-003, CORE-008 and PIVOT-006

Comprehensive Programs in High-Risk and Intermediate-Risk NMIBC to Address a Multi-Billion Dollar Market Opportunity

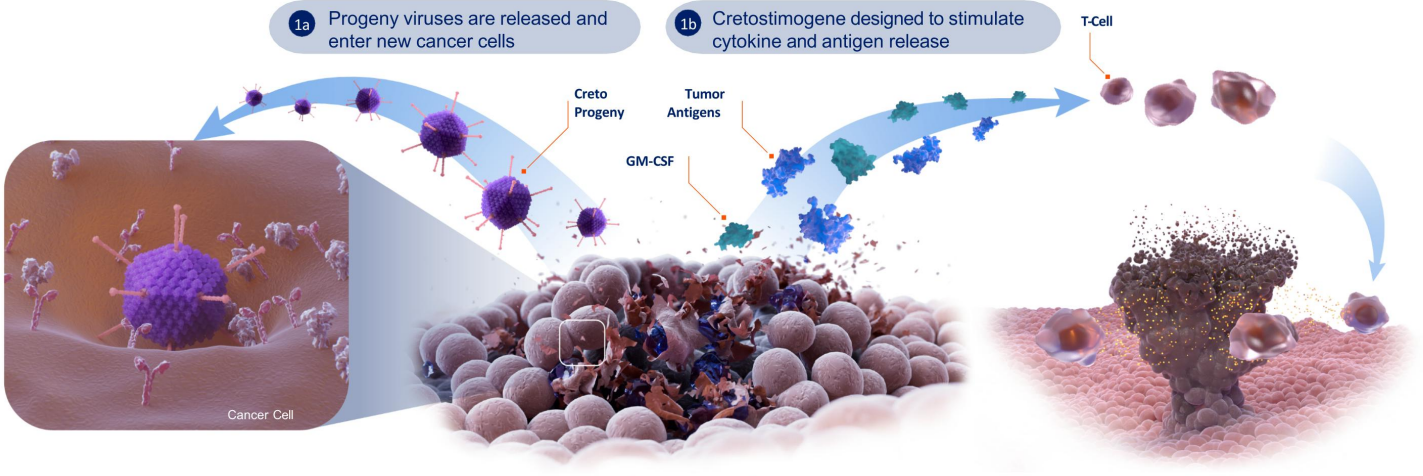


1 Patients with carcinoma in situ, with or without papillary disease. 2 Patients with papillary only. Cohort P is a Phase 2 cohort of BOND-003 and currently not intended for regulatory approval. 3 Includes HG Ta ≤ 3cm
Notes: Timing and achievement of milestone events are based on Company estimates and subject to risks and uncertainties. Actual results may be materially different than projected.

Cretostimogene's Dual Mechanism of Action: Selective Tumor Killing Triggers Durable Anti-Tumor Immune Response

1 **Cretostimogene designed to selectively replicate in and kill cancer cells**

2 **Immune cells attack and kill additional cancer cells**

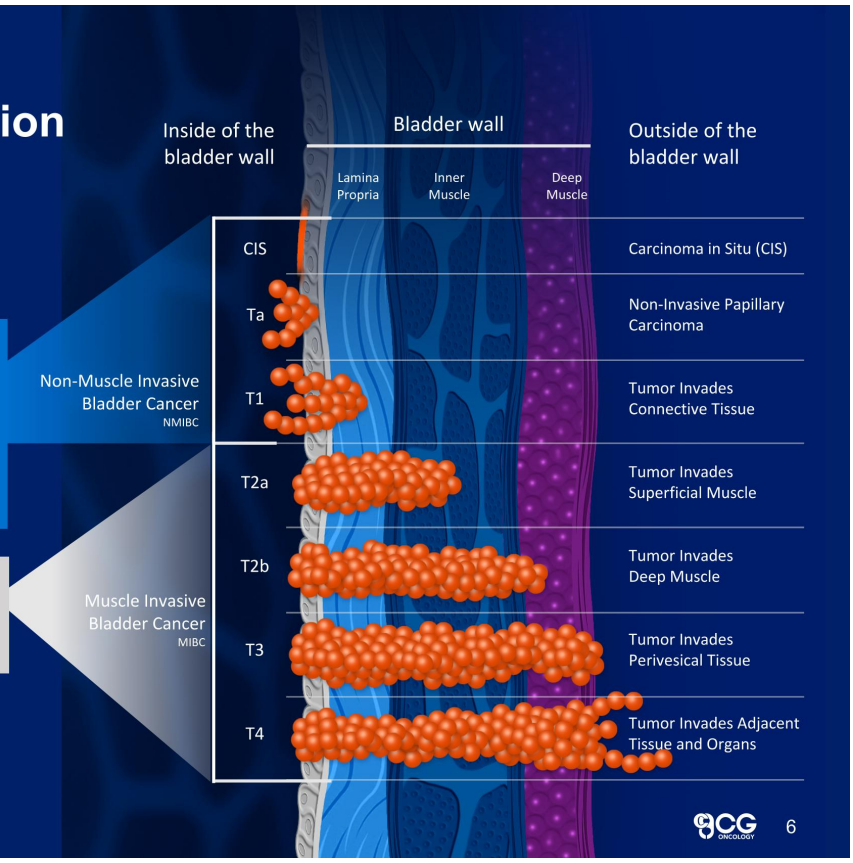


Oncolytic Immunotherapy

NMIBC Represents a Multi-Billion Dollar Market Opportunity in Bladder Cancer

~75% of Newly Diagnosed Bladder Cancer Cases are NMIBC

~25% of Newly Diagnosed Bladder Cancer Cases are MIBC



Cancer of the Urinary Bladder - Cancer Stat Facts. SEER. Chang et al 2016. J Urol. 196:1021-1029.

Patient Journey

1 Symptoms

Patient presents to primary care and/or urologist with symptoms (hematuria, urinary frequency)

2 Testing

Work-up may include cystoscopy, urine cytology, and imaging (CT scan, MRI)

Suspicion of Cancer

3 TURBT[1]

TURBT, followed by tumor staging and grading



4 Ongoing Treatment

Require surveillance and/or treatment every 3 to 6 months for 2 to 5 years

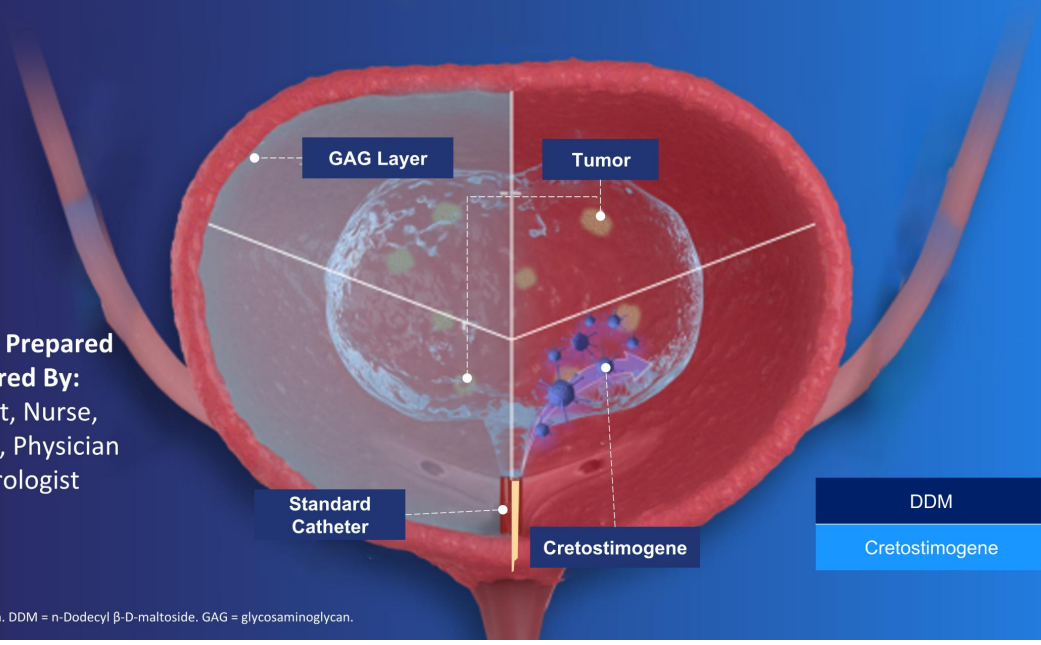
NMIBC

Low-Risk	Intermediate-Risk	High-Risk
TURBT	TURBT	Intravesical BCG (Induction ± Maintenance)
Perioperative Chemotherapy	Perioperative Chemotherapy	Intravesical Chemotherapy
	Intravesical BCG[2]	Cystectomy
		Pembrolizumab, Nadofaragene, N-803 + BCG, TAR-200

[1] TURBT = Transurethral Resection of Bladder Tumor.
[2] Due to BCG shortage, NCCN guidelines no longer recommend BCG therapy for Intermediate-Risk patients.

Note: Per NCCN guidelines, management of High-Risk NMIBC involves cystoscopy (Q3M for Year 1-2, Q6M for Year 3-5), upper tract imaging (baseline imaging and at Year 1, Q1-2Y for Year 3-5), abdomen/pelvis imaging (baseline imaging and as clinically indicated), and urine cytology (Q3M for Year 1-2, Q6M for Year 3-5). Biopsy is conducted during staging and for confirmation of disease when urine cytology is positive or presence of suspicious lesions.

Cretostimogene is Intravesically Administered into the Bladder, Similar to Standard-of-Care BCG Therapy Which Urology Practices Perform Regularly



Procedure Can Be Prepared and Administered By:
Medical Assistant, Nurse, Nurse Practitioner, Physician Assistant, or Urologist

DDM	**~15 minutes**
Cretostimogene	~45 to 60 minutes

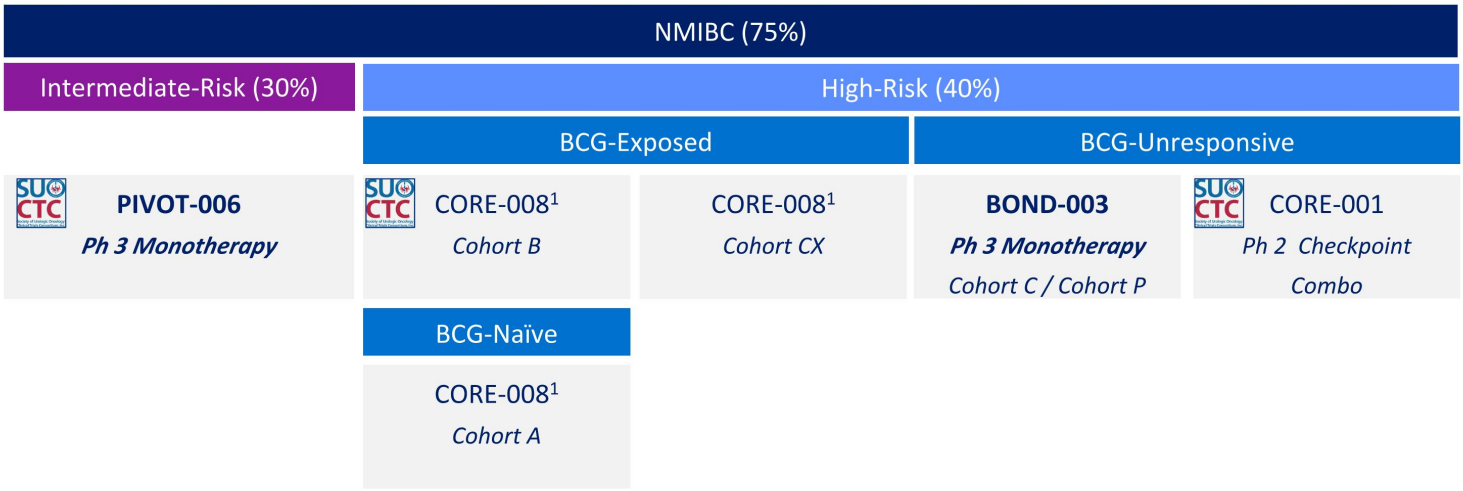
BCG = Bacillus Calmette Guerin. DDM = n-Dodecyl β-D-maltoside. GAG = glycosaminoglycan.

Cretostimogene Programs Across High-Risk & Intermediate-Risk NMIBC Potential to Address More Than 70% of NMIBC Market

85K+ Bladder Cancer (U.S. Incidence)

730K+ Bladder Cancer (U.S. Prevalence)

75% NMIBC



Note: CORE-001, CORE-008 Cohort B, and PIVOT-006 are in partnership with SUO-CTC. [1] CORE-008 is a multi-cohort study evaluating cretostimogene in High-Risk NMIBC.
NMIBC = Non-muscle invasive bladder cancer

BOND-003

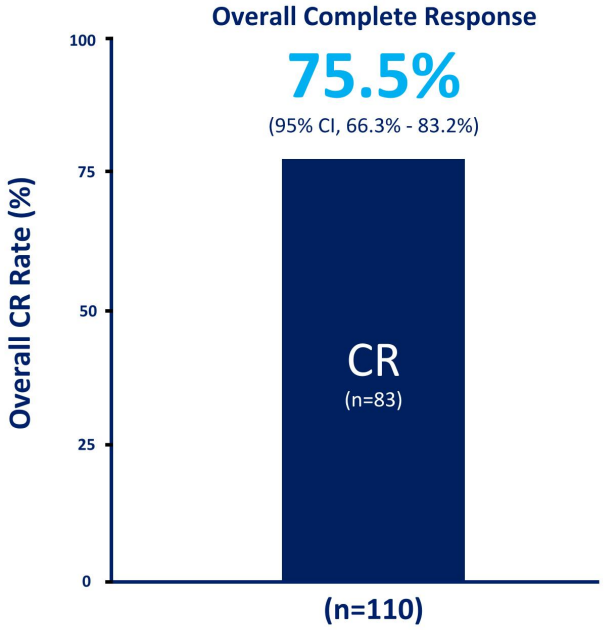
Phase 3 Cretostimogene Monotherapy for BCG-Unresponsive NMIBC (NCT04452591)

BCG-Unresponsive NMIBC	Cretostimogene Single-Arm, Open-Label, Intravesical Administration	CR at Any Time (CIS) EFS (Ta/T1)
Trial Design	**Study Design / Regimen**	**Additional Endpoints**
▪ Pathologically confirmed BCG-Unresponsive CIS or HG Ta/T1 ▪ Have all Ta/T1 disease resected prior to treatment ▪ Trial designed to be compliant with 2018 FDA guidance ▪ Mandatory bladder mapping at 12-mos[2]	▪ Cohort C = BCG-unresponsive CIS with or without Ta/T1 (n=112) Induction course = Weekly x 6 (1×10^{12} vp) ○ Second induction course[1] = Weekly x 6 for non-responders ○ Maintenance courses = Weekly x 3 for complete responders every 3 mos for first 12 mos, every 6 mos for next 24 mos ▪ Cohort P = BCG-unresponsive HG Ta/T1 without CIS (n=54) ○ Same as Cohort C	▪ Cohort C ○ DoR ○ CR at 12 months ○ PFS ▪ Cohort P ○ RFS ○ PFS

RFS = recurrence free survival. PFS = progression free survival. Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years, as well as mandatory bladder mapping at month 12. [1] Second induction course of weekly x 6 for non-responders at month 3. [2] All patients required to undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR.

BOND-003
Cohort C

Cretostimogene Demonstrated Favorable Efficacy and Durability Data in NMIBC



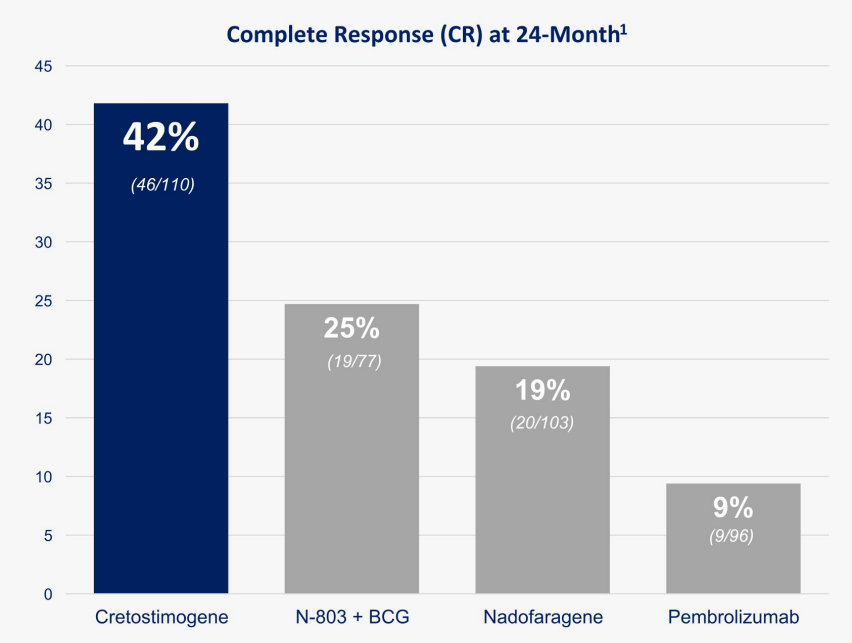
CR Landmark Analysis	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46.4%** (36.8-56.2) *51/110 patients*	**50.7%** (40.9, 59.8)
24-month	**41.8%** (32.5, 51.6)[1] *46/110 patients*	**42.4%** (32.7-51.7%)

- 96.4% treated patients progression-free to MIBC at 24 months
- 81.2% cystectomy-free survival rate at Month 24
  - Among RCs, 83.3% (15/18) were T0 or NMIBC
- All complete responses have been centrally confirmed[2]

Efficacy data cutoff as of June 23, 2025. Efficacy analysis are centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance.
[1] Based on centrally confirmed responders who have reached 24-month evaluation timepoint.All 9 ongoing CRs remained in response at the 24-month assessment, as well as 3 additional patients confirmed to be in CR at Month 24 after further follow-up and central pathologic adjudication.[2] A CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy. In addition, all patients at 12-month timepoint undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR and detect potential occult disease in the bladder.

Cretostimogene

Cretostimogene Has Delivered Remarkable Complete Response (CR) Rate at 24 Months



Note: These data are not based on head-to-head or comparator studies. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

1. Compared to approved drugs with publicly available observed 24-Month CR data. From published data.

- Cretostimogene demonstrated long-term DoR compared to approved drugs[1] in NMIBC with **41.8% of patients in CR at 24 months**
- **90%** of patients in CR at 12 months **maintained in CR at 24 months**
- **No grade 3+ TRAEs** – favorable safety and tolerability results

CIS with or without Ta/T1

Cretostimogene is Well Positioned as Backbone Therapy in NMIBC with Potential Best-in-Disease Durability & Safety in BCG-UR [1]

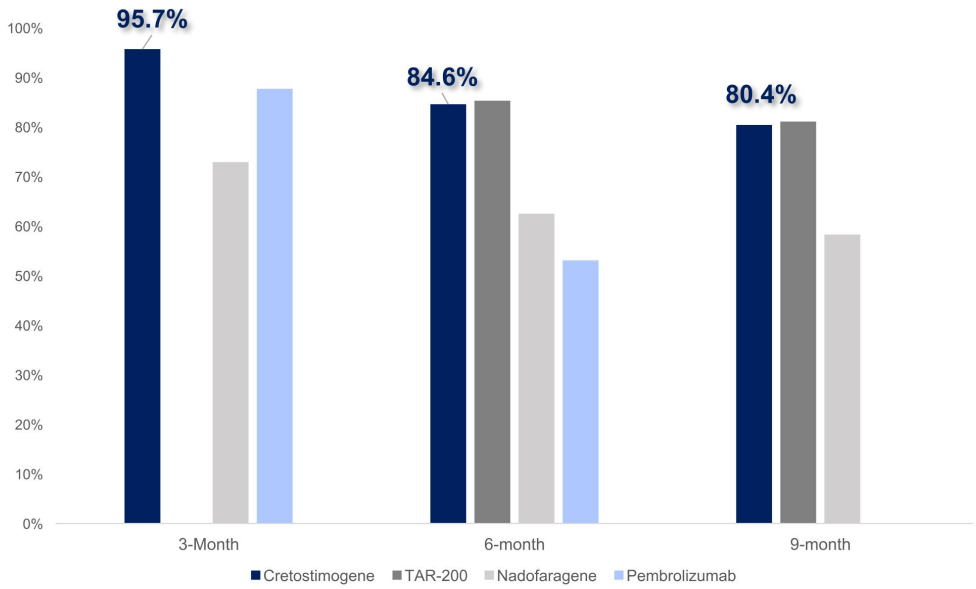
Trial (Status)	BOND-003 COHORT C (Ph3 Ongoing)	SunRISe-1 (Approved)	QUILT 3.032 (Approved)	NCT02773849 (Approved)	KEYNOTE-057 (Approved)
Drug	Cretostimogene	TAR-200	N-803 + BCG	Nadofaragene	Pembrolizumab
Mechanism	Oncolytic Immunotherapy	Gemcitabine via In-Dwelling Device	IL-15 Superagonist + BCG combo	Gene Therapy Secreting IFN	Checkpoint Inhibitor
RoA	Intravesical	Transurethral Procedure	Intravesical	Intravesical	Intravenous
Efficacy Population	110	83	77	98	96
CR at Any Time	**75.5% (83/110)** *[95% CI: 66% - 83%]*	82.4% (70/83) *[95% CI: 73% - 90%]*	62.3% (48/77) *[95% CI: 51% - 73%]*	51.0% (50/98)[5] *[95% CI: 41% - 61%]*	40.6% (39/96) *[95% CI: 31% - 51%]*
CR at 12 Mo	**46.4% (51/110)** *[95% CI: 37% - 56%]*	K-M: 45.9% (39/83)	36.4% (28/77)[4]	24.3% (25/103)	18.8% (18/96)
CR at 24 Mo	***41.8% (46/110)***[2] *[95% CI: 33% - 52%]*	Not Reported	24.7% (19/77)[4]	19.4% (20/103)	9.4% (9/96)[6]
12M DOR	**K-M: 64.2%** *[95% CI: 52% - 74%]*	Observed: 52.9% K-M: 56.2%	58%	46%	46%
24M DOR	**K-M: 60.1%** *[95% CI: 48% - 70%]*	K-M: 51.8%	40%	Not Reported	Not Reported
Free from Progression to MIBC	**96.4% at 24 month**	94.3%	90%	94%	89%
Cystectomy Free Survival	**89.2% at 12 month** **81.3% at 24 month**[3]	86.6% at 12 month[3]	59%[3]	64% at 24-month	84%
Median Time to AE Resolution	**1 Day**	3.1 weeks	Not Reported	Not Reported	Not Reported
Grade 3+ TRAE	**0%**	13%	Not reported; 16% SAE	4%	13%
TR discontinuation	**0%**	3.5%	7%	3%	11%

[1] These data are not based on head-to-head or comparator studies. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies. From published data.[2] All 9 ongoing CRs remained in response at the 24-month assessment, as well as 3 additional patients confirmed to be in CR at Month 24 after further follow-up and central pathologic adjudication. [3] CFS in responders. [4] Derived from ANKTIVA® plus BCG Package Insert (April 2024) using DOR ≥ 12 months and DOR ≥ 24 months to estimate 12 months and 24 months landmark CR rate. [5] ADSTILADRIN® Package Insert (December 2022) and Summary Basis for Regulatory Action. [6] Derived from GU ASCO 2021, Balar et al presentation DOR ≥ 24 months to estimate 24-months landmark CR. References: Merck: (FDA & ODAC presentation slides, NDA/BLA# 125514s-066 for pembrolizumab (https://www.fda.gov/media/133956/download), Balar, AB et al. Lancet Onc. Epub ahead of print. 2021 May 26.; 2021 ASCO GU presentation); FerGene: (Boorjian et al. Lancet Oncol. 2021 Jan;22(1):107-117. Epub 2020 Nov 27) (Narayan et al. Journal of Urology. April 2024 doi:10.1097/JU.0000000000004020). ImmunityBio (ANKTIVA® plus BCG Package Insert; FDA Approval Letter). Janssen (SunRISe-1 – ESMO 2024; Daneshmand et al. Journal of Clinical Oncology. July 24, 2025). CG Oncology (BOND-003 – SUO 2024 and NE AUA 2025; CORE-001 – ASCO 2024).

BOND-003
Cohort P

BCG-Unresponsive Papillary (HG Ta/T1) Patients

Creto High-Grade Event-Free Survival (HG-EFS) vs. DFS/RFS (by K-M) [1]



- BOND-003 Cohort P reported 95.7%, 84.6% and 80.4% HG Event-Free Survival (EFS) at 3, 6 and 9 months, respectively
- No serious treatment-related adverse events (TRAEs) and no discontinuations related to cretostimogene
- No dose delays, missed doses due to TRAEs
- 0% Grade ≥ 3 TRAEs, Serious TRAE, deaths

Note: These data are not based on head-to-head or comparator studies. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

1. Compared to approved drugs with publicly available EFS by K-M From published data.

Papillary Only (HG Ta/T1)

Cretostimogene is Well Positioned in BCG-UR Papillary Only NMIBC with Potentially Best-in-Disease EFS Endpoint[1]

Trial (Status)	BOND-003 COHORT P (Ph3 Ongoing)[1]	SunRISe-1[2]	QUILT 3.032[3]	NCT02773849[4,5]	KEYNOTE-057[6]
Drug	Cretostimogene	TAR-200	N-803 + BCG	Nadofaragene	Pembrolizumab
Mechanism	Oncolytic Immunotherapy	Gemcitabine via In-Dwelling Device	IL-15 Superagonist + BCG combo	Gene Therapy Secreting IFN	Checkpoint Inhibitor
RoA	Intravesical	Transurethral Procedure	Intravesical	Intravesical	Intravenous
Efficacy Population	N=54	N=52	N=72	N=50	N=132
EFS/DFS/HG-RFS					
3 month	**95.7 [95% CI: 83.8, 98.9]**	Not Reported	92.8% [95% CI]*	72.9 [95% CI: 58.2-84.7]	87.7 [95% CI: 80.7-92.3]
6 month	**84.6 [95% CI: 68.6, 92.9]**	85.3 [95% CI: 71.6-92.7]	75.9% [95% CI]*	62.5 [95% CI: 47.4-76.0]	53.1 [95% CI: 44.1-61.2]
9 month	**80.4 [95% CI: 62.3, 90.4]**	81.1 [95% CI: 66.7- 89.7]	Not Reported	58.3 [95% CI: 43.2–72.4]	Not Reported
12 month	**Not Yet Reached**	70.2% [95% CI: 59.2-84.6]	55.4 [95% CI: 42.0-66.8]	43.8 [95% CI: 29.5-58.8]	43.5 [95% CI: 34.9-51.9]
24 month	**Not Yet Reached**	Not Reported	48.3 [95% CI: 34.5-60.7]	33.3 [95% CI: 20.4-48.4]	34.9 [95% CI: 26.4-43.4]
Safety					
Grade 3+ TRAE	**0 (0%)**	13.5%	Not Reported	4%	14%
TR discontinuation	**0 (0%)**	7.7%	7%	3%	11%
SAEs	**0 (0%)**	5.8% including sepsis, spinal fracture (procedure related), and UTI	16%**	11%	13%

Note: These data are not based on head-to-head or comparator studies. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies. 1. SUO 2025 Annual Meeting; 2. JCO - https://doi.org/10.1200/JCO-25-01651 Phase IIb SunRISe-1 study and SUO 2025 Annual Meeting presentation ; 3. Chamie K, et al. NEJM Evid. 2023; 2(1):EVIDoa2200167 *estimated from subsequent landmark reports; **SAEs are combined across multiple cohorts as listed in package insert; 4. Boorjian S, et al. Lancet Oncology. 2021; 22(1):107-117. 5. Narayan VM, et al. J Urol. 2024;212(1):74-86; 6. Necchi A, et al. Lancet Oncology. 2024; 25(6):720-730.

PIVOT-006

Ph 3 Adjuvant Cretostimogene for IR NMIBC, Enrollment Completed Ahead of Schedule in Broad Population of IR NMIBC Patients

Intermediate-Risk (IR) NMIBC (Enrollment Completed)	Cretostimogene vs Surveillance/TURBT Randomized (1:1), Two Arms, Open-Label (n=367)	**Primary Endpoint:** RFS Rate
Population	**Study Design / Regimen**	**Additional Endpoints**

- Pathologically confirmed IR per AUA/SUO Guidelines*
  - Recurrent LG Ta < 12mo
  - Solitary LG Ta > 3cm
  - LG Ta multifocal
  - **Solitary HG Ta ≤ 3cm**
  - LG T1
- All disease removed by TURBT at baseline

- Arm A: Cretostimogene following TURBT
  - Induction course = Weekly x 6 (1×10^{12} vp)
  - Maintenance courses[1] = Weekly x 3 (1×10^{12} vp) for complete responders
- Arm B: Surveillance following TURBT
  - Patients with disease recurrence eligible to receive cretostimogene

- RFS at 12-month and 24-month
- PFS
- Safety

RFS = recurrence free survival. PFS = progression free survival. *Guidelines at the time of enrollment and study start
Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years; mandatory, site-directed biopsy at month 12.
[1] Maintenance course for complete responders weekly x 3 at month 3 and month 6, and once every 3 months at month 9 and month 12.

Intermediate-Risk Landscape

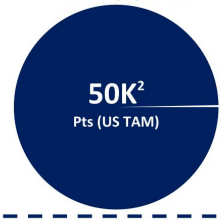
PIVOT-006 Designed to Evaluate Cretostimogene in a Broad Patient Population Across Intermediate-Risk (IR) NMIBC

	Cretostimogene (PIVOT-006) (investigational)	TAR-210 (MoonRIse-1) (investigational)	UGN-102 (Approved)
IR NMIBC LG Newly Diagnosed	●	●	
IR NMIBC LG Recurrent	●	●	✓
HG Ta ≤3cm (solitary)	●		
Adjuvant (non-chemoablative)	●	●	

● = under development for indication
✓ = FDA approved indication

PIVOT-006 Ph 3 Trial

Study designed to enroll:
- All intermediate-risk patients
- First Ph 3 randomized trial in broad IR NMIBC population[1]



MoonRIse-1 Ph 3 Trial

Study not designed to enroll:
- Solitary HG Ta ≤3cm
- FGFR wildtype

Prescribing Information[3]

Not indicated for:
- Solitary HG Ta ≤3cm
- Newly diagnosed LG

1. PIVOT-006 is the first Ph 3 randomized trial in this patient population, encompassing the broadest range of patient types per AUA/SUO Guidelines including HG Ta solitary lesions <3cm. 2. NIH SEER secondary claims data analytics, and management assumptions. 3. Indicated for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)

PIVOT-006

Cretostimogene Significantly Improved Recurrence-Free Survival (RFS) in Intermediate-Risk and **HG Ta NMIBC**

68% Improvement in RFS

0.32 **Hazard Ratio**

95% CI 0.23–0.45 | p<0.0001

- **No Grade ≥3 treatment-related adverse events**
- **No treatment-related discontinuations**
- **PIVOT-006 topline results to be presented as a late-breaking podium presentation at SUO on December 2, 2026**
- **PIVOT-006 data will support a second BLA submission in intermediate-risk and high-grade Ta NMIBC anticipated in Q2 2027**

The median follow-up was 17 months at the time of data cutoff Oct. 26,2026. Recurrence was dated to the first evaluable assessment documenting recurrence. Participants were censored at randomization if no evaluable post-randomization assessment was available; otherwise, censoring occurred at the last evaluable recurrence-free assessment for no recurrence, death, or recurrence/death following ≥1 missed or nonevaluable assessment, and before initiation of new anticancer therapy. Death was not considered an RFS event. CI, confidence interval; HG, high-grade; HR, hazard ratio; NMIBC, non-muscle invasive bladder cancer

CORE-008
Cohort CX

Ph 2 Cretostimogene in Combination for BCG-Exposed HR & BCG-Unresponsive NMIBC (Cohort CX)

HR BCG-Exposed & BCG Unresponsive NMIBC	Cretostimogene + Gemcitabine 1:1 Randomized, Two Arm, Open-Label	**Primary Endpoint:** HG-EFS
Population	**Study Design / Regimen**	**Additional Endpoints**

- Pathologically confirmed BCG-exposed HR & BCG-UR
  - Persistent or recurrent HG Ta or CIS at first evaluation after adequate BCG dose
  - HG recurrence outside of BCG-UR window within 24 mos after last adequate BCG dose
  - HG recurrence within 24 mos after last inadequate BCG dose

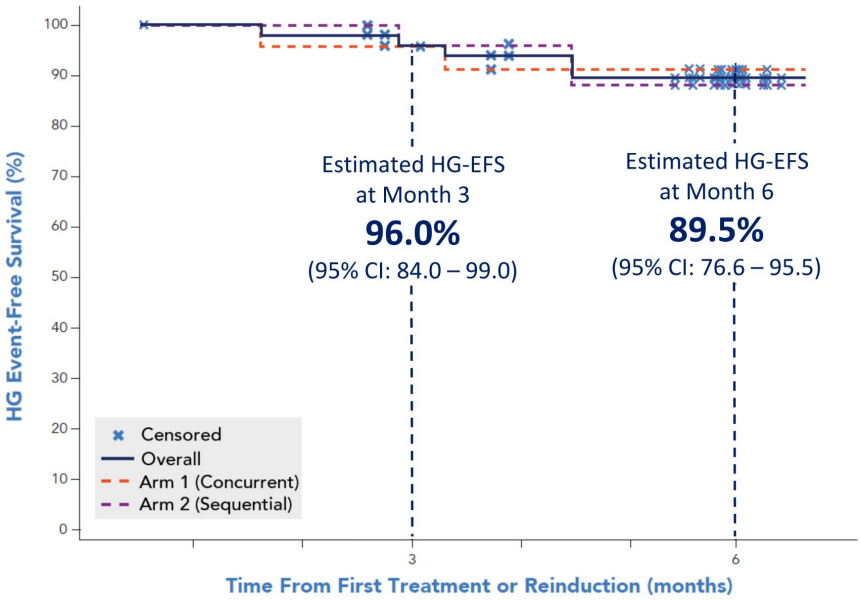
- Cohort CX (CIS-containing or HG Ta/T1)
  - Arm 1 = cretostimogene + gemcitabine (concurrent)
  - Arm 2 = cretostimogene + gemcitabine (sequential)
  - Standard weekly x 6 induction, reinduction and weekly x 3 maintenance until Year 3[1]

- CR at any time
- CR at 12 months
- DoR
- PFS
- CFS

HR = high risk. HG = high grade. LG = low grade. DoR = duration of response. EFS = event free survival. RFS = recurrence free survival. PFS = progression free survival. CFS = cystectomy free survival. Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years

[1] Second induction course of weekly x 6 for non-responders at month 3. Maintenance course for complete responders weekly x 3 every 3 months in Year 1, and every 6 months in Year 2 and Year 3.

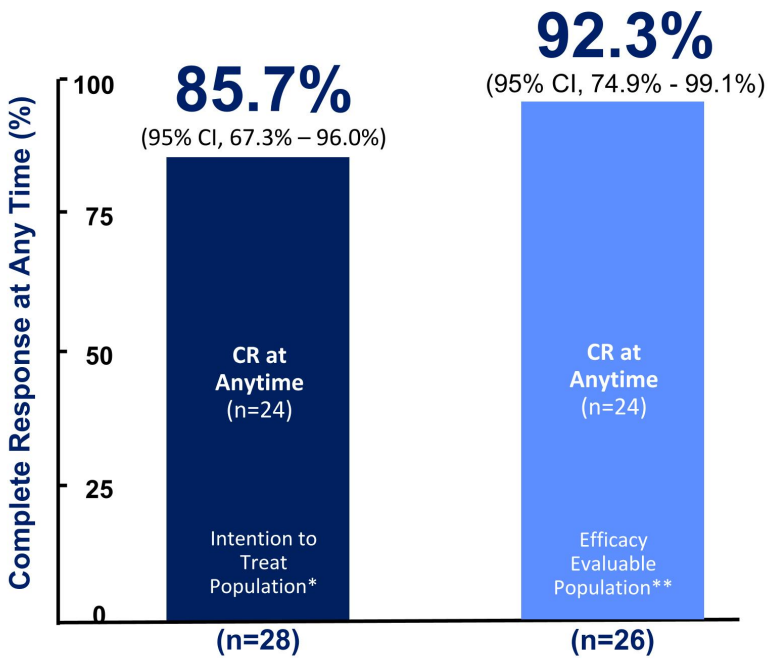
CORE-008 Cohort CX High-Grade Event-Free Survival at 3 and 6-Months (ITT Population)



- **Median follow-up: 6.6 months**
- **No significant differences in HG-EFS by arm**
- **Consistent response among BCG-UR and BCG-exposed subgroups**

BCG-UR= BCG-Unresponsive; CIS= Carcinoma in Situ; HG-EFS= High-Grade Event-Free Survival; MIBC= Muscle Invasive Bladder Cancer; mUC= Metastatic Urothelial Carcinoma; HG-EFS defined as high-grade recurrence/persistence, progression to T1, progression to T2+ and death from any cause; Efficacy data cutoff as of 13MAR2026; Efficacy assessments based on local pathology review; HG-EFS presented in intention to treat (ITT) population representative of all patients randomized on CORE-008 Cohort CX (Arm 1/Concurrent; Arm 2/Sequential); Two patients with CIS at baseline were found with HGT1 at Month 6.

CORE-008 Cohort CX High Complete Response Rates Observed Within CIS-Containing Population



- Includes BCG-Exposed and BCG-Unresponsive patients
- **0% Grade ≥ 3 TRAEs, SAEs or deaths**
- 85.5% (47/55) completed all protocol-defined treatments
  - Arm 1 (Concurrent)- 71.4% (20/28)
  - Arm 2 (Sequential)- 100% (27/27)
- **No patients discontinued on Arm 2 (sequential) due to TRAE**
  - 4 patients withdrew from Arm 1 (concurrent) for persistent grade 1-2 localized TRAEs
- No difference in the proportion of patients with AEs between arms

CIS= Carcinoma in Situ; CR=Complete Response; CR defined as having negative cystoscopy, urine cytology, and biopsy (as indicated). Efficacy data cutoff as of 13MAR2026. Efficacy assessments based on local pathology review. * Intention to treatment (ITT) population includes all participants who are randomized in Cohort CX (Arm 1/Concurrent; Arm 2/Sequential).
** Efficacy evaluable population includes patients who have received at least four doses of cretostimogene, meet the definition of BCG-Unresponsive/BCG-Exposed and have completed a protocol-defined efficacy assessment at Month 3

CORE-008
Cohort A & B

Phase 2 Cretostimogene Monotherapy for BCG-Naïve High-Risk (HR) and BCG-Exposed HR NMIBC (Cohort A and B)

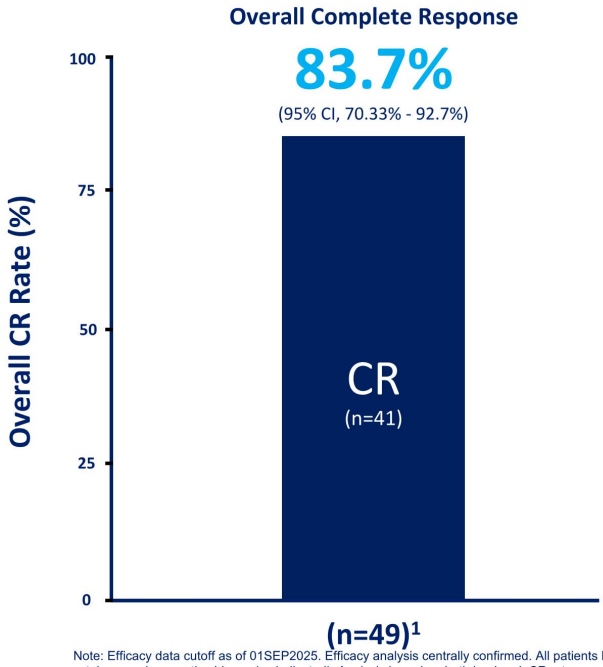
BCG-Naïve & BCG-Exposed (Actively Enrolling) → **Cretostimogene** Two Cohorts (A and B), Two Arms Each, Open-Label → **Primary Endpoint:** CR Rate; HG-EFS[2]

Population	Study Design / Regimen	Additional Endpoints
▪ Cohort A ○ Pathologically confirmed BCG-naïve HR NMIBC ○ No prior treatment with BCG within past 24 months ▪ Cohort B ○ Pathologically confirmed BCG-exposed HR NMIBC ○ Recurrence within 24 months after last adequate BCG dose	▪ Cohort A (BCG-naïve HR NMIBC) ○ CIS ± HG Ta/T1 (n=~50) ○ HG Ta/T1 only (n=~75) ○ Standard weekly x 6 induction, reinduction and weekly x 3 maintenance until Year 3[1] ▪ Cohort B (BCG-exposed HR NMIBC) ○ CIS ± HG Ta/T1 (n=~75) ○ HG Ta/T1 only (n=~75) ○ Standard dosing as above[1]	▪ Cohort A ○ DoR (in CIS) ○ EFS, LG-RFS, CFS ▪ Cohort B ○ DoR (in CIS) ○ EFS, LG-RFS, CFS

HR = high-risk. HG = high grade. LG = low grade. DoR = duration of response. EFS = event free survival. RFS = recurrence free survival. PFS = progression free survival. CFS = cystectomy free survival. Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years; mandatory, site-directed biopsy at month 12.
1. Second induction course of weekly x 6 for non-responders at month 3. Maintenance course for complete responders weekly x 3 every 3 months in Year 1, and every 6 months in Year 2 and Year 3. 2. CIS (CR Rate) and HG Ta/T1 (HG-EFS)

CORE-008 Cohort A

High Initial Response Rates from CORE-008 Cohort A



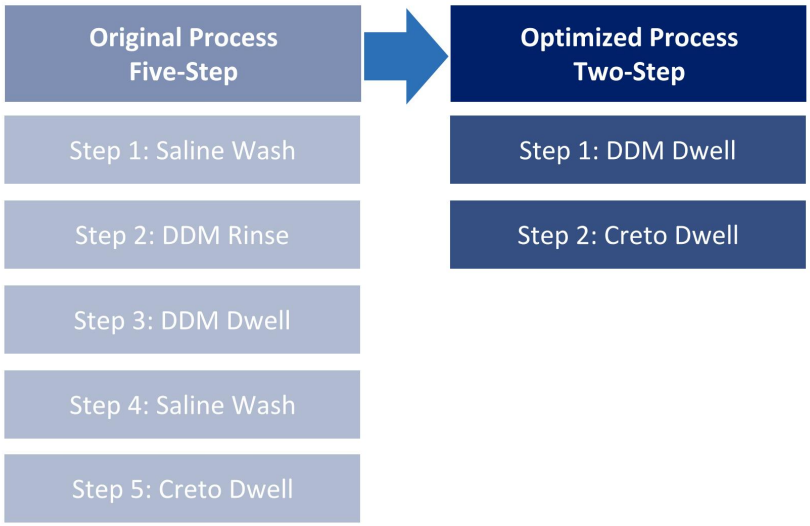
CR Landmark Analysis	CR Rate, % (95% CI)
Original Instillation[2] *(5-step)*	**79.2%** (57.8, 92.9) *19 out of 24 patients*
Optimized Instillation[3] *(2-step)*	**88.0%** (68.8, 97.5)[1] *22 out of 25 patients*

- **0% Grade ≥ 3 TRAEs, SAEs or deaths**
- **No treatment related discontinuations**
- No patients required radical cystectomy
- No treatment-related progression to MIBC or mUC

Note: Efficacy data cutoff as of 01SEP2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior tœnrollment. A CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy (as indicated). Analysis based on both landmark CR rate assessed in clinical trial and DoR by Kaplan-Meier estimate.[1] 49 patients were assessed for efficacy at the time of data cutoff. 4 re-induced patients are pending 6-month assessments.[2] Original instillation included 5-step instillation with series of bladder saline washes followed by DDM and cretostimogene instillations.[3] Optimized instillation streamlined the process to 2-steps inclusive of DDM followed by cretostimogene instillations.

Optimized Instillation

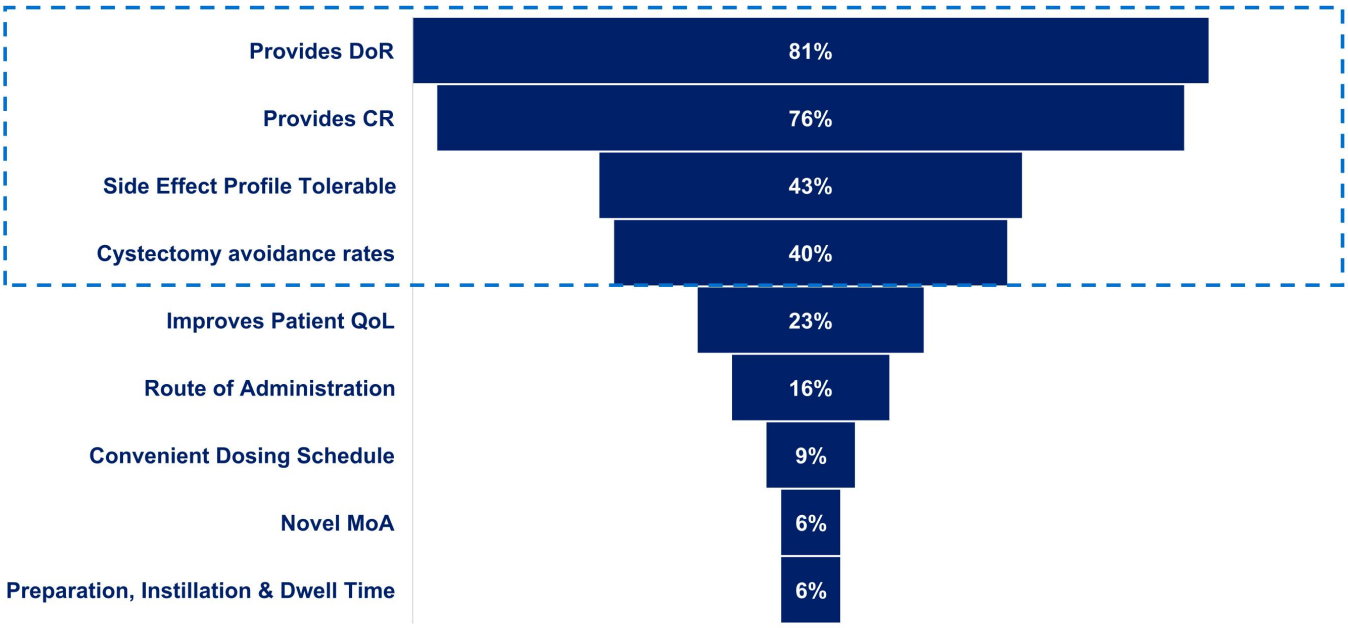
Advancing Cretostimogene to Optimized Instillation



- Cohort A data supports optimized instillation
- Potential meaningful benefit to patients and sites (esp. high-volume centers) with estimated ~20-minute time savings
- Administered via soft catheter by medical assistant, **a urologist or MD does not have to be involved in process**
- **Seamless transition** for BCG sites, seamless integration into established clinical workflows without re-training
- Closed System Drug Transfer Devices (CSTD) enables direct vial>syringe>bladder delivery
- All studies beyond BOND-003 Cohort C use optimized instillation protocol

~25% Time Savings | 3 Steps Eliminated | Improved Benefit to Site & Patient

Key Clinical Metrics Driving HCP Treatment Decisions in BCG-Unresponsive NMIBC*



*Market Research across ~100 US HCPs (n=46 urologists, n=54 uro-oncologists), Survey was fielded Nov-Dec 2025
Chart represents percentages ranking as top 3 factors that drive treatment decisions

CG is Building a Capital-Efficient, High-Touch Approach in Anticipation of a Successful Launch Across a Concentrated Prescriber Network

Field Organization

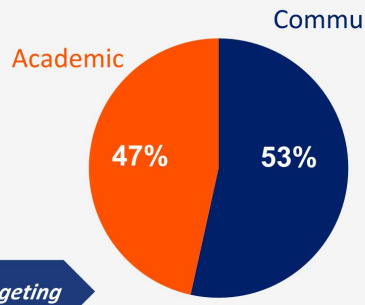
<75
field team



Key Account Managers
Health System Directors
Regional Business Directors
National Account Leads
Medical Science Liaisons
Field Reimbursement Managers

Targeting

Sites



Leading urology center network represent >70% of the **market opportunity** by volume

Reaching

Prescribers



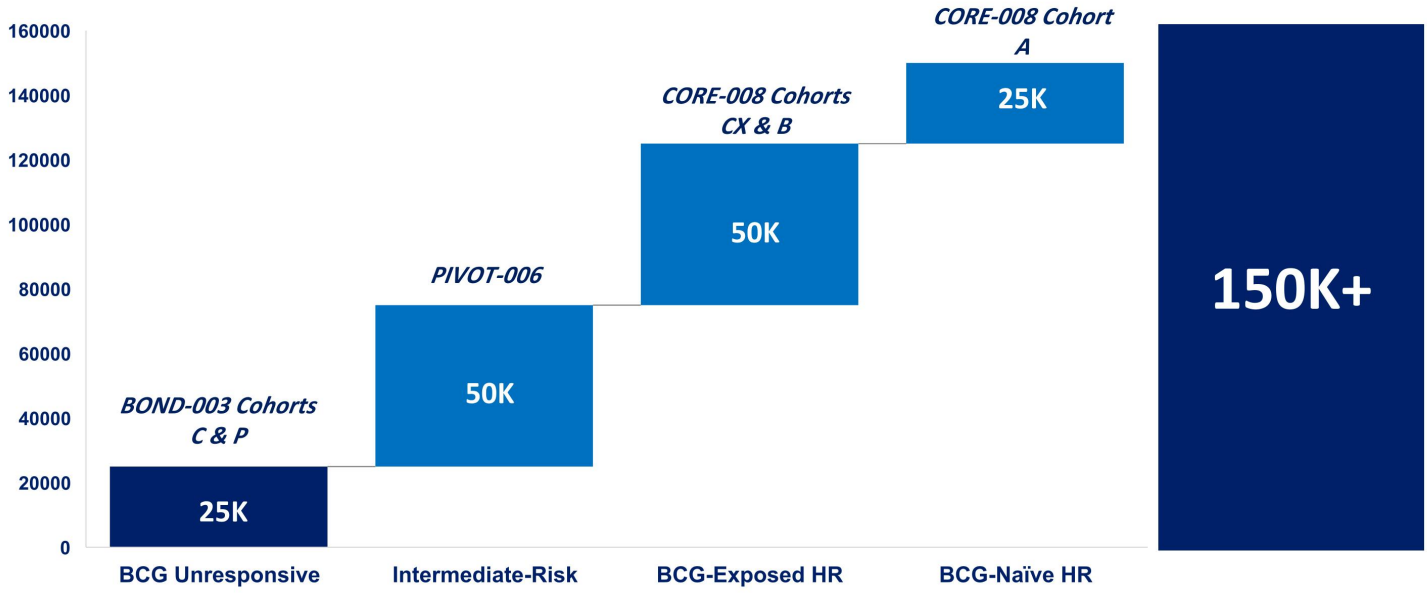
Physicians Treating NMIBC Patients

Top decile (~10 network urology centers) alone account for ~10% of national volume

Community (LUGPA, Independent) | **Academic** (Health Systems, Federal, Comprehensive Care)

The Path to 150K+ Addressable Patients

Annualized WAC of approved therapies in HR NMIBC range from $200K to $690K



NMIBC = Non-muscle invasive bladder cancer; HR = high-risk; IR = Intermediate-risk + HG Ta ≤ 3cm
TAM derived from NIH SEER, secondary claims data analytics, and management assumptions

Anticipated Milestones*

Catalyst Rich Calendar Through Potential First Approval and Launch Followed by Potential Frontline Bladder Indication Expansion

Program	2025	2026*	2027*
High Risk (HR) NMIBC	☑ BOND-003 Cohort C BCG-UR Long-Term Durability Data	☑ CORE-008 Cohort CX BCG-Exp. Topline Data (Creto + Gem)	Completion of BLA Submission BCG-UR (1st Indication)[1]
	☑ BOND-003 Cohort P BCG-UR Topline Data	CORE-008 Cohort CX BCG-Exposed Durability Data	CORE-008 Cohort A BCG-Naïve Durability Data
	☑ CORE-008 Cohort A BCG-Naive Data*	BOND-003 Cohort P BCG-UR Durability Data	Initiation of BCG-Exposed Ph 3 Trial
	☑ Initiation of Cretostimogene BLA Submission		BOND-003 Cohort C BCG-UR Long-Term Data
Intermediate Risk (IR) NMIBC	☑ PIVOT-006 Enrollment Completed	☑ PIVOT-006 Topline Data	Completion of BLA Submission (2nd Indication)

Clinical Regulatory

BCG-UR = BCG-unresponsive. *Note: Timing and achievement of milestone events are based on Company estimates and subject to risks and uncertainties. Actual results may be materially different than projected. 1. BCG-unresponsive NMIBC indication expansion to now include high-grade papillary-only disease

CG ONCOLOGY

Attacking Bladder Cancer for a Better Tomorrow™



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Leadership with Deep Industry Experience with Track Record of Success in Drug Development and Commercialization



Arthur Kuan
Chairman, President & Chief Executive Officer

- 13 years of expertise within the NMIBC space
- 2020 Forbes 30 Under 30 featured honoree in healthcare



Swapnil Bhargava, Ph.D.
Chief Technical Officer

- Supported multiple INDs, BLAs, and modalities to the clinic and market (TIVDAK®, PADCEV®, and ADCETRIS®)



Jim DeTore
Chief Financial Officer

- 30+ years of life sciences expertise
- Raised over a billion dollars in equity capital



Vijay Kasturi, M.D.
Chief Medical Officer

- 25+ years as GU Medical Oncologist
- Managed launch plan for BAVENCIO® and FOTIVDA®



Isabel Kalofonos
Chief Commercial Officer

- 20+ years driving launches and commercial execution
- Led launches of ELAHERE®, PALSONIFY™ and TAKHZYRO®



Josh Patterson, Esq.
General Counsel & CCO

- 25 years as in-house counsel in biopharmaceutical industry
- Over $2.25B in transaction experience

Our Vision

We see a world where urologic cancer patients can benefit from our innovative immunotherapies to live with dignity and have an enhanced quality of life.

Our Mission

We are focused on developing bladder-sparing therapeutics for patients afflicted with bladder cancer.

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Attacking Bladder Cancer for a Better Tomorrow™