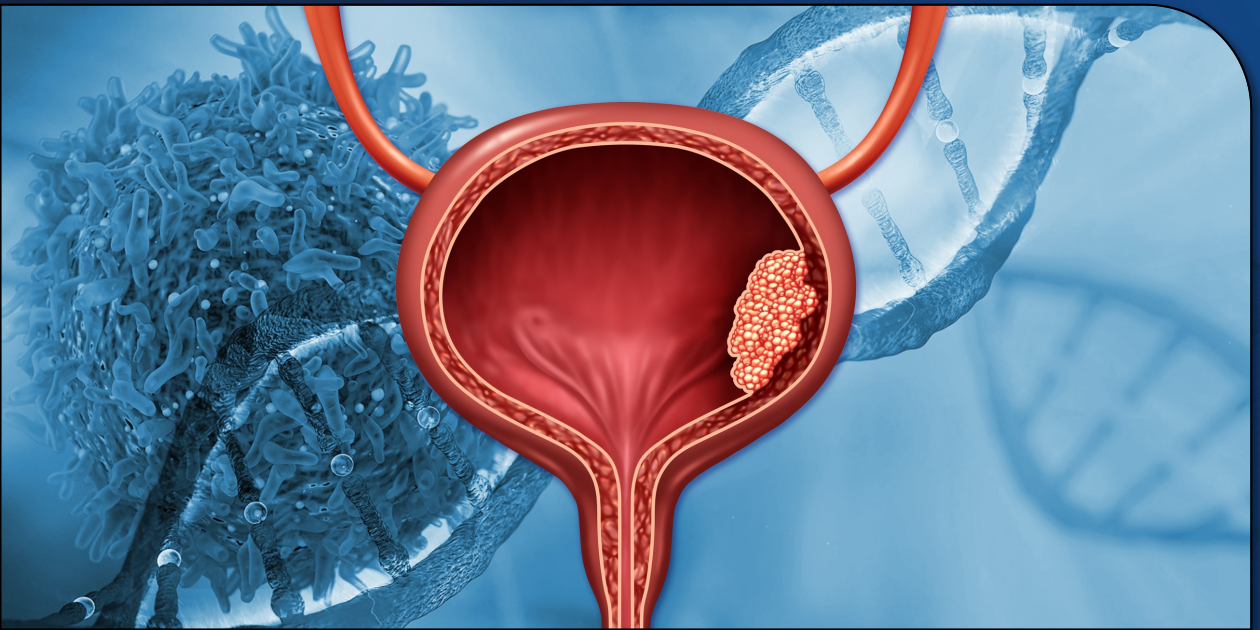
Putting Precision Into Practice for Bladder Cancer Treatment

Insights for Individualized Care Across the Disease Continuum

PeerView Live

BCAN 20 Years of Impact



A CME Satellite Symposium Held in Conjunction with the American Urological Association Annual Meeting 2025 (AUA2025).

Welcome and Introduction



Sia Daneshmand, MD
Professor of Urology and Medicine (Oncology)
Clinical Scholar
Director of Urologic Oncology
USC Norris Comprehensive Cancer Center
Los Angeles, California

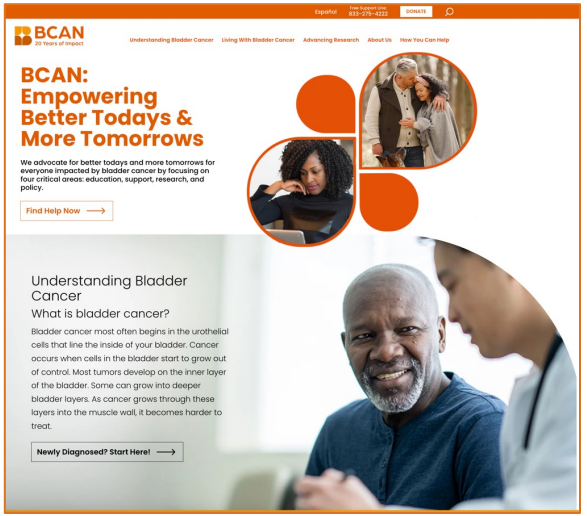
Our Goals for Today

- **Augment your knowledge** of efficacy and safety data for modern treatment strategies across bladder cancer stages
- **Equip you with skills to** incorporate regimens with novel modes of action into the individualized care plans of patients with bladder cancer
- **Provide you with guidance** on team-based approaches to proactively mitigate, monitor for, and manage adverse events

BCAN Is an Excellent Resource for Professionals, Patients, and Caregivers

BCAN
20 Years of Impact

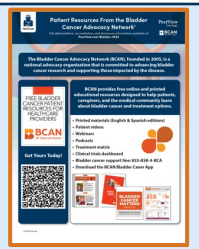
When diagnosed with bladder cancer, patients—and their caregivers—may feel overwhelmed by the number of treatment options for urothelial carcinoma. BCAN provides educational resources to help patients feel better prepared to make informed decisions.



In addition to giving patients and caregivers support to cope with the disease, **BCAN also offers free resources for healthcare providers to share with patients:**

- **Printed materials**
- **Animated videos**
- **Webinars**
- **Podcasts**
- **Treatment matrix**
- **Clinical trials dashboard**
- **Bladder Cancer Support Line: Call 833-ASK-4-BCA**

See the BCAN Practice Aid for full details on the BCAN website, a QR code for professionals to download resources for patients, and more!



Downloadable Resource Available

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Unmet Needs Across the Disease Spectrum

- Many patients with **NMIBC** do not receive intravesical BCG[1]
- Many of those with **NMIBC** who are unresponsive to BCG experience recurrence or progression[2]

- Close to half of patients with **MIBC** worldwide may not receive curative-intent therapy[3]
- Patients who have undergone radical cystectomy for **MIBC** often have impaired HRQOL and a high risk of recurrence[4]

- More than half of patients with **mUC** may not receive 1L systemic treatment[4]
- Many patients with **mUC** who progress on 1L or 2L therapy do not receive subsequent treatment[4]

1. Tyson M et al. *J Clin Oncol*. 2019;37(suppl 15):e16012. 2. Shore ND et al. *Urol Oncol*. 2021;39:642-663. 3. Westergren DO et al. *J Urol*. 2019;202:905-912.
4. Choi H et al. *Transl Androl Urol*. 2020;9:2997-3006. 5. Roupret M et al. *Eur Urol*. 2021;79:62-79. 4. Morgans AK et al. *Clin Genitourinary Cancer*. 2025;23:102270.

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Unmet Needs Across the Disease Spectrum

- Development of effective, safe, and durable intravesical treatment remains a critical unmet clinical need for patients who want to avoid radical cystectomy
- Effective approaches post radical cystectomy are key to lowering risk of recurrence
- Strategies for treatment sequencing after metastatic progression are needed
- Clinical trial enrollment allows for modern advances to reach patients

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International Bladder Cancer Group Risk Categories[1,2]

Risk Category	Tumor Characteristics	Outcomes
Low risk	Ta **low grade (LG)**: solitary, primary, and ≤3 cm	Low risk of recurrence/progression
Intermediate risk	Anything that falls between low risk and high risk	Recurrence is main concern
High risk	Any **HG** (Ta, T1, **CIS**) Any **T1**	Progression is main concern

High risk: 30% progression, ~75% recurrence
Low risk: <5% progression, ~45% recurrence

1. Kamat AM et al. *J Clin Oncol.* 2016;34:1935-1944. 2. Roumiguié M et al. *Eur Urol.* 2022;82:34-46.

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Definition of BCG-Unresponsive Disease[1-4]

At least one of the following:

Persistent or recurrent **CIS** with or without non–muscle-invasive papillary disease within 12 mo of completion of **adequate** BCG therapy

Recurrent **HG Ta/T1** tumor within 6 mo of completion of **adequate** BCG therapy

HG T1 disease at the first evaluation following BCG induction

Adequate BCG therapy defined as at least 5 of 6 doses of iBCG + at least 2 additional doses of mBCG

1. Kamat A et al. *J Clin Oncol*. 2016;34:1935-1944. 2. Lerner SP et al. *Bl Cancer*. 2016; 2:165-201.
3. https://www.fda.gov/media/101468/download. 4. Li R et al. *Eur* Urol. 2024; 86:516-527

PeerView

Snapshot of Treatment Approaches for High-Risk NMIBC Unresponsive to BCG

Downloadable Resource Available

FDA Approved

- Immune checkpoint inhibition via pembrolizumab[1] (FDA approved January 2020)
- Viral gene transfer: nadofaragene firadenovec[10-12] (FDA approved December 2022)
- IL-15 superagonist Nogapendekin alfa inbakicept-pmln[13] (FDA approved April 2024)

Under Investigation

- Sustained release of gemcitabine via TAR-200
  - SunRISe-1[5-7]
  - SunRISe-3[8]
  - SunRISe-5[9]
  - FDA breakthrough designation
- FGFR inhibition via intravesical delivery of erdafitinib
  - TAR-210[2a]
- Oncolytic adenovirus cretostimogene grenadenorepvec (CG0070)[3,4]

[a] intermediate-risk NMIBC. [b] BCG-naive. 1. Balar AV et al. *Lancet Oncol*. 2021;22:919-930. 2. Vilaseca A et al. AUA 2024. Abstract PD48-02. 3. Tyson MD et al. AUA 2024. Abstract P2-02. 4. Li R et al. *J Clin Oncol*. 2022;40(suppl 16). Abstract 4597. 5. Daneshmand S et al. AUA 2023. Abstract LBA 02-03. 6. Necchi A et al. ESMO 2023. Abstract LBA105. 7. van der Heijden MS et al. ESMO 2024. Abstract LBA85. 8. https://clinicaltrials.gov/study/NCT05714202. 9. Porten S et al. SUO 2024. Abstract 134. 10. Boorjian SA et al. *Lancet Oncol*. 2021;22:107-117. 11. Narayan VM et al. *Front Oncol*. 2024;14:1359725 12. Boorjian SA et al. EAU 2024. Abstract A0583. 13. Chamie K et al. *NEJM Evid*. 2022;2.

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Implementing Approved Therapies for Patients With High-Risk NMIBC



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Associate Editor European Urology
Cleveland, Ohio

Intravesical Gemcitabine and Docetaxel for BCG-Unresponsive NMIBC[1]

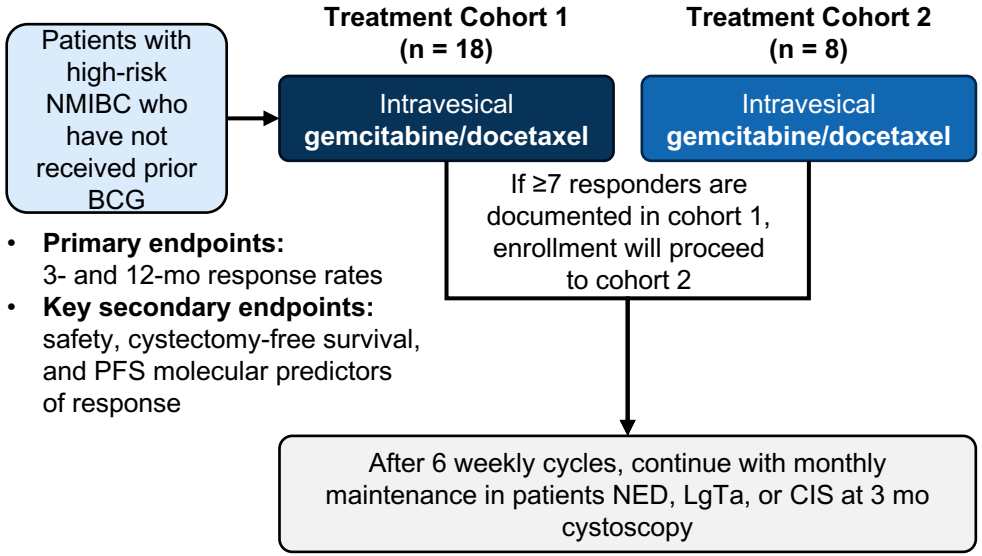
- Intravesical gemcitabine + docetaxel remains the de facto standard of care in the BCG-unresponsive NMIBC setting
- It is not currently FDA approved due to the absence of level 1 evidence supporting its use in this setting; however, this combination has demonstrated excellent and durable efficacy outcomes in large single-center series
- Furthermore, this combination is cost effective, familiar to prescribing physicians and nurses, and has no significant side effects

1. Li R et al. *Eur Urol*. 2024; 86:516-527.

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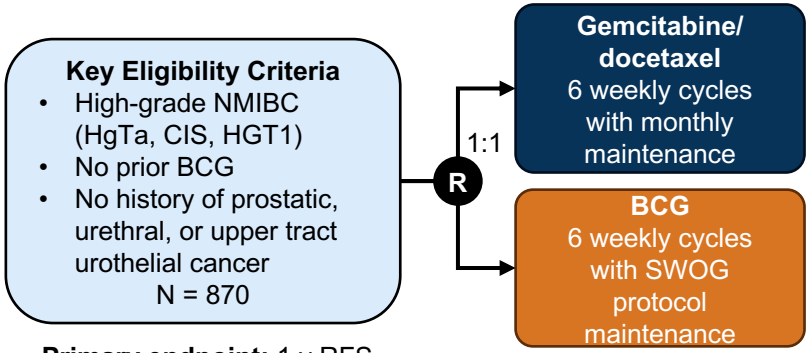
Intravesical Gemcitabine and Docetaxel for BCG-Naïve NMIBC[1,2]

Sequential Intravesical Gemcitabine and Docetaxel



- **Primary endpoints:** 3- and 12-mo response rates
- **Key secondary endpoints:** safety, cystectomy-free survival, and PFS molecular predictors of response

Phase 3 BRIDGE Trial



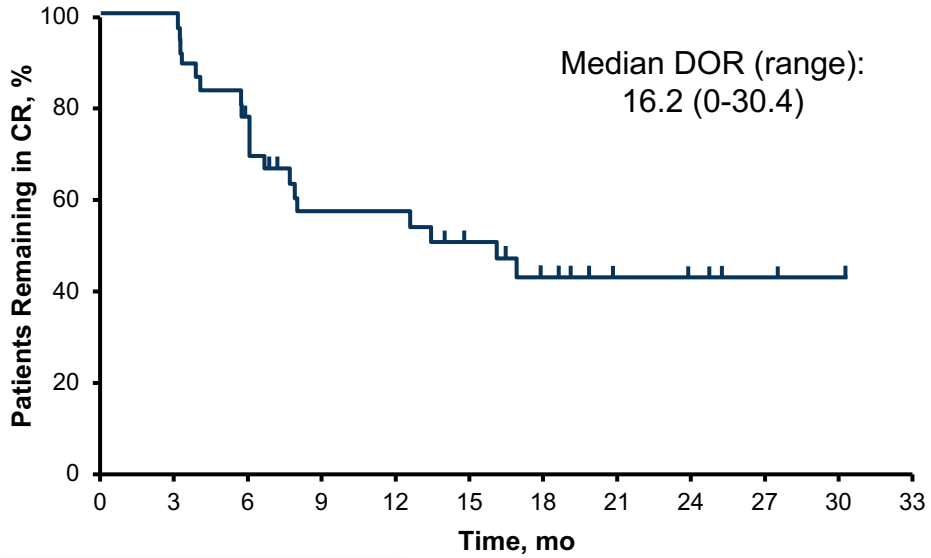
- **Primary endpoint:** 1 y RFS

1. McElree IM et al. *J Urol*. 2022;208:589-599. 2. Kates M et al. *Eur Urol Focus*. 2023;9:561-563.

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Immunotherapy for BCG-Unresponsive, High-Risk NMIBC[1]

KEYNOTE-057 Cohort A: CIS ± Papillary Disease (High-Grade Ta or T1)



Best Response	Patients (N = 96)	
	n (%)	95% CI
CR	39 (40.6)	30.7-51.1
Non-CR	56 (58.3)	47.8-68.3
Progression to CT2	0	N/A
NE	1 (1.0)	0-5.7

- Upstaging to ≥pT2 in 8.3% of patients

Extended minimum follow-up of 26.3 mo
- Of 39 responders, 13 (33.3%) remained in CR ≥18 mo and 9 (23.1%) remained in CR ≥24 mo as of the data cutoff date
- No new safety risks were identified

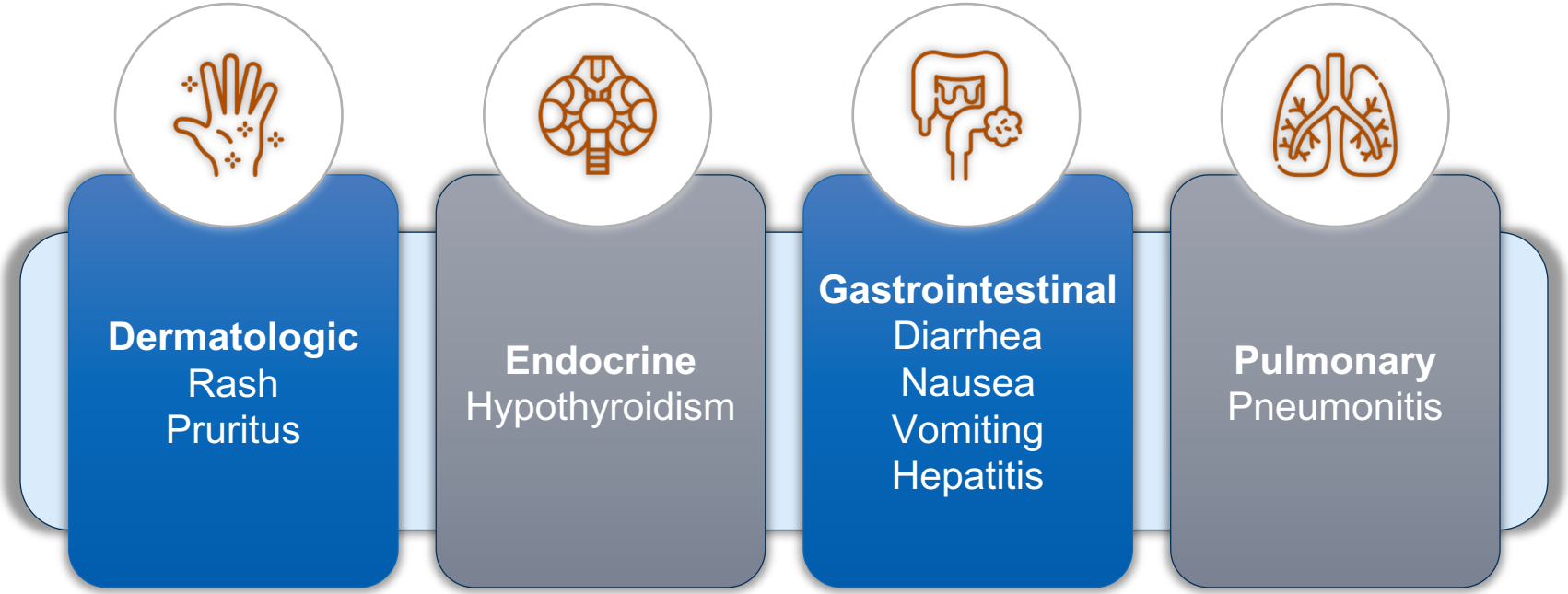
January 2020

Pembrolizumab was FDA approved for the treatment of patients with BCG-unresponsive, high-risk NMIBC with CIS ± papillary tumors who are ineligible for or have elected not to undergo cystectomy

1. Balar AV et al. *Lancet Oncol*. 2021;22:919-930.

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irAEs With Immune Checkpoint Inhibitors Can Affect Any Organ



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Investigational Checkpoint Inhibitor Strategies for BCG-Unresponsive or BCG-Naïve NMIBC[1-4]

Phase 3 POTOMAC[1]

High-Risk NMIBC
- Any HG
- Any T1
- Multiple, recurrent and large (>3 cm) Ta
- No prior BCG therapy

R

N = 1,018

- BCG induction only + durvalumab
- BCG induction/ maintenance + durvalumab
- BCG induction + maintenance (24 mo)

- **Primary endpoint:** DFS

Phase 3 KEYNOTE-676[2]

High-Risk NMIBC
- Recurrence after induction BCG therapy only

R

N = ~1,405

- BCG + pembrolizumab
- BCG

- **Primary endpoint:** CR in patients with CIS

Phase 1/2 ADAPT-BLADDER[3]

BCG-unresponsive high-risk NMIBC

R

N = 55

- Cohort 1: durvalumab monotherapy
- Cohort 2: durvalumab + BCG
- Cohort 3: durvalumab + EBRT (BCG retreatment)—crossover to durvalumab monotherapy
- Cohort 4: durvalumab + gem/doc

- **Primary endpoints**
  - Phase 1: RP2D
  - Phase 2: CR

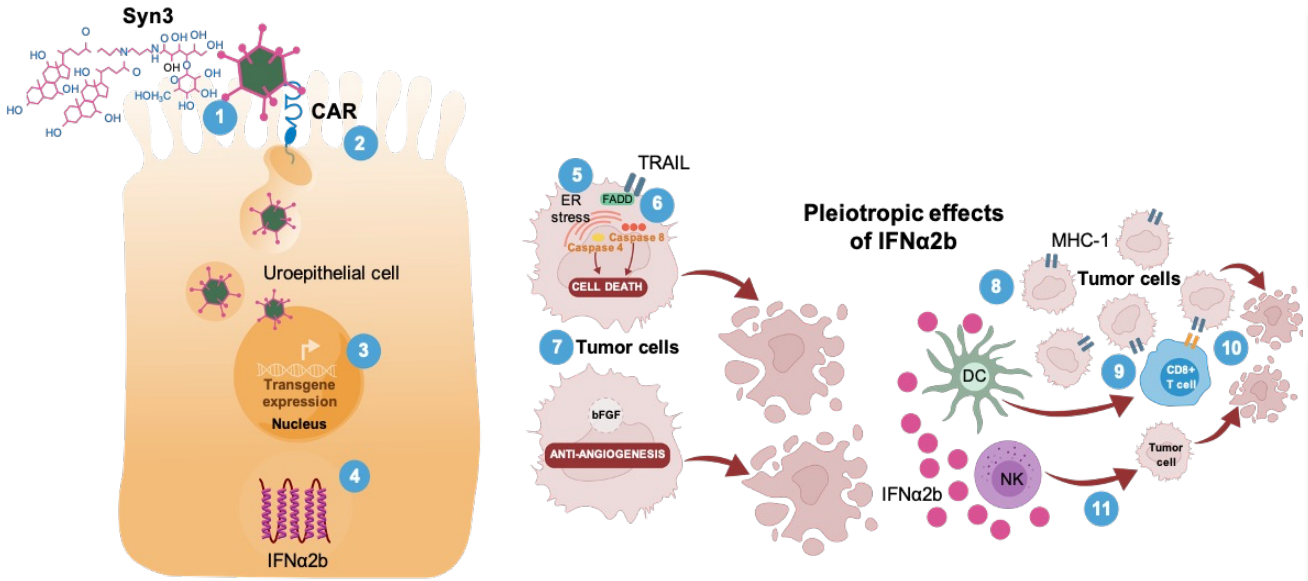
CR in 24 of 27 patients (87%)[4]

1. https://clinicaltrials.gov/study/NCT03528694. 2. https://clinicaltrials.gov/study/NCT03711032. 3. https://clinicaltrials.gov/study/NCT03317158.
4. Hahn NM et al. ASCO GU 2025. Abstract 667.

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Gene Therapy for NMIBC

Nadofaragene firadenovec is a nonreplicating adenoviral vector–based gene therapy that delivers human *IFNα2b*-cDNA to urothelial cells and Syn3 to enhance viral transduction to the urothelium. *IFNα2b*-cDNA is transcribed into IFNα2b protein in bladder epithelial cells, where it exhibits direct and indirect immunomodulatory effects inhibiting tumor growth[1-3]



Phase 3
Primary Analysis[4]

- 55/103 (53.4%) of patients with CIS (± high-grade Ta or T1 tumor) had a CR within 3 mo of first dose
- Response was maintained in 25/55 (45.5%) patients at 12 mo

December 2022

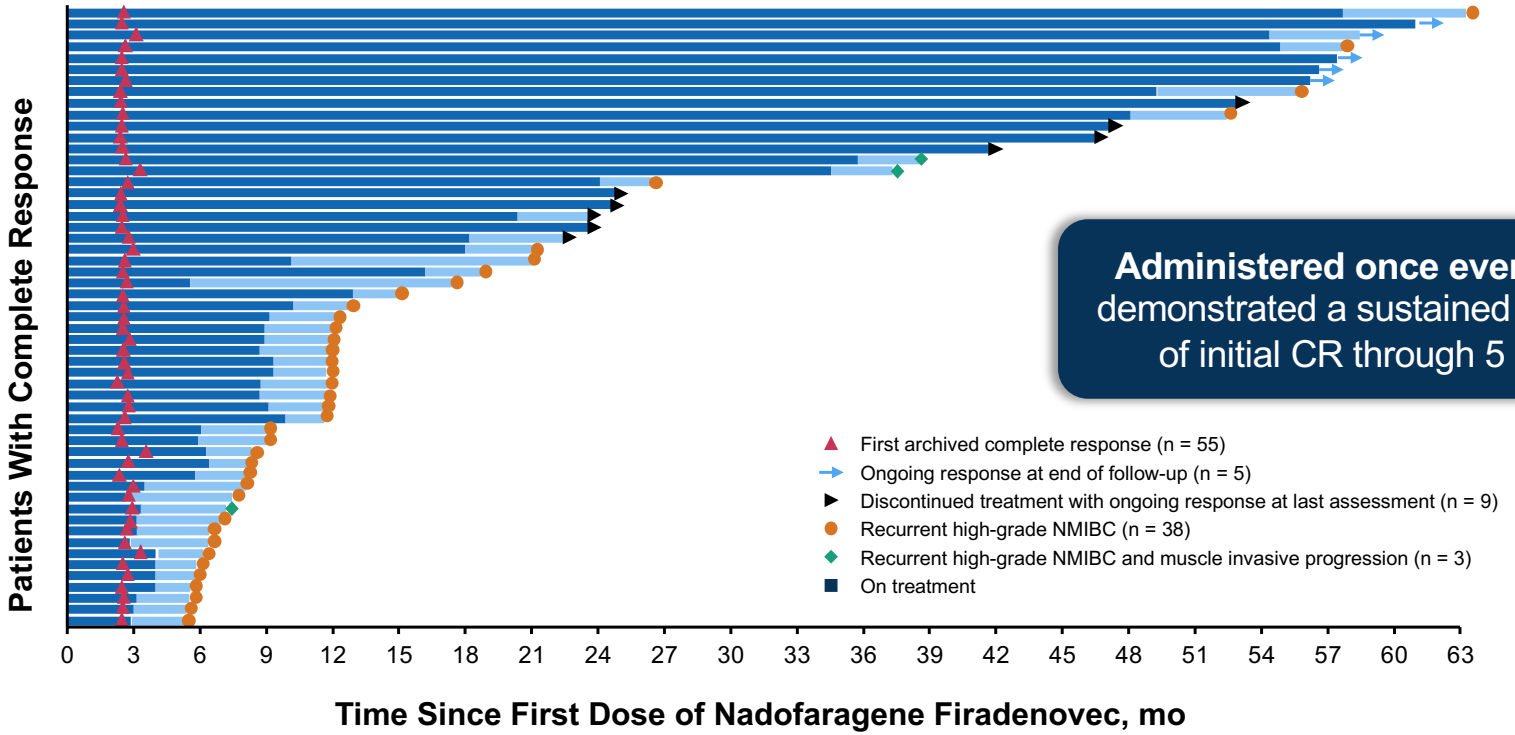
First gene therapy approved by the FDA for the treatment of adult patients with high-risk, BCG-unresponsive NMIBC with CIS ± papillary tumors

1. Boorjian SA et al. *Lancet Oncol*. 2021;22:107-117. 2. Boorjian SA et al. SUO 2023. Abstract 164. 3. Narayan VM et al. *Front Oncol*. 2024;14:1359725.
4. Boorjian SA et al. EAU 2024. Abstract A0583.

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Nadofaragene Firadenovec: 5-Year Follow-Up[1]

Time to CR and DOCR



Administered once every 3 mo, demonstrated a sustained durability of initial CR through 5 years

1. Narayan VM et al. *J Urol.* 2024;212:74-86.

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Nadofaragene Firadenovec: 5-Year Follow-Up[1]

	CIS (n = 103)	High-Grade Ta or T1 Cohort (n = 48)	All Patients (N = 151)
Cystectomy-free survival rate, % (95% CI)			
12 mo	73 (62.9-80.5)	83 (69.2-91.2)	76 (68.4-82.3)
24 mo	63 (53.1-72.1)	72 (57.2-83.0)	66 (58.1-73.4)
36 mo	54 (43.5-63.2)	64 (48.1-75.6)	57 (48.5-64.7)
48 mo	49 (38.6-58.7)	59 (43.1-71.4)	52 (43.6-60.1)
60 mo	43 (32.2-53.7)	59 (43.1-71.4)	49 (40.0-57.1)

At 60 months, nadofaragene firadenovec allowed bladder preservation in nearly half of the patients

Only 5 patients (4 with CIS and 1 with Ta/T1) experienced clinical progression to muscle-invasive disease

1. Narayan VM et al. *J Urol.* 2024;212:74-86.

PeerView

Nadofaragene Firadenovec: Tolerable Safety Profile[1]

- Study drug–related TEAEs in safety population out to 60 months (n = 157)

	Grade 1 or 2 No. (%)	Grade 3 No. (%)	Grade 4 or 5 No. (%)
Patients with study drug–related AEs[a]	104	6	0
Types of events			
Discharge around the catheter during instillation	39 (25)	0	0
Fatigue	31 (20)	0	0
Bladder spasm	25 (16)	1 (0.6)	0
Micturition urgency	23 (15)	2 (1.3)	0
Chills	18 (11)	0	0
Dysuria	19 (12)	0	0
Pyrexia	16 (10)	0	0
Syncope	0 (0.0)	1 (0.6)	0
Hypertension	2 (1.3)	1 (0.6)	0
Urinary incontinence	6 (3.8)	1 (0.6)	0

[a] Events occurring in at least 10% of all treated patients during the study period.

1. Narayan VM et al. *J Urol.* 2024;212:74-86.

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Ongoing Studies for Nadofaragene Firadenovec in NMIBC[1]

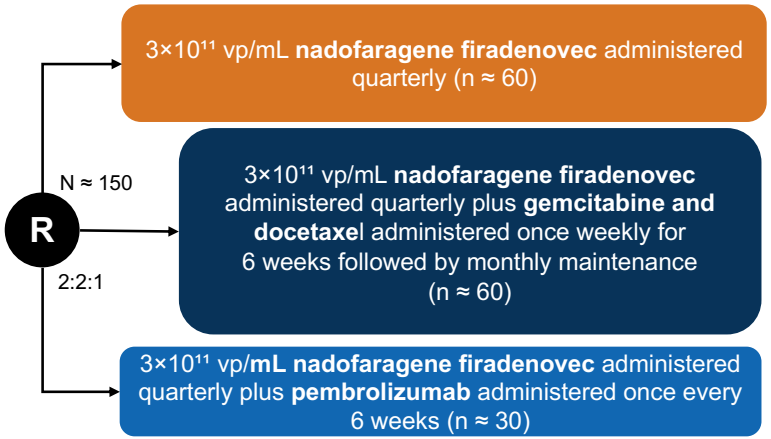
Phase 2 ABLE-22

Key inclusion criteria

- ≥18 years with HG BCG-unresponsive NMIBC with CIS ± Ta/T1
- TURBT within 14-70 days of first study treatment
- At least 8 weeks since last adjuvant intravesical therapy[a]
- No evidence of muscle-invasive or metastatic disease

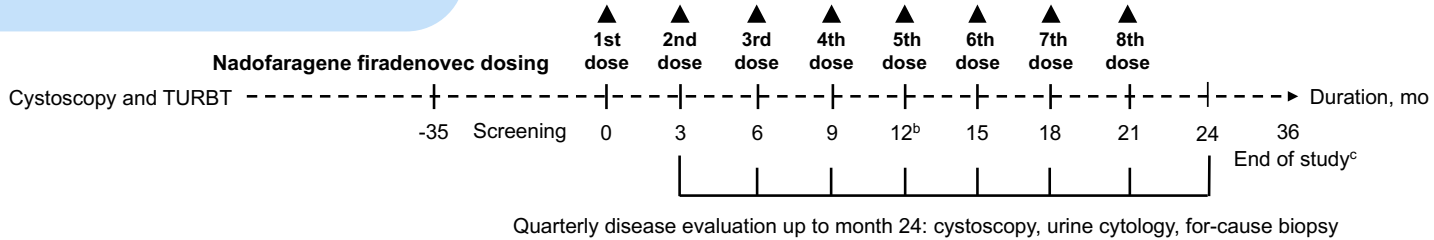
Key exclusion criteria

- Current or previous evidence of muscle-invasive or metastatic disease



Re-induction

In participants with disease persistence, re-induction will be offered once at month 3 followed by maintenance treatment in absence of recurrence or progression



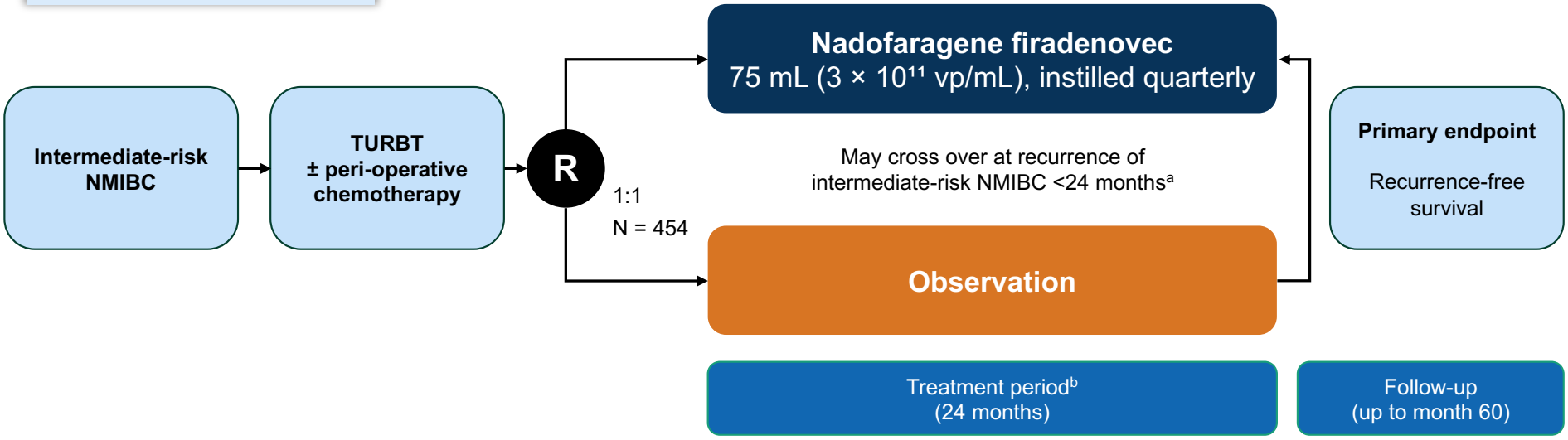
[a] Excluding a single postoperative dose of a cytotoxic agent following TURBT or BCG therapy within 5 weeks before biopsy required for study entry. [b] Continued treatment after month 12 will be offered in absence of disease recurrence or progression following first instillation. [c] Data will be collected annually up to month 36 from participants who have completed the month-24 assessment visit or who have discontinued treatment due to disease recurrence or progression.

1. https://www.clinicaltrials.gov/study/NCT06545955.

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Ongoing Studies for Nadofaragene Firadenovec in NMIBC[1]

Phase 3 ABLE-32



Participants will be followed based on the surveillance schedule of the AUA/SUO guideline (quarterly over the 24-month treatment period)

[a] Participants in the observation arm with intermediate-risk NMIBC recurrence before month 24 will be offered quarterly instillations of nadofaragene firadenovec up to 24 months in the absence of disease recurrence or progression.
Thereafter, participants will enter the follow-up period, which will be completed at month 60 regardless of when treatment was initiated.
[b] Up to 8 intravesical instillations with nadofaragene firadenovec.
1. https://www.clinicaltrials.gov/study/NCT06510374.

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Ongoing Studies for Nadofaragene Firadenovec in NMIBC[1,2]

Phase 4 ABLE-41: Real-World Use

N ~ 200
- Adults ≥18 years
- Planned enrollment at ~50 US urology sites
- FPFV was in September 2023

Key inclusion criteria
- Patients treated with nadofaragene firadenovec at physician discretion

Key exclusion criteria
- Patients who received nadofaragene firadenovec in a previous clinical trial
- Patients currently enrolled in a clinical trial

Primary endpoint:
CR rate

Enrollment date

Index date (first **nadofaragene firadenovec** dose)

Subsequent **nadofaragene firadenovec** doses approximately Q3M at physician discretion

End of study

Prospective data collection for up to 24 months

Baseline and demographic data collection

Enrollment to first **nadofaragene firadenovec** dose

First to last **nadofaragene firadenovec** dose

Patient and caregiver surveys before first dose

Physician survey 1 month after first dose

Patient and caregiver surveys at each routine visit and end of study

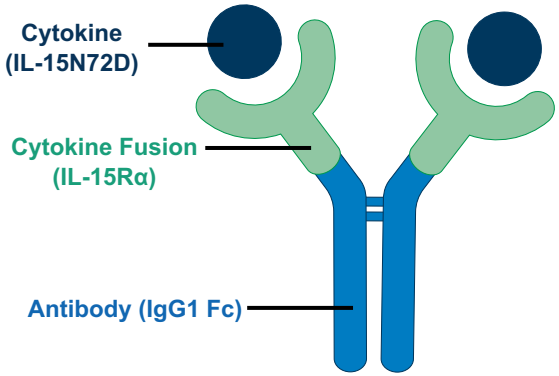
Physician surveys at 12 and 24 months

1. https://www.clinicaltrials.gov/study/NCT06026332. 2. Daneshmand S et al. ASCO GU 2024. Abstract TPS705.

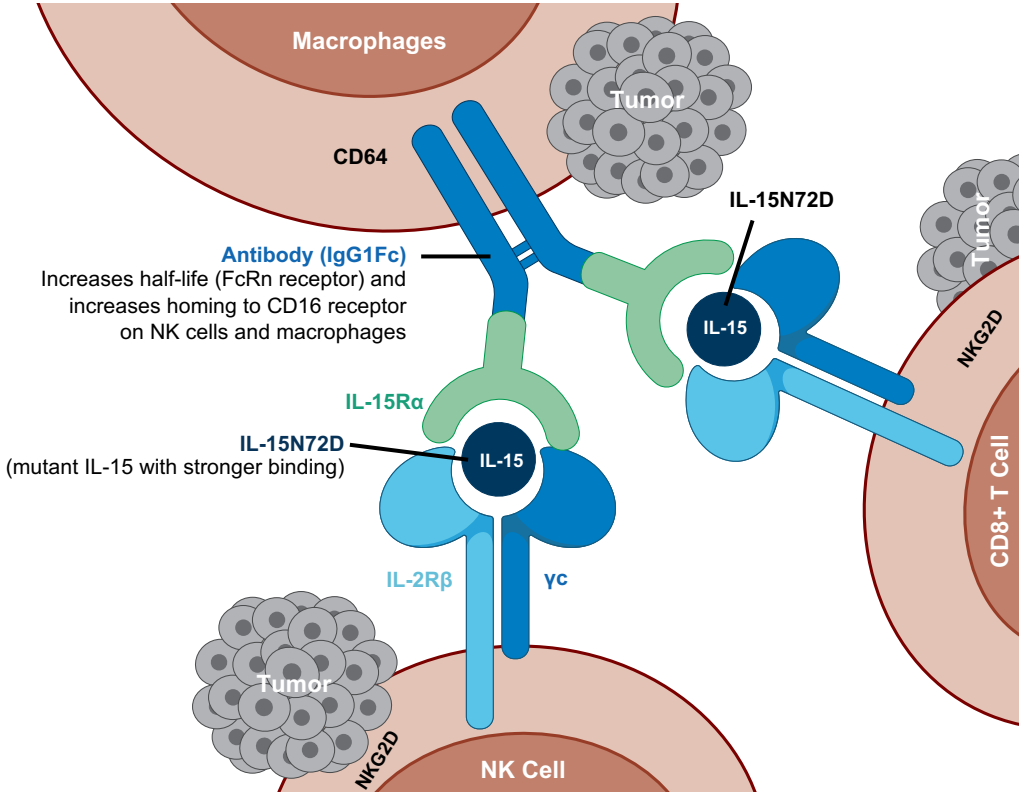
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IL-15 Superagonist: Nogapendekin Alfa Inbakicept-pmln (NAI/N-803)[1,2]

NAI/N-803:
IL-15 Superagonist Antibody Cytokine Fusion Protein



IL-15N72D and IgG1 Fc target, activate, and proliferate endogenous killing cells NK, CD8+ T cells without inducing T reg stimulation

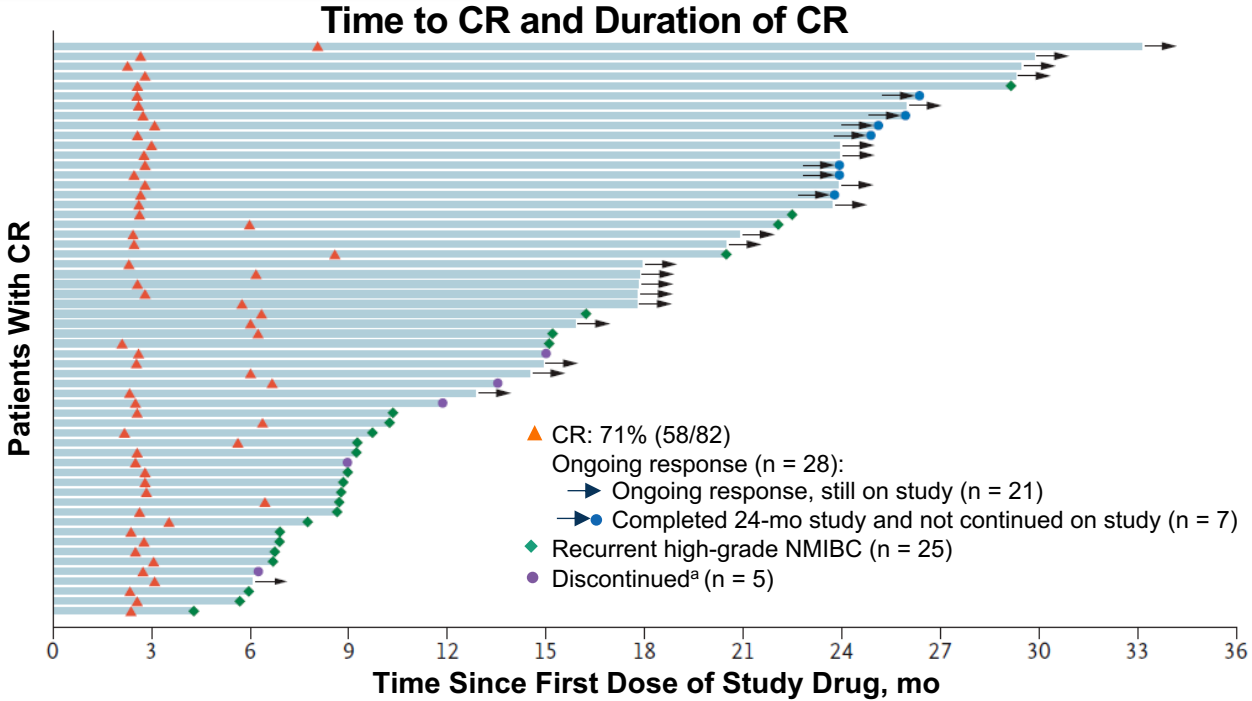


1. Chamie K et al. *J Clin Oncol*. 2021;39(suppl 6):510. 2. Li Z et al. *J Hematol Oncol.* 2025;18:19.

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Benefit From NAI Plus BCG in BCG-Unresponsive NMIBC-CIS Disease[1]

Phase 2/3 QUILT-3.032



April 2024

NAI + BCG was FDA approved for BCG-unresponsive NMIBC with CIS with or without papillary tumors[2,3]

[a] Withdrew, death unrelated to treatment, lost to follow-up, received other therapy.

1. Chamie K et al. *NEJM Evidence*. 2023;2:EVIDoa2200167.
2. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nogapendekin-alfa-inbakicept-pmln-bcg-unresponsive-non-muscle-invasive-bladder-cancer. 3. Anktiva (nogapendekin alfa inbakicept-pmln) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf.

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Benefit From NAI Plus BCG in BCG-Unresponsive NMIBC-CIS Disease[1]

Phase 2/3 QUILT-3.032

71% CR rate at any time	**26.6 mo** Median duration of CR
62% CR rate at 12 mo	**53%** CR rate at 24 mo
90% Avoidance of cystectomy in responders	**89%** Cystectomy-free at 24 mo
55% DFS rate at 12 mo	**19 mo** Median DFS

AUA 2025 Updated data support initial findings
Chang S et al.

1. Chamie K et al. *NEJM Evidence*. 2023;2:EVIDoa2200167.

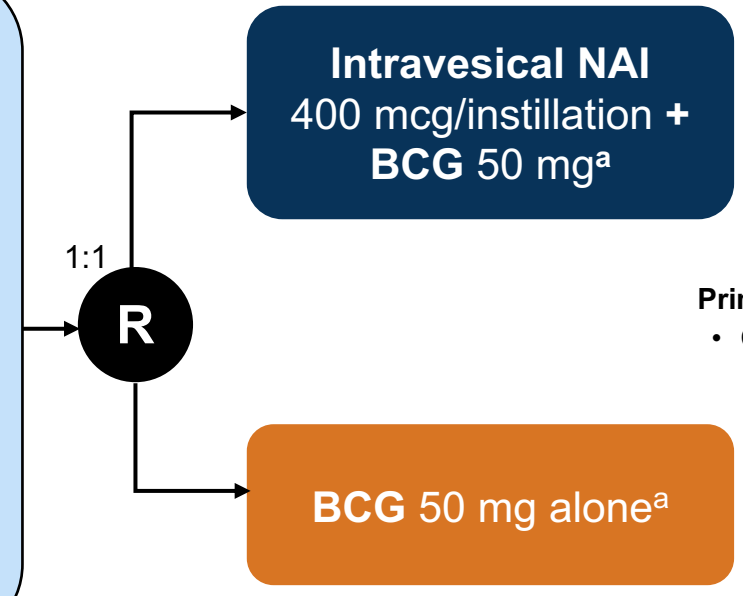
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Ongoing Trial Assessing NAI Plus BCG[1,2]

Phase 2 QUILT-2.005

Key Eligibility Criteria

- High-risk NMIBC
- **Cohort A:** CIS ± Ta or T1
- **Cohort B:** high grade papillary Ta or T1
- Diagnostic biopsy within 3 months of treatment start and a cystoscopy demonstrating no resectable disease within 6 weeks
- BCG-naïve (or last BCG >3 years prior)
- Have not received more than a single post-operative dose of mitomycin C or gemcitabine following the most recent screening TURBT/biopsy



Primary endpoint

- CR, DFS

[a] Weekly for six consecutive weeks, followed by maintenance treatment for 3 consecutive weeks at 3, 6, 12, and 18 months.

1. https://clinicaltrials.gov/study/NCT02138734. 2. Reddy S et al. AUA 2024.

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Safety of NAI Plus BCG[1,a]

Summary	Cohorts A and B Combined[c] (N = 161), no. (%)
Patients with at least 1 TEAE grade 1 or 2	139 (86)
Patients with at least 1 TEAE grade 3	32 (20)
Patients with at least 1 TEAE grade 4; or grade 5	3 (2); 1 (1)
Patients with at least 1 TEAE with outcome of death	1 (1)
Patients with at least 1 immune-related grade 3 TEAE	3 (2)

TEAE, no (%)[b]	Grade 1-2	Grade 3	Grade 4	Grade 5
Dysuria	49 (30)	1 (1)	0	0
Pollakiuria	41 (25)	1 (1)	0	0
Hematuria	40 (25)	4 (2)	0	0
Urinary tract infection	30 (19)	3 (2)	0	0
Fatigue	30 (19)	0	0	0
Micturition urgency	29 (18)	0	0	0
Chills	19 (12)	0	0	0

[a] Summary of safety results and most common TEAEs. All patients treated with nogapendekin alfa inbakicept and Bacillus Calmette–Guérin.
[b] Table shows TEAEs occurring in ≥10% of patients receiving nogapendekin alfa inbakicept and Bacillus Calmette–Guérin.
[c] Cohort A = CIS; Cohort B = high-grade Ta/T1 papillary NMIBC.
1. Chamie K et al. *NEJM Evidence*. 2023;2:EVIDoa2200167.

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BCAN: Helpful Resources for Patients



Download the Practice Aid!

Updated for 2025!



Let's Review a Patient Case: NMIBC

Carol

- 75-year-old with NMIBC
- ECOG PS: 1
- CIS + high grade Ta
- BCG-unresponsive
- Undergoes repeat TURBT; no residual tumor
- Has arthritis
- Lives far from clinic

Panel Discussion

What FDA-approved options are available to her NOW?

- Systemic immune checkpoint blockade with pembrolizumab
- Gemcitabine/docetaxel sequential treatment
- Nadofaragene firadenovec (dosed every 3 months)
- NAI (dosed weekly)

What's the ideal choice and why?

Patient Perspectives Are Important—Let Your Patients Know

2025 New Faces of Bladder Cancer Survey Is Open!

bcan.org/the-2025-new-faces-of-bladder-cancer-survey-is-open/

Why Participate?

Patient input matters – Let your patients know that by sharing their perspectives, they can help BCAN:

- Develop better programs and resources tailored to patient needs
- Advocate more effectively for bladder cancer patients
- Drive research that reflects what truly matters to patients

BCAN
20 Years of Impact

PeerView

Unlocking the Next Wave of Therapeutic Innovations for NMIBC



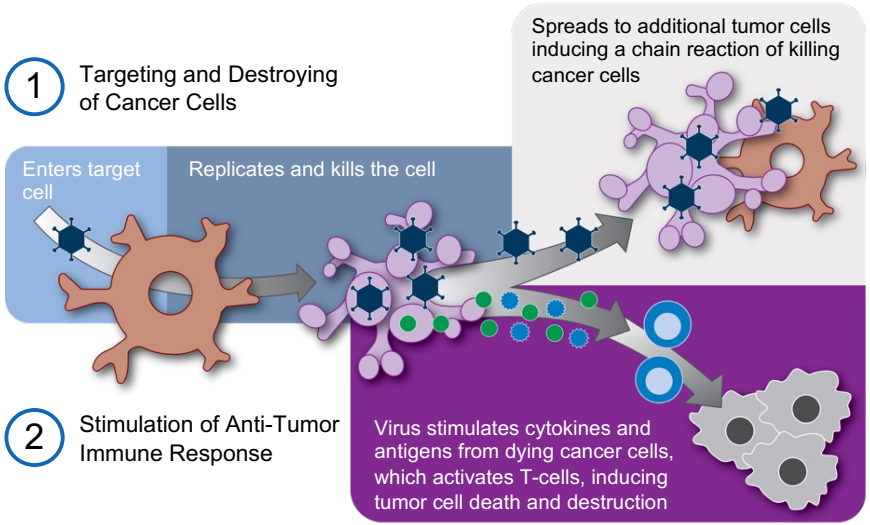
Sarah P. Psutka, MD, MS, FACS
Associate Professor
Associate Director, Urologic Oncology
Fred Hutchinson Cancer Center
University of Washington Medical Center
Seattle, Washington

Oncolytic Adenovirus Advances in NMIBC

Cretostimogene grenadenorepvec (CG0070)[1]

- Ad5-based oncolytic vaccine engineered to express GM-CSF and replicate selectively in tumor cells with mutated or deficient RB

Oncolytic Immunotherapy: Selective Oncolysis and Potent Anti-Tumor Immune Response



Phase 2 CORE-001 Trial
Single-arm study of CG0070
in combination with pembrolizumab in patients with BCG-unresponsive, NMIBC with CIS

54% CR rate at 24-month landmark

1. Li R et al. ASCO 2024. Abstract 4601.

PeerView

Phase 3 BOND-003: CG0070 in High-Risk BCG-Unresponsive NMIBC With CIS[1]

Key Eligibility Criteria

- Pathologically confirmed high-risk BCG-unresponsive NMIBC with CIS ± HG Ta/T1
- All HG Ta/T1 disease resected prior to treatment
- Mandatory biopsies at 12-month assessment

N = 112

Cretostimogene Grenadenorepvec

Induction course→ weekly × 6

Second induction → weekly × 6
(for nonresponders)

Maintenance Course
→ Weekly × 3 every 3 months (Q3M) for **year 1**
→ Weekly × 3 every 6 months (Q6M) for **year 2**

Primary Endpoint

- CR at any time

1. https://clinicaltrials.gov/study/NCT04452591.

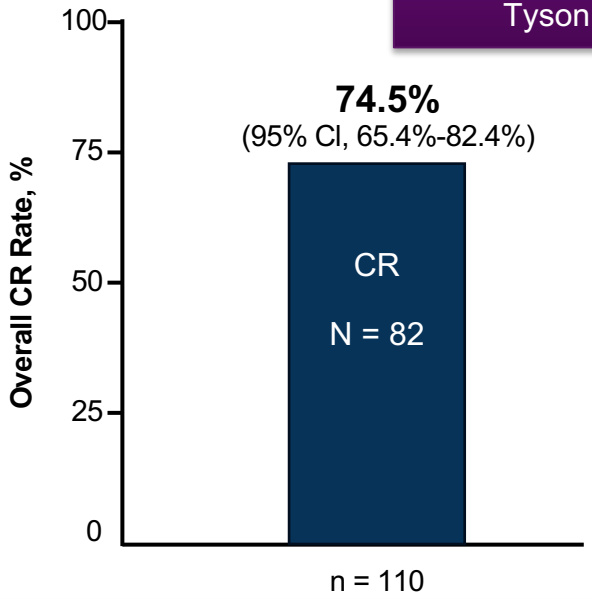
PeerView

Response Rates: CG0070 in High-Risk BCG-Unresponsive NMIBC With CIS[1]

AUA 2025 Update
BOND-003 Cohort C
Tyson M et al.

Phase 3 BOND-003 Trial
Intravesical CG0070 monotherapy for patients with high-risk BCG-unresponsive NMIBC

CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46%** (36.9, 56.1) 51 out of 110 patients	**50%** (39.6, 58.9)
24-month	There are 25 confirmed CRs that have reached 24-month timepoint and beyond	**41%** (30.4, 50.8)



- Among patients who achieved a CR, 64% and 57% of patients maintained a CR at 12 and 24 months, respectively
- The median duration of response had not yet been reached but exceeded 27 months
- No grade ≥3 treatment-related adverse events or discontinuations reported

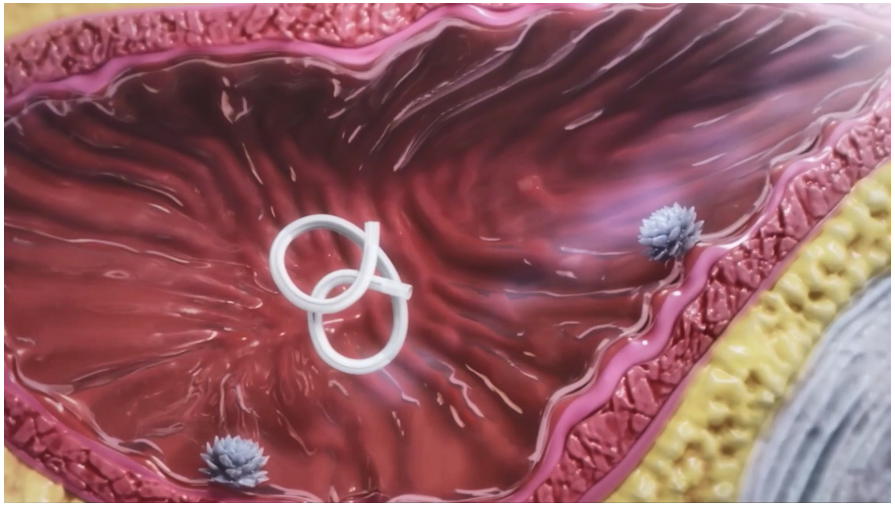
1. Tyson MD et al. SUO 2024. LBA.

PeerView

TAR-200 Advances in Intravesical Drug Delivery for NMIBC[1,2,a]

TAR-200

Intravesical drug delivery system that enables a sustained release of gemcitabine into the bladder, increasing the dwell time of the local drug concentration



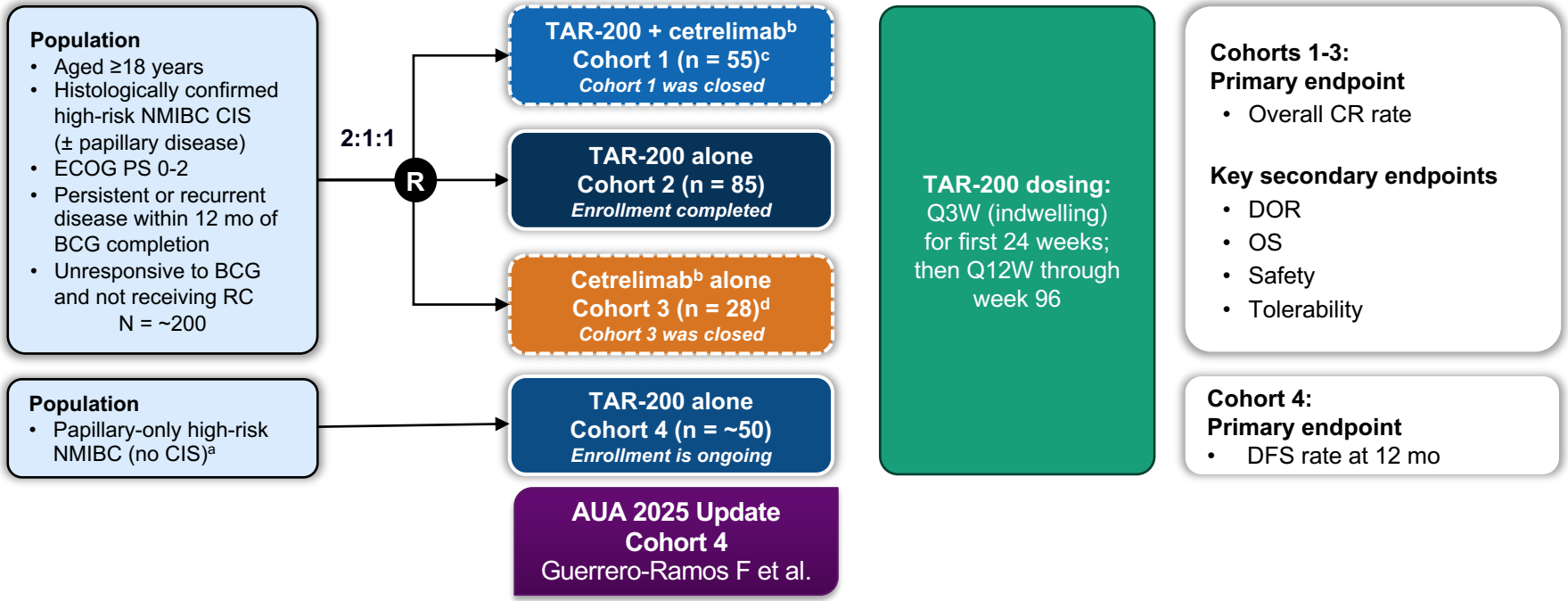
- TAR-200 is placed in the bladder with an inserter (similar to a urinary catheter)
- Once released into the bladder, it curls into a pretzel shape
- A small, flexible wire maintains the shape
- Well tolerated by the patient
- Patient does not feel TAR-200
- No limitations to patient activity with TAR-200
- The drug load may cause dysuria or burning

[a] Slide courtesy of Sia Daneshmand, MD.

1. Daneshmand S et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 2. Tyson MD et al. *J Urol.* 2023:209:890-900.

PeerView

SunRISe-1: TAR-200 in BCG-Unresponsive, High-Risk NMIBC[1-7]



The clinical data cutoff was January 2, 2024.

[a] Patients with BCG-unresponsive papillary-only high-risk NMIBC (high-grade Ta, any T1) per protocol amendment 4. [b] Cetrelimab is an anti–programmed cell death-13,4; cetrelimab dosing was through week 78. [c] 55 patients were randomized, and 53 were treated in cohort 1. [d] 28 patients were randomized and treated in cohort 3.

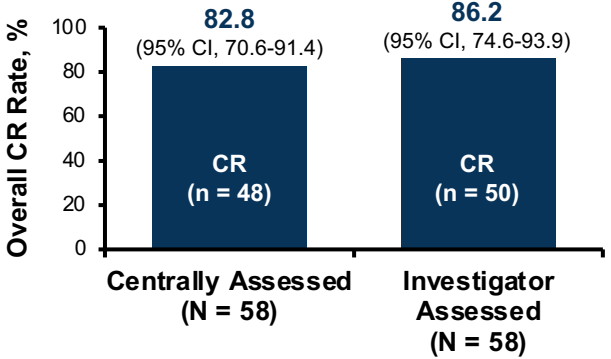
[e] Imaging (CT/MRI) was performed every 24 weeks through year 3.

1. Lerner SP et al. *Urol Oncol*. 2009;27:155-159. 2. https://www.fda.gov/media/101468/download. 3. DeAngelis N et al. *Cancer Chemother Pharmacol*. 2022;89:515-527.
4. Felip E et al. *Cancer Chemother Pharmacol*. 2022;89:499-514. 5. Vilaseca A et al. AUA 2024. Abstract PD48-02. 6. Jacob J et al. AUA 2024. Abstract P2-01.
7. van der Heijden MS et al. ESMO 2024. Abstract LBA85.

PeerView

SunRISe-1: TAR-200 Monotherapy in BCG-Unresponsive, High-Risk NMIBC (Cohort 2)[1-6]

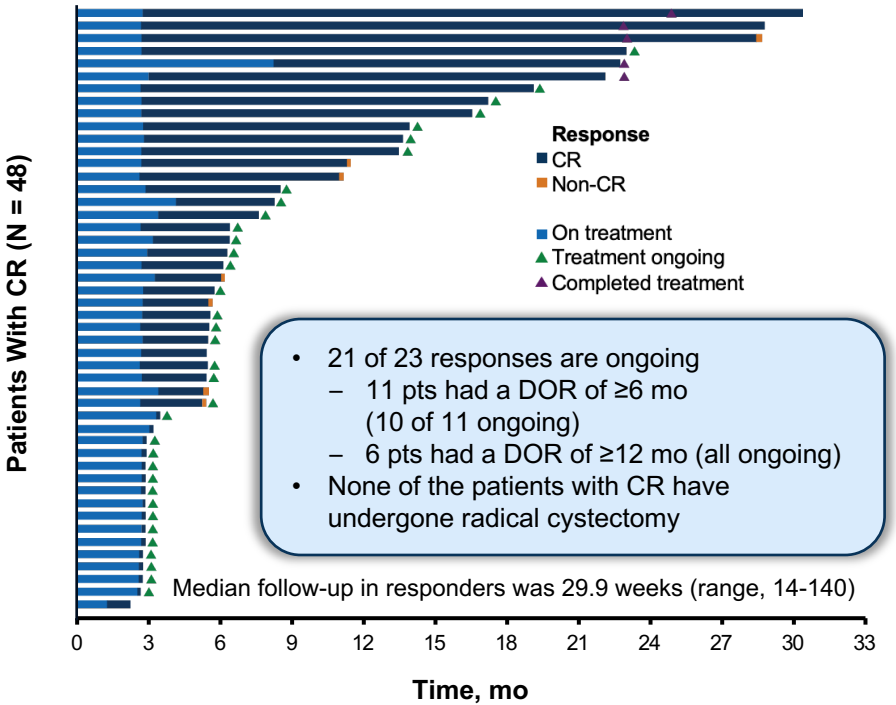
CR Rate in Patients With High-Risk NMIBC CIS



Landmark Time	DOR % (95% CI)
6 months	93% (61-99)
12 months	84% (49-96)

AUA 2025 Update
Durability and PROs
Jacob J et al.

FDA Breakthrough Therapy Designation



- 21 of 23 responses are ongoing
  - 11 pts had a DOR of ≥6 mo (10 of 11 ongoing)
  - 6 pts had a DOR of ≥12 mo (all ongoing)
- None of the patients with CR have undergone radical cystectomy

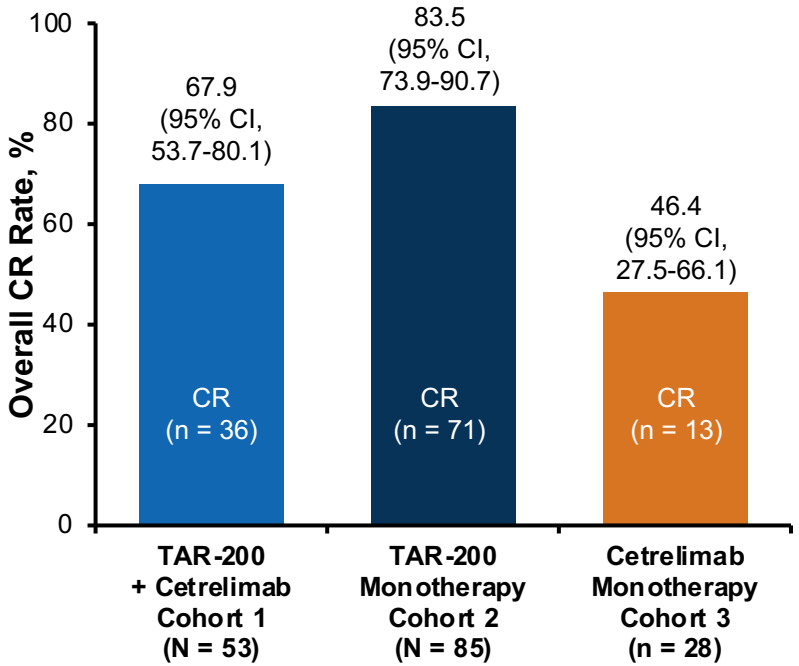
Median follow-up in responders was 29.9 weeks (range, 14-140)

1. https://clinicaltrials.gov/study/NCT04640623. 2. Daneshmand S et al. AUA 2023. Abstract LBA 02-03. 3. Necchi A et al. ESMO 2023. Abstract LBA105.
4. Jacob J et al. AUA 2024. Abstract P2-01. 5. van der Heijden MS et al. ESMO 2024. Abstract LBA85. 6. Daneshmand S et al. Western Section AUA 2024. Abstract 371.

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Improved CR With TAR-200 in BCG-Unresponsive, High-Risk NMIBC[1]

Centrally Assessed CR Rate at Any Time[a,b]



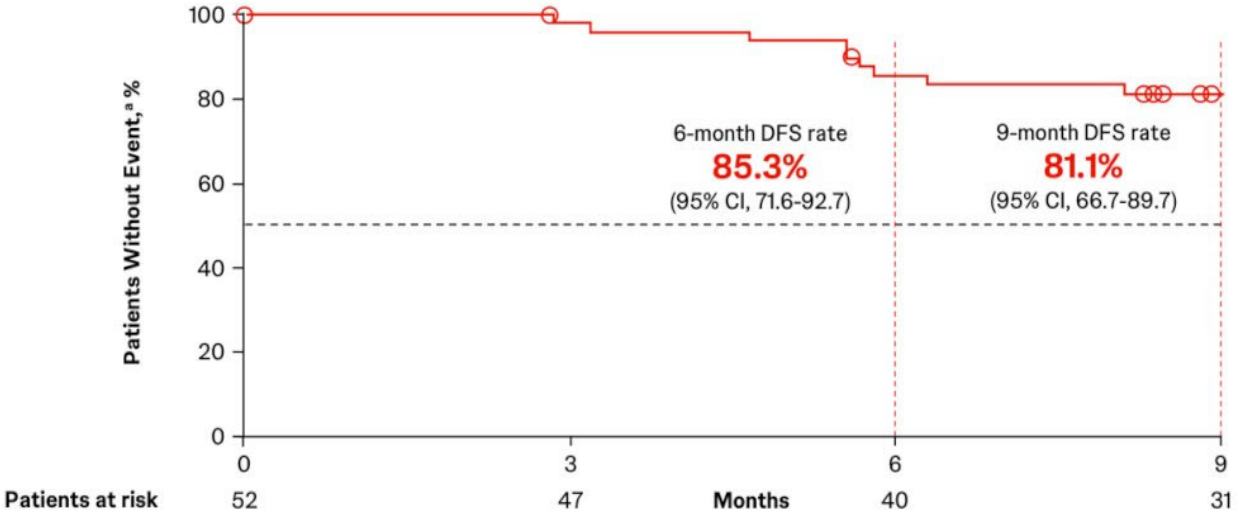
	TAR-200 + Cetrelimab Cohort 1 (N = 53)	Tar-200 Monotherapy Cohort 2 (N = 85)	Cetrelimab Monotherapy Cohort 3 (N = 28)
Estimated 12-mo CR rate, % (95% CI)	56.7 (41.2-69.6)	57.4 (40.6-71.0)	22.8 (8.6-41.1)
Estimated 12 mo DOR rate, % (95% CI)	75.9 (57.5-87.2)	65.7 (45.2-80.1)	48.5 (17.9-73.7)
Median follow-up in responders, mo (range)	21.8 (9.2-35.9)	9.2 (3.7-36.6)	18.2 (11.3-33.1)
Patients remaining in response, % (n/N)	75 (27/36)	82 (58/71)	54 (7/13)

1. van der Heijden MS et al. ESMO 2024. Abstract LBA85.

PeerView

AUA 2025: TAR-200 Monotherapy Demonstrated Improved DFS Rates in Papillary Disease–Only High-Risk NMIBC (Cohort 4)[1]

Disease-Free Survival

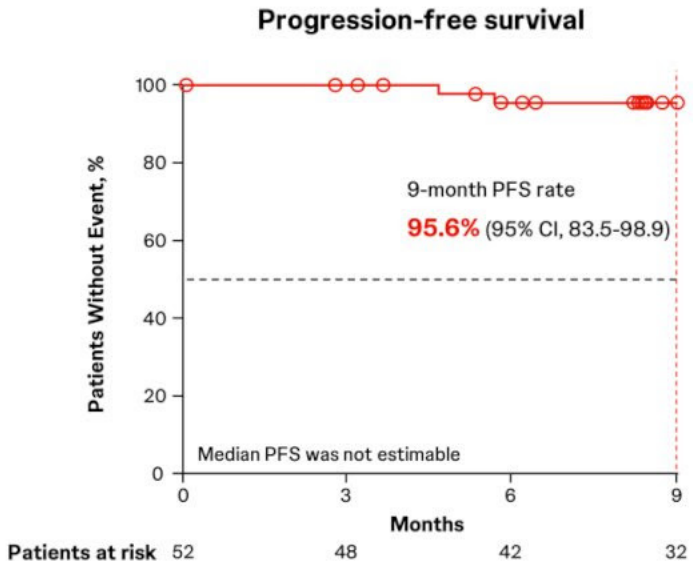


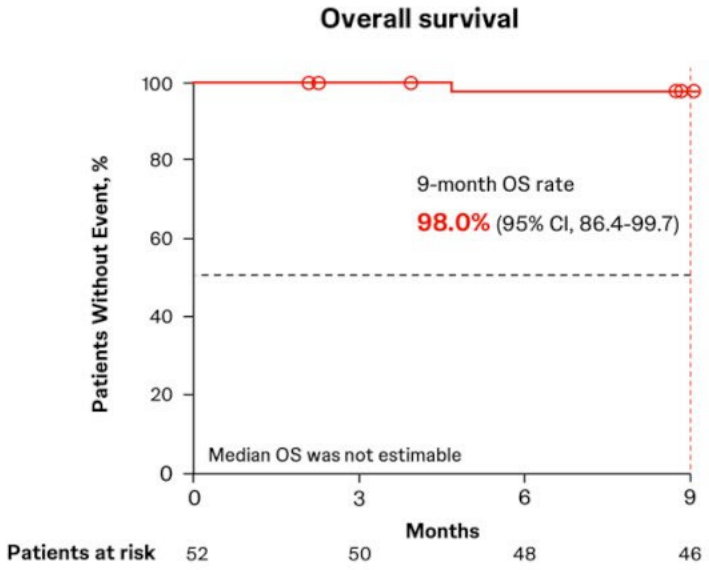
- Overall, only 5.8% of patients (3 of 52) underwent radical cystectomy
- Regardless of T stage, TAR-200 demonstrated strong activity
  - Consistently high DFS rates were seen across high-grade Ta and T1 disease (82.1% and 79.4%, respectively)
  - Reflects sustained tissue penetration achieved with TAR-200 via the iDRS

1. Guerrero-Ramos F et al. AUA 2025.

PeerView

AUA 2025: TAR-200 Monotherapy Resulted in 9-Month OS Rate of 98% in Papillary Disease–Only High-Risk NMIBC (Cohort 4)





The PFS rate at 9 months was 95.6%, and although OS data were still immature, the OS rate was 98% at 9 months

1. Guerrero-Ramos F et al. AUA 2025.

PeerView

TAR-200 Monotherapy: Safety Profile[1,2]

- **Most AEs were grade 1 or 2, with onset within 12 weeks of treatment initiation**
  - Resolution of most AEs within 2 weeks
- 61 patients (71.8%) had ≥1 TRAEs[a]
- 4 patients (4.7%) had ≥1 serious TRAEs
- 7 patients (8.2%) had grade 3 TRAEs
- **Few patients (n = 4; 4.7%) discontinued treatment due to AEs[b]**
- No treatment-related deaths were reported

Patients With Events, n (%)	TAR-200 (N = 85)[c]	
	Any Grade	Grade ≥3
≥1 AE	73 (85.9)	19 (22.4)
≥1 TRAE[a,d]	61 (71.8)	7 (8.2)
Pollakiuria	30 (35.3)	0
Dysuria	25 (29.4)	1 (1.2)
Micturition urgency	13 (15.3)	0
Urinary tract infection	13 (15.3)	1 (1.2)
Hematuria	8 (9.4)	0
Noninfective cystitis	7 (8.2)	0
Urinary tract pain	6 (7.1)	2 (2.4)
Bladder pain	3 (3.5)	1 (1.2)
Urinary retention	2 (2.4)	1 (1.2)
Renal impairment	1 (1.2)	1 (1.2)
Urosepsis	1 (1.2)	1 (1.2)

[a] An AE was categorized as related if the investigator determined that there was a possible, probable, or causal relationship between the AE and TAR-200 or the insertion or removal procedure or urinary placement catheter. [b] Treatment-related AEs leading to discontinuation were noninfective cystitis (n = 3), dysuria (n = 1), and pollakiuria (n = 1). [c] Safety is shown for all patients who received at least 1 dose of TAR-200 in the safety analysis set (N = 85).
[d] TRAEs by preferred term of any grade were reported in ≥5% of patients, and all TRAEs by preferred term of grade ≥3 are listed.
1. van der Heijden MS et al. ESMO 2024. Abstract LBA85. 2. Daneshmand S et al. Western Section AUA 2024. Abstract 371.

PeerView

Phase 3 SunRISe-3: BCG-Naïve, High-Risk NMIBC[1]

Key Eligibility Criteria

- Patients with histologically confirmed high-risk NMIBC (high-grade Ta, any T1, or CIS)[a]
- BCG-naïve (no prior BCG, or last exposure >3 y prior to randomization)
- Age ≥18 y
- ECOG PS 0-2

N = 1,135
(enrollment completed)

1:1:1

R

Group A
TAR-200 (**gemcitabine** 225 mg Q3W [induction phase] and Q12W [maintenance phase]) + **cetrelimab**

Group B
BCG (QW for 6 wk [induction] and QW for 3 wk at weeks 12, 24, 48, 72, and 96 [maintenance])

Group C
TAR-200 (**gemcitabine** 225 mg Q3W [induction phase] and Q12W [maintenance phase])

- **Primary endpoint:** EFS (time from randomization to first occurrence of high-risk disease, progression,[b] or any-cause death, whichever occurs first[c])
- **Secondary endpoints:** overall CR rate (CIS only)[d]/duration of CR,[e] RFS, TTP, OS, cancer-specific survival, safety and tolerability, PROs

[a] All visible papillary disease must be fully resected (absent) prior to randomization and documented at baseline cystoscopy; local urine cytology at screening must be negative or atypical for high-grade UC in patients with papillary-only disease. All AEs associated with any prior surgery and/or intravesical therapy must have resolved to CTCAE v5.0 grade <2 prior to randomization.
[b] Progression defined as stage increase from Ta to T1 or from CIS to T1 or progression to MIBC (T ≥2) or lymph node (N+) or distant (M+) disease, whichever occurs first.
[c] For patients with CIS, persistent disease at 6 mo is also considered an EFS event. [d] Proportion of patients with CIS who have no presence of HR disease at 6 mo.
[e] Time from first CR achieved to first evidence of recurrence, progression, or any-cause death, whichever occurs first.

1. https://clinicaltrials.gov/study/NCT05714202.

PeerView

Phase 3 SunRISe-5: Recurrent, High-Risk Papillary NMIBC[1,2]

Key Eligibility Criteria

- Histologically confirmed, **papillary-only high-risk NMIBC** (high-grade Ta or any T1), recurrent within the first year of last dose of BCG
- No CIS at time of papillary recurrence
- RC refusing or ineligible
- ECOG PS <3

Stratification Factors

- T stage
- Prior BCG

N = ~250

1:1

R

Group A (n = ~125)
TAR-200 monotherapy
Q3W during an induction phase
Q12W during a maintenance phase

Crossover
Patients in group B may receive TAR-200 after positive study result at any planned analyses

Group B (n = ~125)
Intravesical gemcitabine
OR
intravesical mitomycin
weekly during induction phase and monthly during maintenance phase

Primary endpoint

- DFS

Key secondary endpoints

- RFS
- Time to next intervention
- Time to progression
- Time to disease worsening
- OS
- Safety and tolerability
- PROs/HRQOL

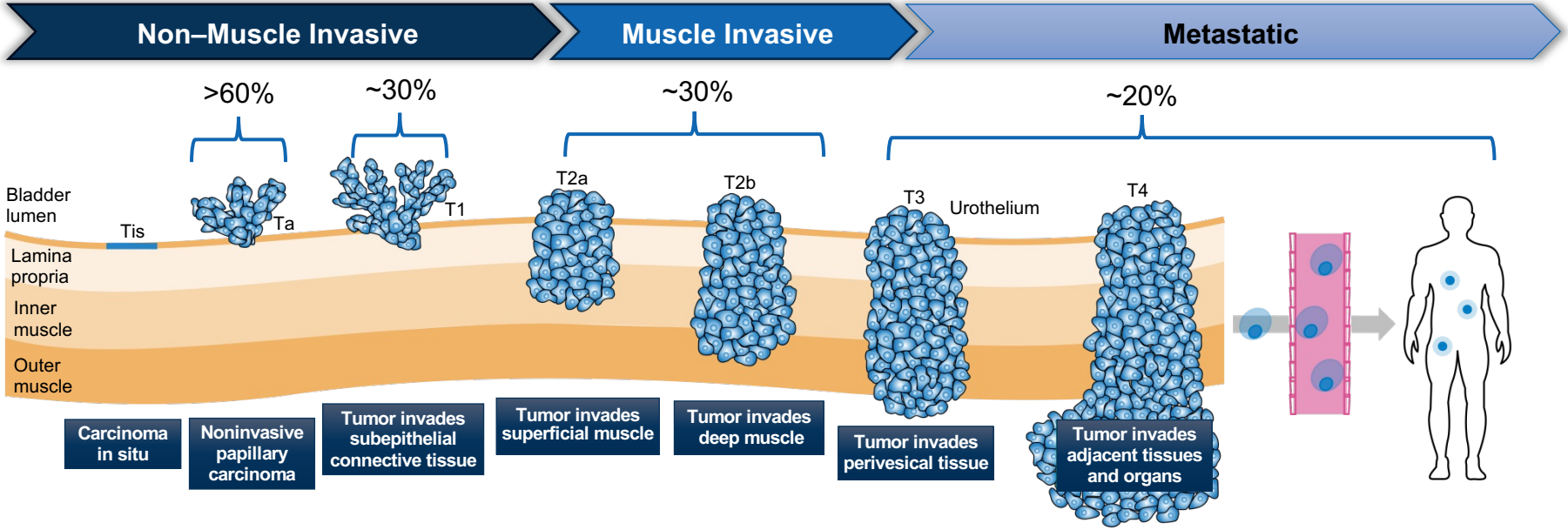
- DFS is defined as time from randomization to first recurrence of high-risk NMIBC (high-grade Ta, any T1 or CIS), progression, or any cause death, whichever occurs first

The study will evaluate whether TAR-200 will prolong DFS when compared with intravesical chemotherapy in patients with papillary-only high-risk NMIBC recurrent after BCG therapy who refuse or are unfit for RC

1. Porten S et al. SUO 2024. Abstract 134. 2. https://clinicaltrials.gov/study/NCT06211764.

PeerView

FGFR Mutations Are Frequently Observed in Bladder Cancer[1]



FGFR inhibitors can be effective across the disease spectrum

1. Knowles MA et al. *Nat Rev Cancer*. 2015;15:25-41.

PeerView

Importance of Discussing Genomic Testing With Patients

Eligibility for FGFR inhibition requires patients to undergo testing for genomic alterations

- **Flatiron database analysis of >700 eligible patients showed that fewer than half had undergone testing[1]**
  - Of those who were tested, 21% had an *FGFR* mutation but only 42% received erdafitinib[1]
  - **Options include specifically testing tumors for *FGFR3* alterations** (eg, RT-PCR companion assay) **or more comprehensive approaches** (eg, NGS panels, liquid biopsy)

The goal is to offer patients the full range of available therapeutic options to ensure the best possible outcome

1. Nimgaonkar N et al. *JAMA Oncol*. 2022;8:1070-1072.

PeerView

TAR-210 Erdafitinib Intravesical Delivery: First-in-Human Phase 1 Trial[1,2,a]

Molecular Eligibility

A flexible molecular eligibility strategy is used to detect *FGFR* alterations

- Local or central fresh/archival tissue–based testing by NGS or PCR

OR

- Urine cell-free DNA NGS testing

Cohort 1

- **High-risk NMIBC** (high-grade Ta/T1, no CIS, papillary only), BCG-experienced/unresponsive and not receiving RC
- TURBT with **complete resection** of all visible disease prior to treatment

Cohort 3

- **Intermediate-risk NMIBC**, recurrent, history of low-grade only Ta/T1 disease
- **Visible target lesions** prior to treatment (chemoablation design)

Response is assessed every 3 mo with continued treatment for up to 1 y if recurrence-free (cohort 1) or CR (cohort 3)

Part 1
Dose Escalation

BOIN

TAR-210-D
Dose level 2

TAR-210-B
Dose level 1

- Non-RC patients: cohort 1 and cohort 3 combined
- Placement every 3 mo

Part 2
Dose Expansion

Expansion Cohort 1

Expansion Cohort 3

Expansion of both dose levels

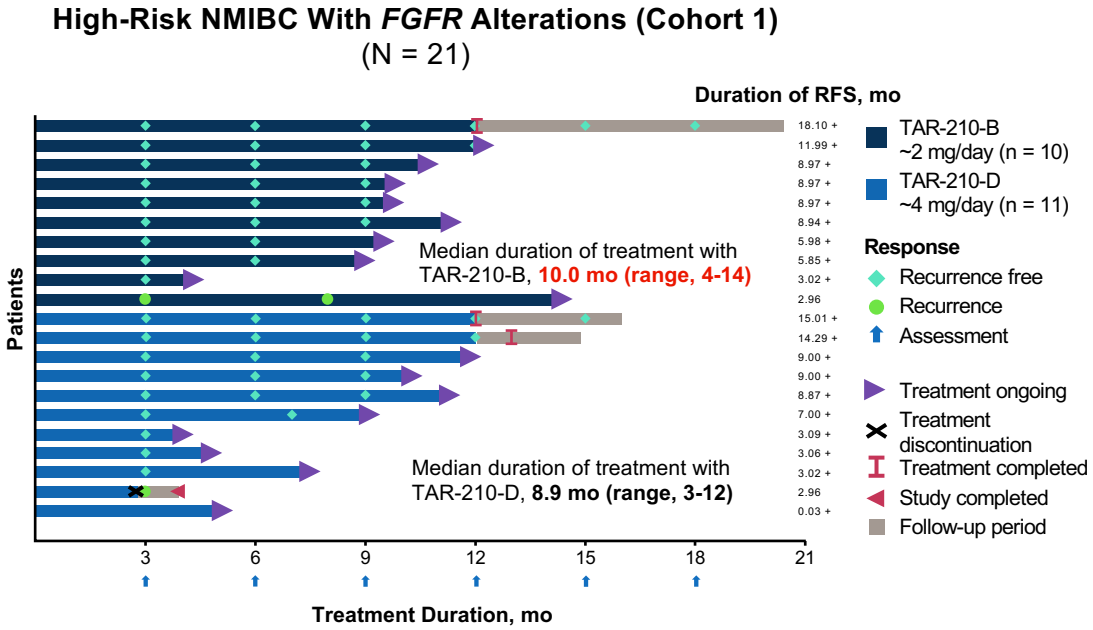
- **Primary endpoint:** safety (AEs, AE severity, DLTs)

[a] Clinical cutoff date: March 22, 2024.

1. Vilaseca A et al. AUA 2024. Abstract PD48-02. 2. https://clinicaltrials.gov/study/NCT05316155.

PeerView

TAR-210 High-Risk NMIBC (Cohort 1): Response Rate[1]



- **90% estimated 12-mo RFS rate[a]** (n = 21)
  - Median RFS was not estimable
  - 2 of 21 patients have recurred
  - Median duration of follow-up: 8.9 months
- No difference observed in RFS between the TAR-210 dose levels

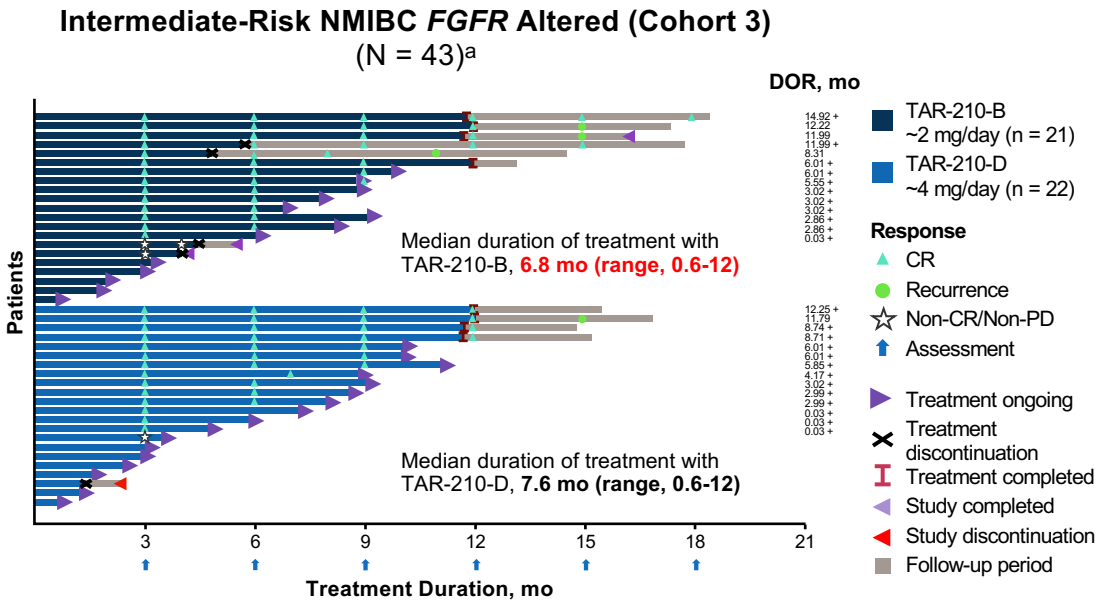
\+ Indicates patient was censored.

[a] All treated patients were efficacy evaluable. RFS was estimated using the Kaplan–Meier method.

1. Vilaseca A et al. AUA 2024. Abstract PD48-02.

PeerView

TAR-210 Intermediate-Risk NMIBC (Cohort 3): Response Rate[1]



- Overall, 31 patients were evaluable for response[b]
- **90% CR rate**, with 28/31 patients achieving a CR at week 12
  - Overall, **100% of patients achieved a clinical response**; 3 patients had a non-CR/non-PD response
- Consistent CR rate seen across both doses
- 86% (24/28) of CRs were ongoing at time of clinical cutoff

Durable Response Rate at Specific Landmarks[c]	% (95% CI)
6 months	100 (100-100)
9 months	89 (43-98)

\+ Indicates patient was censored.

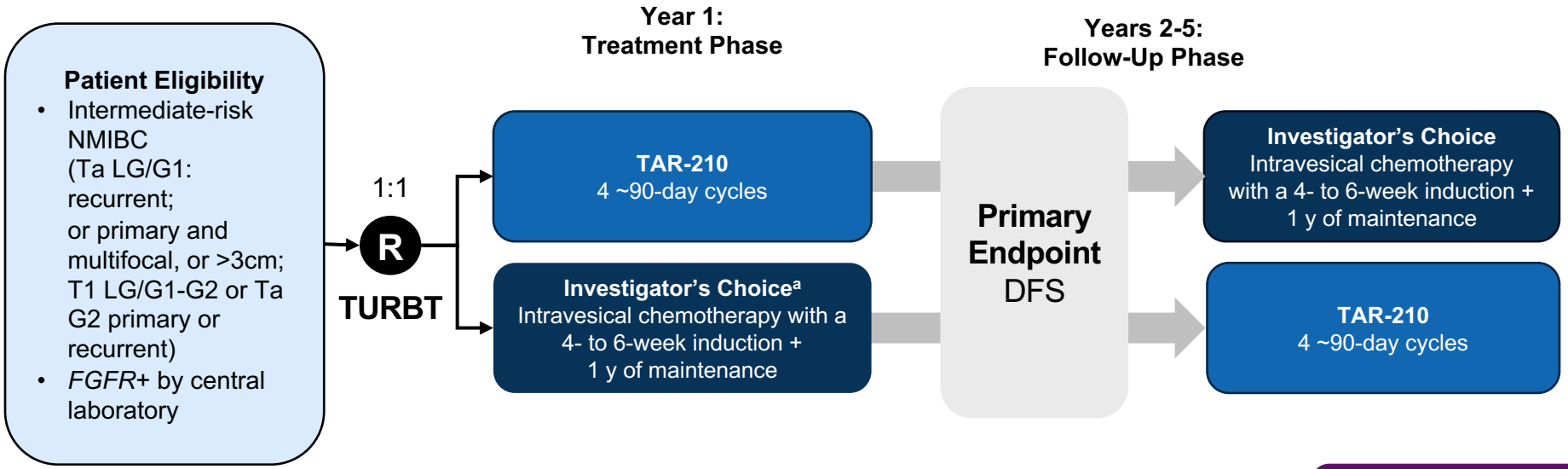
[a] 43 patients were treated; 31 patients were efficacy evaluable for CR and DOR. [b] Efficacy evaluable patients were those having at least one disease evaluation or discontinuing treatment prior to their first disease evaluation for either PD or recurrence. [c] DOR was estimated using the Kaplan–Meier method.

1. Vilaseca A et al. AUA 2024. Abstract PD48-02.

PeerView

Phase 3 MoonRISe-1 Underway[1,2]

TAR-210 vs IV chemotherapy in intermediate-risk NMIBC with susceptible *FGFR* alterations



AUA 2025 Update
Li R et al.

[a] Gemcitabine or mitomycin C.

1. https://clinicaltrials.gov/study/NCT06319820. 2. Li R et al. SUO 2024. Abstract 130.

PeerView

Other Ongoing Opportunities[1,2]

Detalimogene Voraplasmid (EG-70)

- Non-viral intravesical gene therapy
- Phase 1 portion of the **LEGEND** trial
  - Tolerable safety profile and an overall CR rate of 73% in patients with NMIBC (CIS)
- Phase 2 portion of the **LEGEND** trial:
  - Cohort 1 (BCG unresponsive with CIS)
  - 71% of patients dosed with EG-70 achieved a CR
    - ➢ 67% achieving a CR at 3 months; 47% achieving a CR at 6 months

Sasanlimab

- Subcutaneous anti–PD-1 monoclonal antibody
  - Phase 1 trial
  - 21.1% PR and 31.6% SD
- Phase 3 **CREST**
  - Sasanlimab + BCG significantly improved EFS in BCG-naïve, high-risk NMIBC patients compared with BCG alone

AUA 2025 Update
Shore N et al.

1. Taylor JA et al. ASCO GU 2025. Abstract 802. 2. Steinberg G et al. *Future Oncol*. 2024 May;20(14):891-901.

PeerView

Let's Review a Different Patient Case: NMIBC

Philip

- 72-year-old with NMIBC
- ECOG PS: 0
- CIS + high grade Ta
- BCG-unresponsive
- Undergoes gem/doce x6
- 6 mo later: recurrent papillary tumor (2 cm)

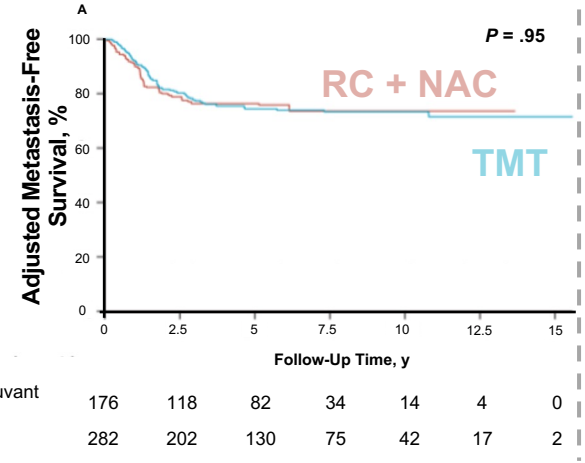
Panel Discussion

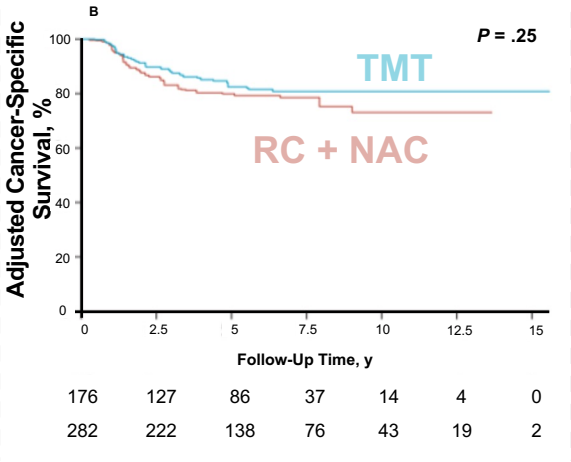
What options should you be prepared to offer in the future?

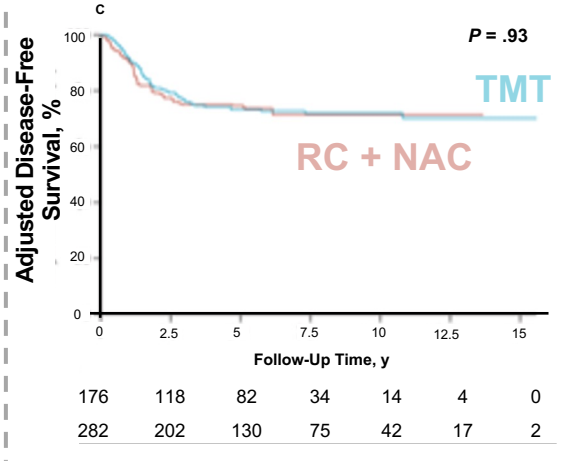
- TAR-200
- TAR-210
- CG0070

- What are the important patient conversations?
- When do you send for genomic testing?
- How do you think about care team education/logistics?

Radical Cystectomy Versus Trimodality Therapy for MIBC[1]







No. at Risk							
RC + NAC or adjuvant chemotherapy	176	118	82	34	14	4	0
TMT	282	202	130	75	42	17	2

RC + NAC or adjuvant chemotherapy	176	127	86	37	14	4	0
TMT	282	222	138	76	43	19	2

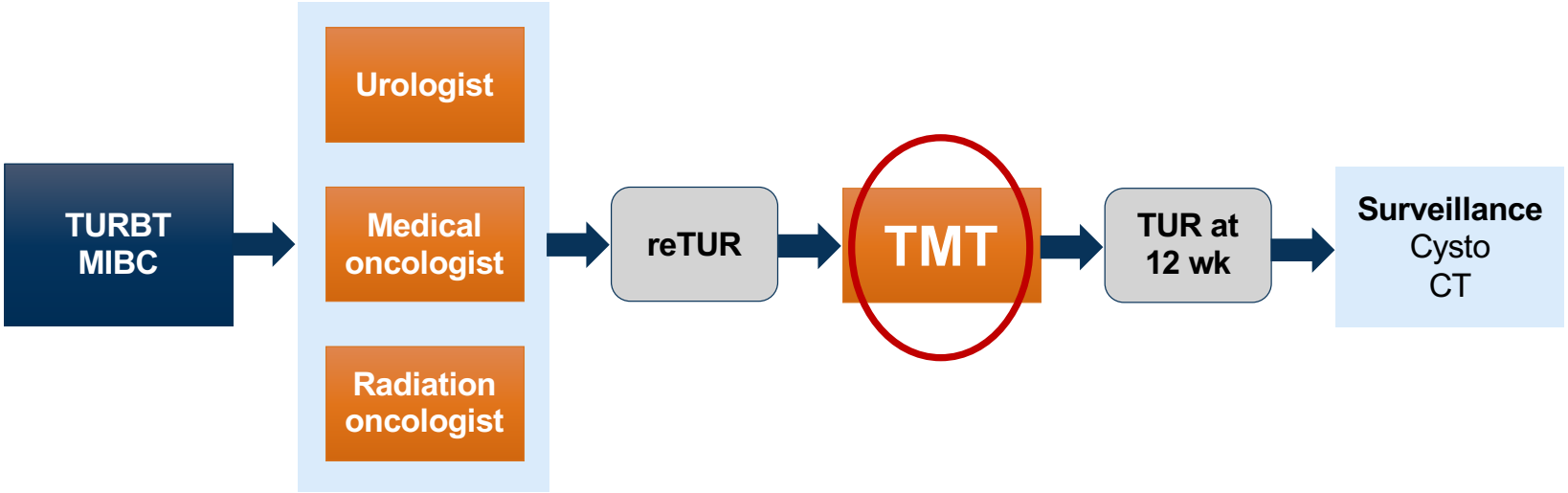
RC + NAC or adjuvant chemotherapy	176	118	82	34	14	4	0
TMT	282	202	130	75	42	17	2

- Similar oncological outcomes between RC and TMT for select patients with MIBC
- TMT, in the setting of multidisciplinary shared decision-making, should be offered to all suitable candidates with MIBC—not just patients with significant comorbidities for whom surgery is not an option

1. Zlotta AR et al. *Lancet Oncol.* 2023; 24: 669-681.

PeerView

Trimodality Therapy (TMT) in MIBC[1]



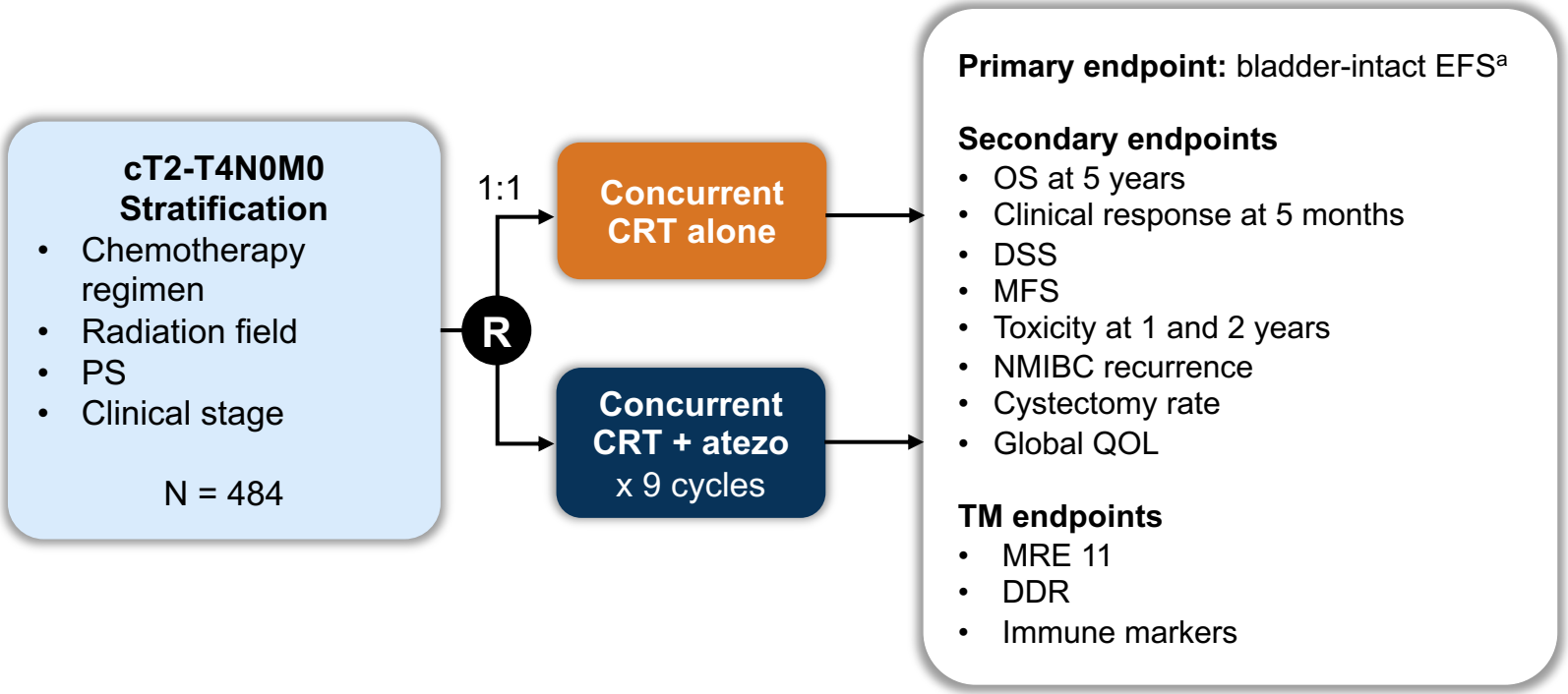
- Complete transurethral resection of the bladder tumor followed by radiotherapy with chemosensitizing chemotherapy
- Valid alternative option to RC for patients with MIBC who would like bladder preservation
- Lack of randomized clinical trials assessing TMT vs RC

1. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.

PeerView

Harnessing IO for Trimodality Therapy in MIBC[1]

Phase 3 S1806: Randomized Trial of Concurrent Chemoradiotherapy ± Atezolizumab in Localized MIBC[1]



[a] Bladder-intact EFS includes: Muscle-invasive recurrence in the bladder; regional pelvic soft tissue or nodal recurrence; distant metastases; bladder cancer or toxicity-related death; or cystectomy.

1. https://clinicaltrials.gov/study/NCT03775265.

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Perioperative Morbidity/Mortality Management With RC Is a Key Factor in the Care of Patients With MIBC[1-9]

The standard of care for MIBC (T2-T4a N0M0) includes RC with cisplatin-based NAC,[1] which has demonstrated a 23% increase in survival benefit versus RC only[2], however:

- Up to 50% of patients with MIBC are ineligible for such neoadjuvant treatment[3,4]
- Patients receiving cisplatin-based NAC can experience a decrease in general health status and lean muscle mass, increased asthenia and GI AEs, and a delay in time to RC[5-8]

There is a high unmet need for effective neoadjuvant treatments for patients with MIBC who are cisplatin-ineligible or do not want cisplatin who:

- Maintain overall health status
- Do not delay or increase complications of planned RC for comorbid patients with MIBC

1. Scarpato KR et al. *Res Rep Urol*. 2015;7:143-151. 2 Grossman HB et al. *N Engl J Med*. 2003;349:859-866. 3. Thompson RH et al. *BJU Int*. 2014;113:E17-E21.
4. Jiang DM et al. *Nat Rev Urol*. 2021;18:104-114. 5. Fukushi K et al. *Int J Clin Oncol*. 2017;22(2):366-372. 6. Rimar KJ et al. *Bladder Cancer*. 2018;4(4):411-418.
7. Pfister C et al. *Eur Urol*. 2021;79(2):214-221. 8. Nuijens ST et al. *Urol Oncol*. 2024;42(4):117.e11-117.
9. EAU Guidelines. Edn. presented at the EAU Annual Congress Paris 2024. ISBN 978-94-92671-23-3.

SunRISe-4: Improved Responses With Neoadjuvant TAR-200 Plus Cetrelimab Versus Cetrelimab Monotherapy[1,2,a]

Key Eligibility Criteria
- Aged ≥18 years
- Histologically confirmed cT2-T4a N0M0 MIBC
- ECOG PS of 0-1
- Ineligible for or refusing cisplatin-based neoadjuvant chemotherapy
- Scheduled for RC

N = 160

Stratification
- Visible residual disease at TURBT: complete vs incomplete (≤3 cm)
- Tumor stage at MIBC diagnosis: cT2 vs cT3-4a

R 5:3

4 CYCLES

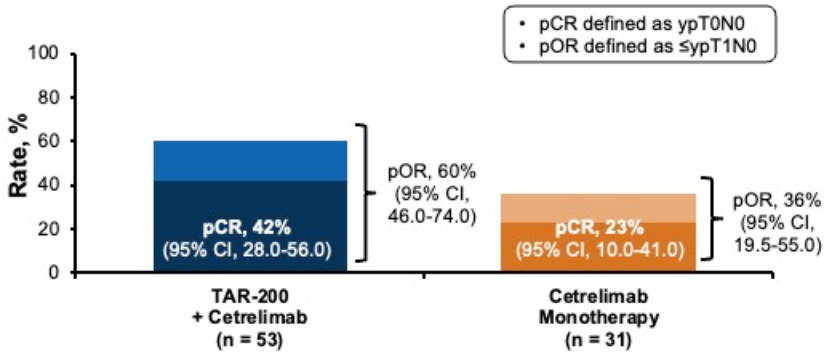
TAR-200 + cetrelimab *Cohort 1*
TAR-200 225 mg gemcitabine Q3W (indwelling) 12 weeks **+ cetrelimab IV** for 12 weeks

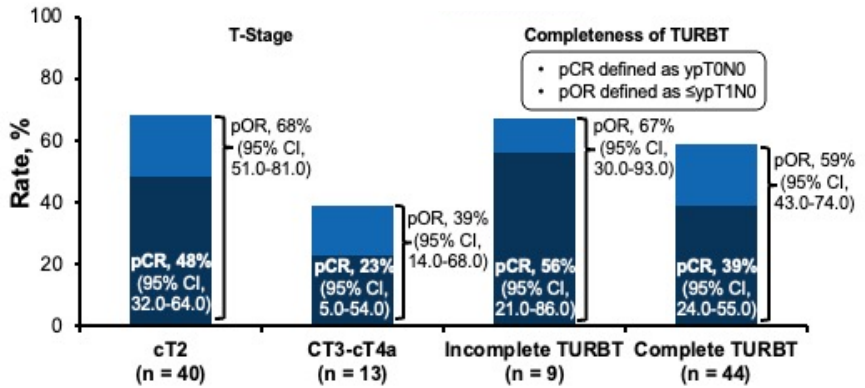
Cetrelimab monotherapy *Cohort 2*
Cetrelimab IV alone for 12 weeks

Follow-up Weeks 4-108
- Every 4 weeks until Week 12 post RC
- Every 12 weeks until Week 108 post RC (end of study)

Primary end point
- pCR rate (ypT0N0)

Secondary end points
- Recurrence-free survival
- Safety





[a] Protocol-specified RC window: 11 to 15 weeks; At data cutoff (May 31, 2024): 76 patients had undergone RC (Cohort 1: n = 50; Cohort 2: n = 26).

1. https://clinicaltrials.gov/study/NCT04919512. 2. Necchi A et al. ESMO 2024. Abstract LBA84.

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SunRISe-4: Safety Profile[1,2]

- Most frequent TRAEs in either cohort were **grade 1-2 urinary events**
- ECOG PS was preserved in the majority of patients in both cohorts
- There were no clinically significant changes in BMI, albumin, creatinine, and hemoglobin during the neoadjuvant period
- Across both cohorts (N = 76), median time from neoadjuvant initiation to RC was 13.5 weeks (range, 4.1-19.4)
  - 64 of 76 (84%) patients had RC within the protocol-specified window
  - Among 8 patients who had RC after the protocol-specified window, only 1 RC was delayed because of a TRAE (hematuria in the cetrelimab monotherapy cohort)

Patients With ≥1 event	Within 30 d Post RC			Within 90 d Post RC		
n (%)	Overall (N = 60)	TAR-200 + Cetrelimab (n = 38)	Cetrelimab Monotherapy (n = 22)	Overall (N = 38)	TAR-200 + Cetrelimab (n = 23)	Cetrelimab Monotherapy (n = 15)
Post-RC morbidity						
≥1 TEAE any grade	48 (80)	29 (76.3)	19 (86.4)	31 (81.6)	18 (78.3)	13 (86.7)
Serious TEAE	24 (40)	17 (44.7)	7 (31.8)	15 (39.5)	11 (47.8)	4 (26.7)
Grade ≥3 TEAE	25 (41.7)	16 (42.1)	9 (40.9)	15 (39.5)	10 (43.5)	5 (33.3)
Post-RC mortality						
Any cause	1 (1.7)	0	1 (4.5)	2 (5.3)	1 (4.3)	1 (6.7)

1. https://clinicaltrials.gov/study/NCT04919512. 2. Psutka SP et al. EAU 2025.

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Continued Advances in MIBC and Updates in mUC



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Co-Leader, Cancer Clinical Investigation Program
Associate Director for Translational Research
Tisch Cancer Institute
New York, New York

Bladder-Sparing Options for Responders?

TURBT + Chemo-Immunotherapy Alone for MIBC[1-3]

HCRN GU16-257

Key Eligibility Criteria
- MIBC
- cT2-4aN0M0

N = 76

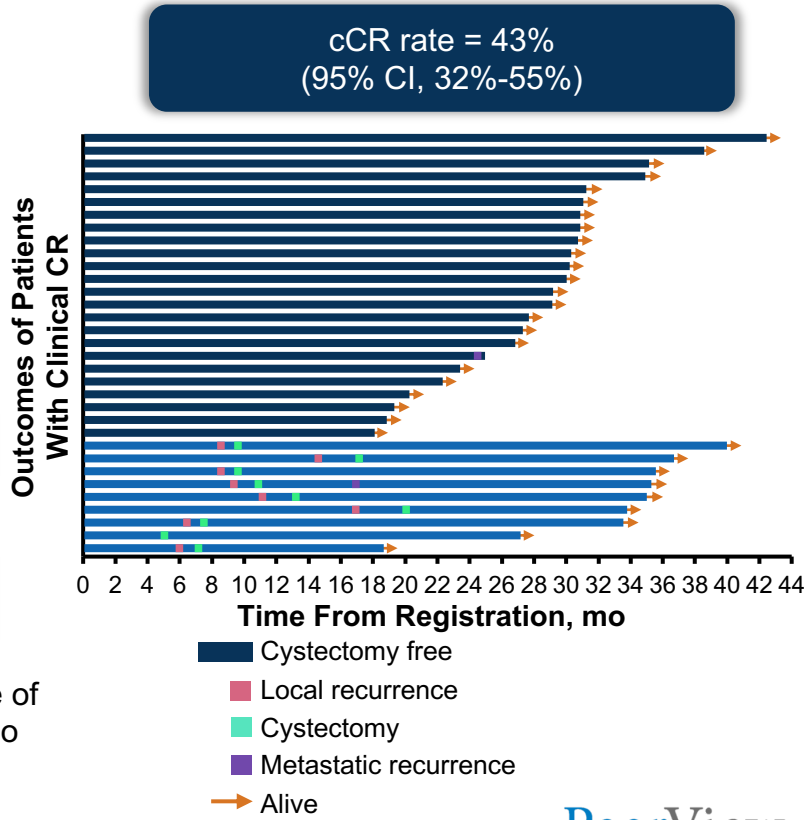
DNA sequencing

Gem/cis + nivolumab x 4 cycles

Clinical restaging: cystoscopy + biopsies, urine cytology, MRI
n = 72

- Cystectomy[a] n = 1
- Clinical CR n = 33
- No clinical CR n = 39
  - Cystectomy n = 34
  - Nonprotocol therapy n = 5
- No cystectomy[a] n = 32
  - **Nivolumab** x 4 mo

Co-primary endpoints: cCR rate and performance of cCR in predicting treatment benefit (ie, 2-y MFS if no cystectomy and pCR in immediate cystectomy)



[a] Treatment based on patients' choice.

1. Galsky MD et al. ASCO 2021. Abstract 4503. 2. Galsky MD et al. ASCO GU 2023. Abstract 447. 3. Galsky MD et al. *Nat Med.* 2023;29:2825-2834.

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Bladder-Sparing Options for Responders?[1,2]

RETAIN-1:
phase 2 risk-adapted approach to identify patients for cystectomy-sparing active surveillance following NAC with accelerated AMVAC

RETAIN-2:
phase 2 risk-adapted approach after neoadjuvant chemo-immunotherapy (ddMVAC + nivolumab)

Comparison of RETAIN-1 vs RETAIN-2 Results

	RETAIN-1 (ddMVAC)	RETAIN-2 (ddMVAC + Nivolumab)
Mutation pos	47%	44%
Active Surveillance	36%	31.4%
Median duration of f/u	40 mo	22 mo
In AS (mets free)	64%	82%
In cystectomy (ypT0)	15%	**40%**
In ITT (ypT0 + cCR)	27%	**54%**
In AS (no local recurrence)	38%	68%
In AS (metastases-free with intact unirradiated bladder)	48%	60%

1. Geynisman D et al. *J Clin Oncol*. 2025;43:1113-1122. 2. Ghatalia P et al. ASCO GU 2025. Abstract 815.

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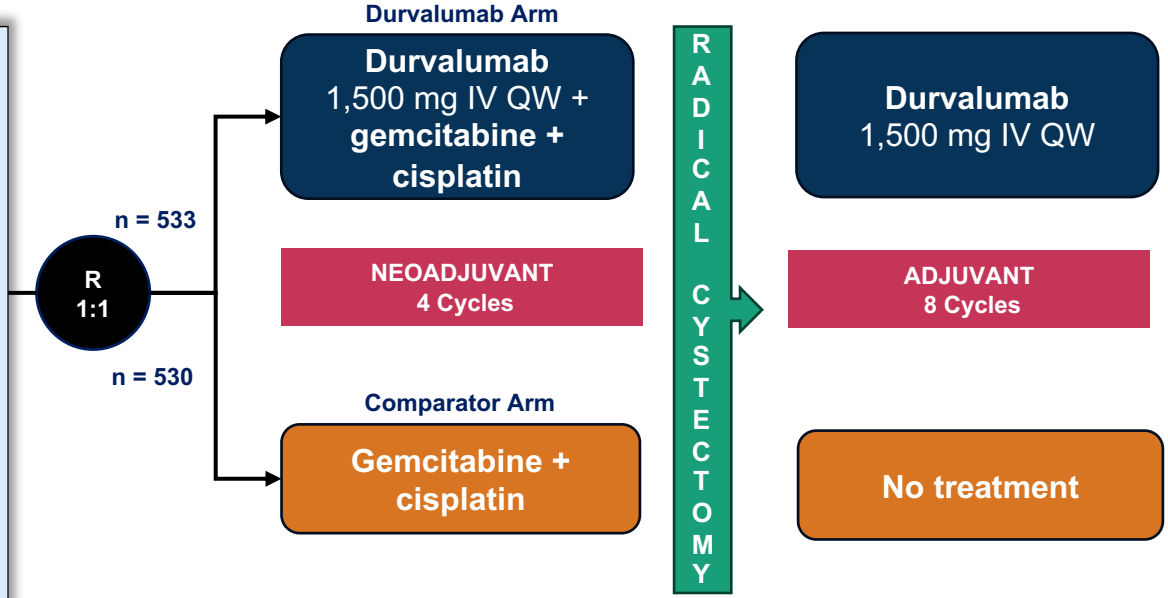
Phase 3 NIAGARA: Perioperative Durvalumab With Neoadjuvant Chemotherapy in Operable Bladder Cancer[1]

Key Eligibility Criteria

- Cisplatin-eligible MIBC
- Clinical stage T2-T4aN0/N1/M0
- UC or UC with divergent differentiation or histologic subtypes
- Evaluated and confirmed for radical cystectomy
- CrCl >40 mL/min per 1.73 m^2 per BSA

Stratification Factors

- Clinical tumor stage (T2N0 vs >T2N0)
- Renal function (CrCl >60 mL/min vs >40 to <60 mL/min)
- PD-L1 status (high vs low or negative)



EFS was defined as:

- Progressive disease that precluded RC
- Recurrence after RC
- Date of expected surgery in patients who did not undergo RC
- Death from any cause
- Other: DFS, DSS, MFS, HRQOL, 5-year OS

1. Powles TB et al. *N Engl J Med*. 2024; 391:1773-1786.

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Phase 3 NIAGARA: Baseline Characteristics[1]

NIAGARA: Baseline Characteristics (ITT)

Characteristics		Durvalumab (n = 553)	Comparator (n = 530)
Age	Median, y (range)	65 (34-84)	66 (32-83)
Sex, %	Male	82	82
Race, %	White	66	68
	Asian	29	27
	Black/other	2	1
	Not reported	3	4
ECOG PS, %	0	78	78
	1	22	22
Smoker, %	Yes (current or former)	71	75
Renal function, %	CrCl ≥60 mL/min	81	81
	CrCl ≥40 to <60 mL/min	19	19
Tumor stage, %	T2N0	40	40
	>T2N0	60	60
PD-L1 expression, %	High	73	73
	Low/negative	27	27
Histology, %	UC	86	83
	UC with VH	14	17
Regional lymph nodes, %	N0	85	94
	N1	5	6

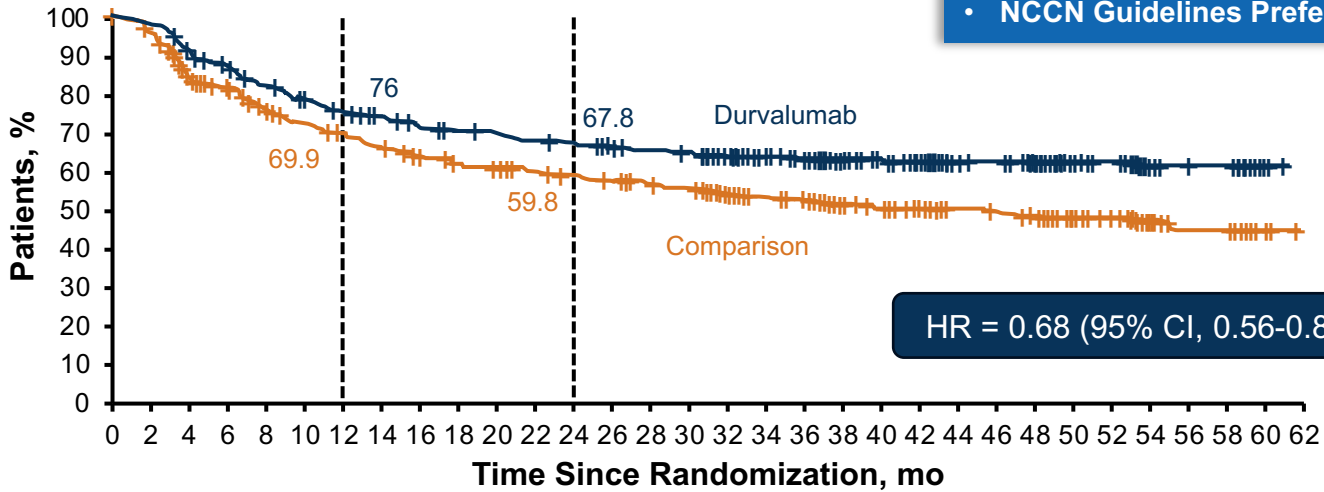
1. Powles TB et al. *N Engl J Med*. 2024; 391:1773-1786.

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Phase 3 NIAGARA: Durvalumab Improved EFS[1,a]

March 2025

- FDA approved[2,3]
- NCCN Guidelines Preferred Regimen[4]



HR = 0.68 (95% CI, 0.56-0.82); *P* < .001

No. at Risk

Durvalumab	533	475	424	386	356	344	330	315	282	255	202	141	115	86	81	32	20	20	1	0
Comparison	530	437	381	343	313	296	281	264	228	214	172	132	94	69	62	24	18	16	2	0

EFS benefit consistent across prespecified subgroups

[a] Median follow-up: 42.3 months.

1. Powles TB et al. *N Engl J Med*. 2024; 391:1773-1786. 2. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-muscle-invasive-bladder-cancer. 3. Imfinzi (durvalumab) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761069s050lbl.pdf. 4. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.

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Perioperative Durvalumab Plus NAC Improved Secondary Endpoints[1,2,a]

	Durvalumab Arm n = 533	Comparator Arm n = 530
No. of events, n (%)	152 (28.5)	201 (37.9)
Median MFS (95% CI), months	NR (NR-NR)	NR (48-NR)
HR (95% CI)	**0.67** (0.54-0.83); nominal *P* < .001	
Death from bladder cancer, n (%)	85 (15.9)	114 (21.5)
Median DSS (95% CI), months	NR (NR-NR)	NR (NR-NR)
HR (95% CI)	**0.69** (0.52-0.91); nominal *P* = .008	
No. of deaths/total no. (%)	136/553 (25.5)	169/530 (31.9)
Median OS	NR	NR
HR (95% CI)	**0.75** (95% CI, 0.59-0.93); *P* = .01	

AUA 2025 Update

DFS benefit was observed in the overall population and across subgroups

Meeks JJ et al.
Abstract PD-37-09
Tuesday 4/29/25

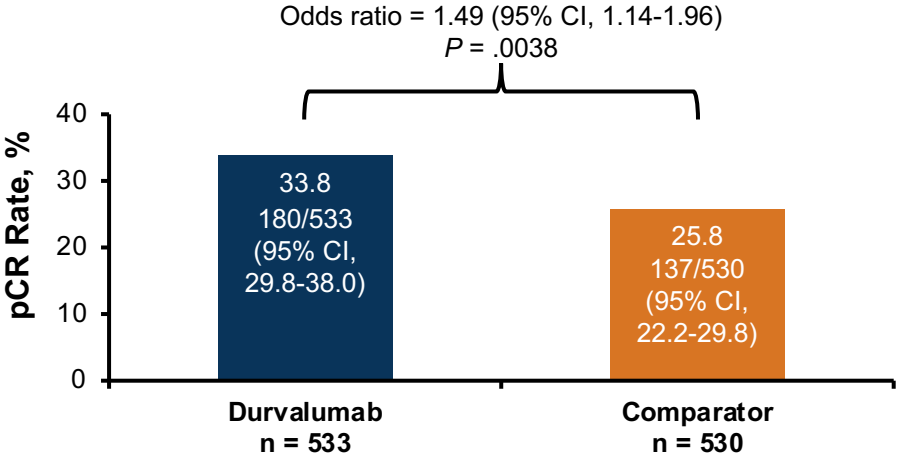
[a] Median follow-up: 42.3 months.

1. Powles TB et al. *N Engl J Med*. 2024; 391:1773-1786. 2. Galsky MD et al. ASCO GU 2025. Abstract 659.

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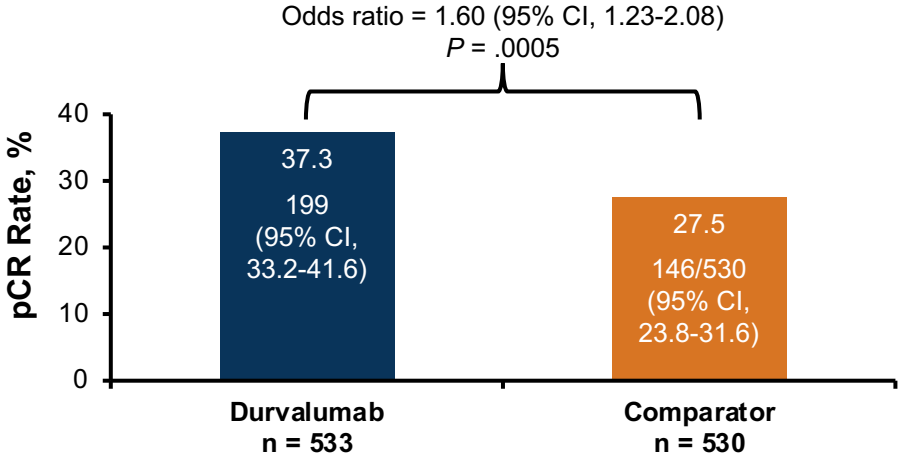
NIAGARA: pCR Rate[1]

Formal Analysis (January 2022)



- The planned formal analysis for pCR was not statistically significant (threshold for significance, *P* = .001)
- 59 evaluable samples were incorrectly considered nonresponders rather than their true result

Re-analysis (April 2024)



- The re-analysis showed nominal statistical significance in favor of the durvalumab arm
- This analysis includes the results of the 59 omitted samples (28 additional pCRs)[a]

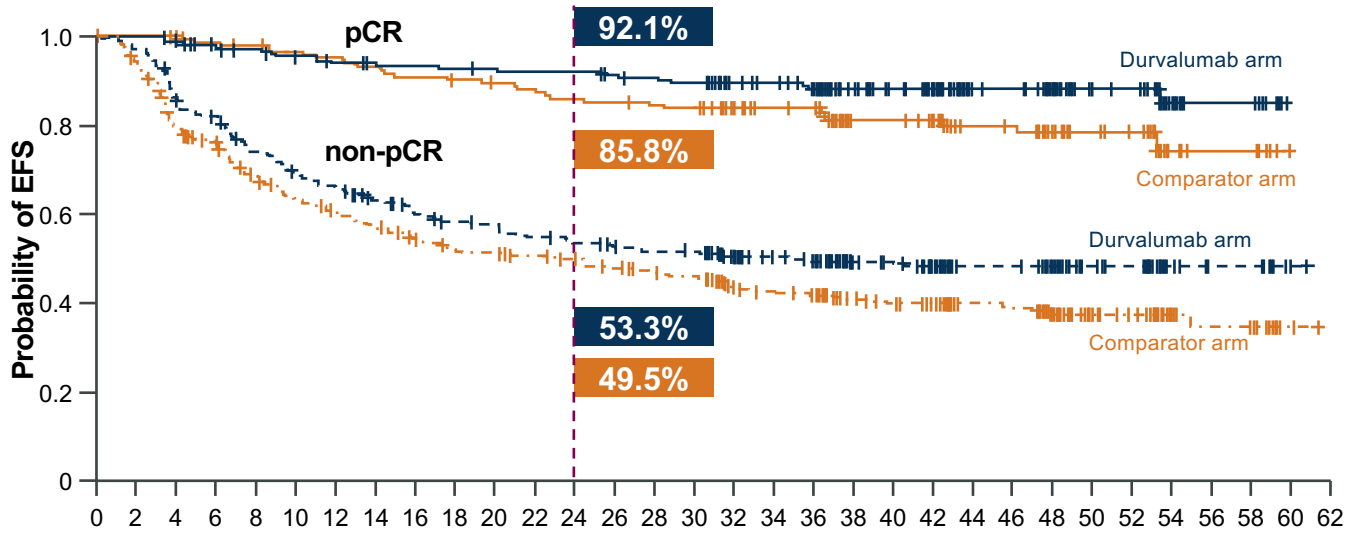
1. Powles TB et al. *N Engl J Med*. 2024;391:1773-1786.

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NIAGARA: EFS (pCR and Non-pCR Groups)[1,a]

EFS by Pathologic Staging

- Perioperative D + NAC improved EFS in both groups



No. of Patients at Risk

pCR: D arm	199	199	195	188	185	180	176	174	173	172	171	170	170	166	164	162	145	142	134	111	103	90	70	69	57	40	39	14	9	9	0	0
pCR: C arm	146	146	144	140	139	136	134	131	128	126	124	121	119	118	116	115	105	101	100	79	79	73	58	57	38	30	27	9	6	6	0	0
non-pCR: D arm	334	320	280	266	239	221	210	196	183	176	173	165	160	155	151	150	137	127	121	103	99	89	71	71	58	46	42	18	11	11	1	0
non-pCR: C arm	384	352	293	275	242	222	209	197	185	174	172	167	162	155	148	144	123	118	114	98	93	86	74	72	56	39	35	15	12	10	2	0

pCR

	Durvalumab n = 199	Comparator n = 146
No. events, n (%)	23 (12)	29 (20)
Median EFS (95% CI), mo	NR (NR-NR)	NR (NR-NR)
EFS HR (95% CI)	**0.58** (0.332-0.999)	

non-pCR

	Durvalumab n = 334	Comparator n = 384
No. events, n (%)	164 (49)	217 (57)
Median EFS (95% CI), mo	34.7 (20.5-NR)	22.8 (15.5-30.6)
EFS HR (95% CI)	**0.77** (0.631-0.948)	

ITT

EFS HR (95% CI)	**0.68** (0.56-0.82)

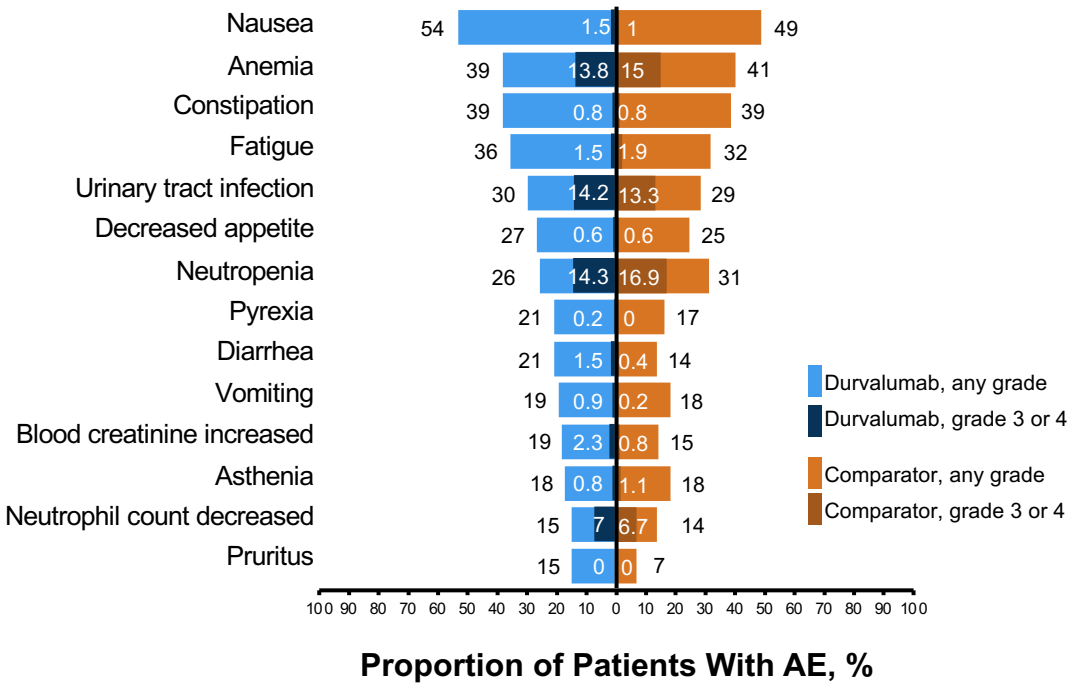
[a] Data cutoff Apr 29, 2024. Exploratory post-hoc analysis. Event-free survival by blinded independent central review or by central pathology review. Tick marks indicate patients with censored data.

1. Galsky MD et al. ASCO GU 2025. Abstract 659.

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Durvalumab Plus Neoadjuvant Chemotherapy Was Tolerable and Had No New Safety Signals[1]

NIAGARA: Most Frequently Reported AEs (Overall)



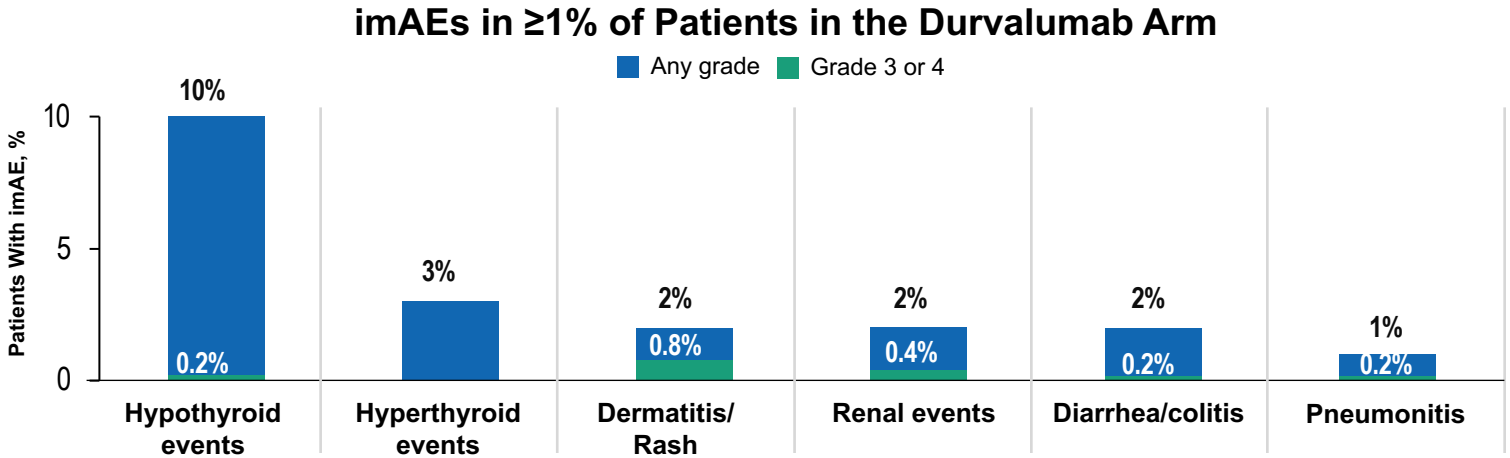
Durvalumab + neoadjuvant chemotherapy compared with neoadjuvant chemotherapy alone

- TRAEs: 40.6% vs 40.9%
- TRAE leading to death: 0.6% vs 0.6%
- Did not compromise patients' ability to complete surgery: 80% of patients in each group underwent RC

1. Powles TB et al. *N Engl J Med*. 2024; 391:1773-1786.

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NIAGARA: Immune-Mediated AEs Were Mostly Low Grade and Consistent With the Known Profile of Durvalumab[1,a]



- imAEs were reported in 21% (111/530; grade 3/4, 3%) of patients in the durvalumab arm
- There were 45/111 (41%) patients who had all imAEs resolved in the durvalumab arm
- Unresolved imAEs were mainly low-grade hypothyroid events, which were manageable with replacement therapy

[a] imAEs were reported in 3% (16/526; grade 3/4 0.2% [1/526]) of patients in the comparator arm. There were 7/16 (44%) patients who had all their imAEs resolved in the comparator arm. Data cutoff Apr 29, 2024. imAEs are defined as AEs of special interest that were consistent with an immune-mediated mechanism of action with no clear alternative cause and resulted in the use of systemic glucocorticoids, other immunosuppressants, or endocrine therapy. Resolved includes outcomes of recovered/resolved and recovered/resolved with sequelae. The overall study period includes AEs that occurred between the first dose of study treatment, and whichever occurred first: 1) 90 days after the last dose of treatment, surgery, or last adjuvant visit; 2) date of first dose of subsequent anti-cancer therapy; or 3) data cutoff date.

1. Galsky MD et al. ASCO GU 2025. Abstract 659.

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Adjuvant MIBC Trials With PD-L1/PD-1 Inhibitors

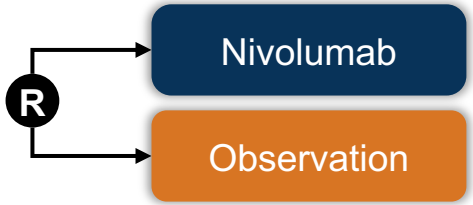
IMvigor010[1]



- **Primary endpoint:** DFS
- **Key secondary endpoints:** OS, DSS, distant MFS, NUTRFS

Did not meet DFS primary endpoint

CheckMate -274[2]



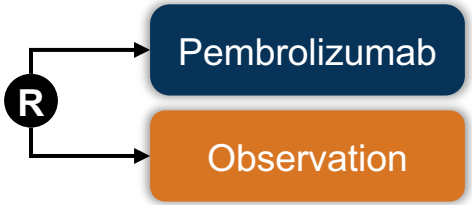
- **Primary endpoint:** DFS
- **Key secondary endpoints:** OS, NUTRFS, DSS

Met DFS primary endpoint

August 2021

FDA approved

AMBASSADOR[3]



- **Coprimary endpoints:** DFS and OS
- **Key secondary endpoints:** OS and DFS in PD-L1–positive and PD-L1–negative patients

Met DFS primary endpoint

1. https://clinicaltrials.gov/study/NCT02450331. 2. https://clinicaltrials.gov/study/NCT02632409. 3. https://clinicaltrials.gov/study/NCT03244384.

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Advancing Treatment Options in the 1L mUC Setting via Combination Approaches

Platinum-Based Chemotherapy + Immune Checkpoint Inhibition

- **No improvement in survival**
  - Investigator's choice chemotherapy + atezolizumab (phase 3 IMvigor130)[1]
  - Investigator's choice chemotherapy + pembrolizumab (phase 3 KEYNOTE-361)[2]
- **Awaiting results**
  - Investigator's choice chemotherapy + durvalumab ± tremelimumab (phase 3 NILE)[3]
- **Improved survival**
  - Gem/cis + nivolumab (phase 3 CheckMate -901)[4]
  - FDA approved March 2024; EMA approved April 2024

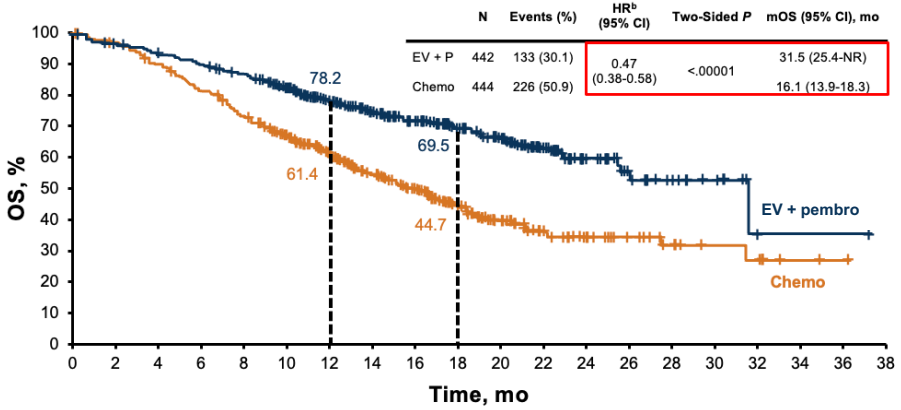
ADC + Immune Checkpoint Inhibition

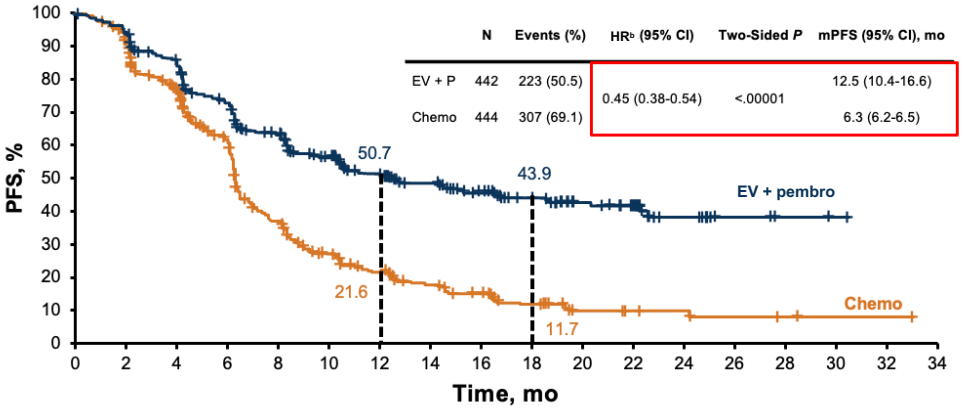
- **Improved survival**
  - Enfortumab vedotin + pembrolizumab (phase 3 EV-302)[5]
  - FDA approved December 2023; EMA approved August 2024

1. Galsky MD et al. *Lancet*. 2020;395:1547-1557. 2. Powles T et al. *Lancet Oncol*. 2021;22:931-945. 3. https://clinicaltrials.gov/study/NCT03682068.
4. van der Heijden MS et al. *N Engl J Med.* 2023;389:1778-1789. 5. Powles T et al. *N Engl J Med.* 2024;390:875-888.

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Phase 3 EV-302: Enfortumab Vedotin Plus Pembrolizumab Improved OS and PFS Versus Chemo Alone[1,2,a]





Risk of death was reduced by 53% in patients who received EV + pembrolizumab

Risk of progression or death was reduced by 55% in patients who received EV + pembrolizumab

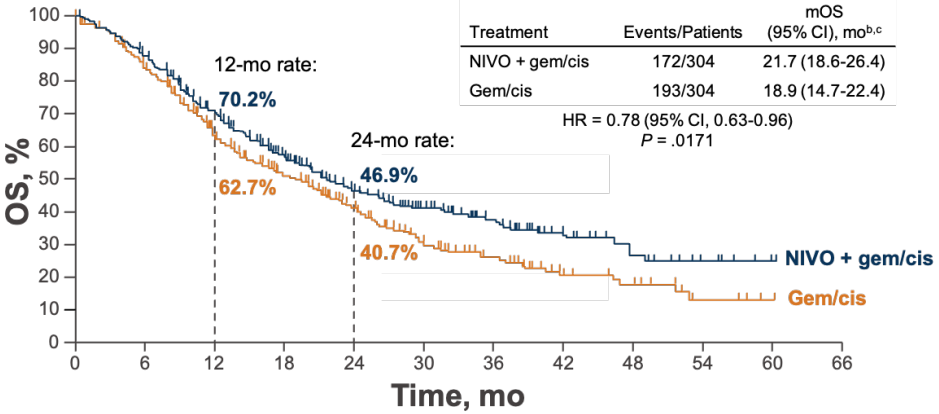
Results were maintained with 12 months of additional follow-up

[a] Data cutoff: August 8, 2023; FPI: April 7, 2020; LPI: November 9, 2022. Median survival follow-up: 17.2 mo. OS at 12 and 18 mo was estimated using Kaplan–Meier method. PFS at 12 and 18 mo as estimated using Kaplan–Meier method. [b] Calculated using stratified Cox proportional hazards model; HR <1 favors the EV + pembrolizumab arm.

1. Powles T et al. *N Engl J Med.* 2024;390:875-888. 2. Powles T et al. ASCO GU 2025. Abstract 664.

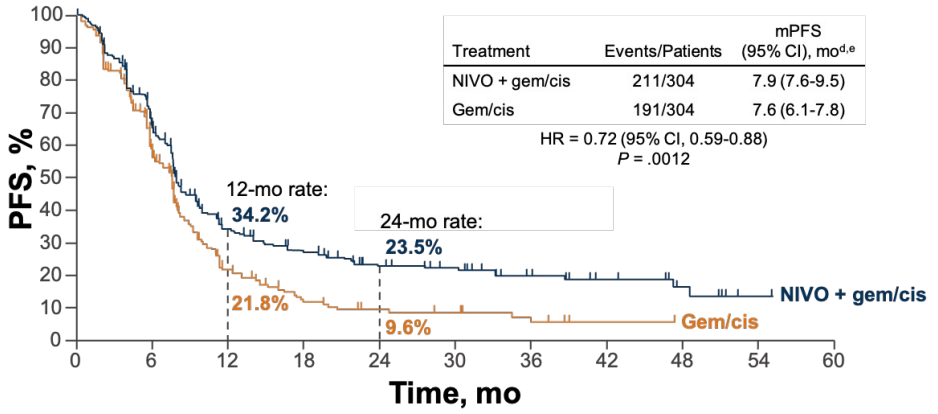
PeerView

Phase 3 CheckMate -901: Nivolumab Plus Gem/Cis Improved PFS and OS Versus Gem/Cis Alone[1,2,a]



Treatment	Events/Patients	mOS (95% CI), mo[b,c]
NIVO + gem/cis	172/304	21.7 (18.6-26.4)
Gem/cis	193/304	18.9 (14.7-22.4)

HR = 0.78 (95% CI, 0.63-0.96)
P = .0171



Treatment	Events/Patients	mPFS (95% CI), mo[d,e]
NIVO + gem/cis	211/304	7.9 (7.6-9.5)
Gem/cis	191/304	7.6 (6.1-7.8)

HR = 0.72 (95% CI, 0.59-0.88)
P = .0012

NIVO + gem/cis is the first 1L concurrent immune checkpoint inhibitor + chemotherapy combination to improve OS in this setting

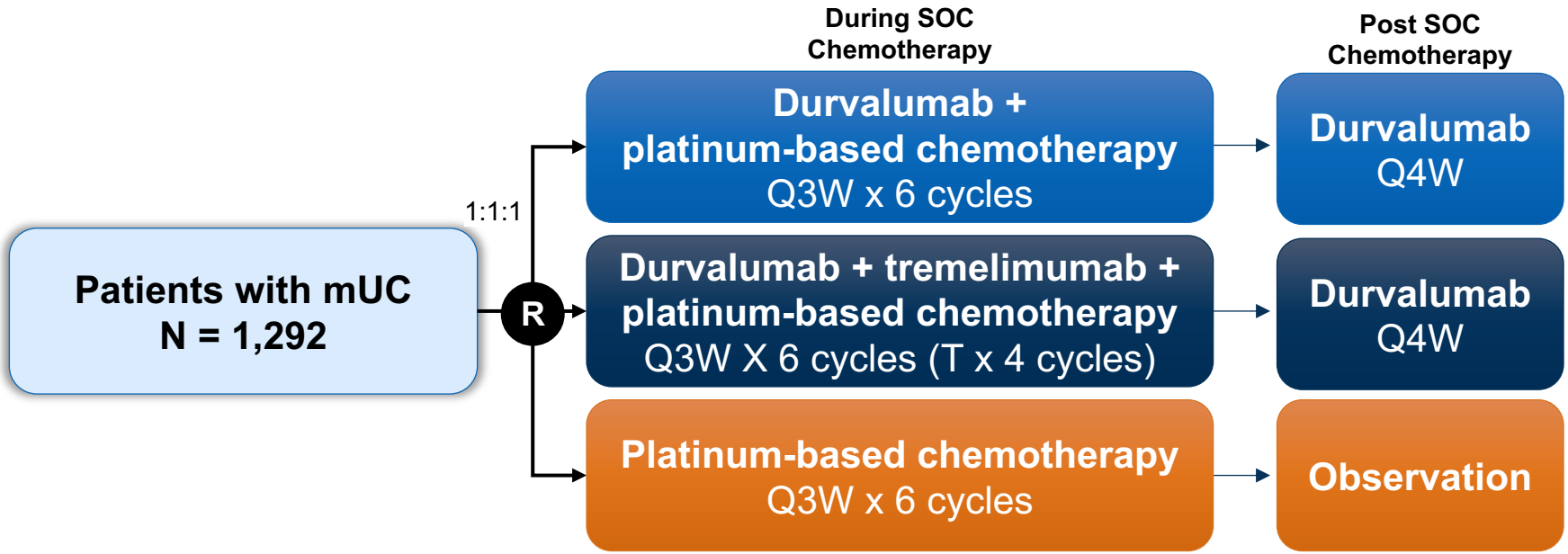
NIVO + gem/cis demonstrated statistically significant and clinically meaningful improvements in PFS vs gem/cis alone as 1L treatment for unresectable or mUC

[a] Median (range) study follow-up, 33.6 (7.4-62.4) mo. [b] OS was estimated in all randomized patients and defined as time from randomization to death from any cause. For patients without documented death, OS was censored on the last date the patient was known to be alive. For randomized patients with no follow-up, OS was censored at randomization. [c] OS final analysis statistical boundaries: *P* boundary = .0311; critical HR = 0.7980. [d] PFS was estimated in all randomized patients and defined as time from randomization to first documented disease progression (per BICR assessments using RECIST v1.1) or death due to any cause, whichever occurred first. Patients who did not progress or die were censored at last evaluable tumor assessment. Patients without on-study tumor assessments who did not die were censored at randomization. Patients who started any subsequent anticancer therapy without prior reported progression were censored at last evaluable tumor assessment before initiation of subsequent therapy. [e] PFS final analysis statistical boundaries: *P* boundary = .01; critical HR = 0.7734.

1. https://clinicaltrials.gov/study/NCT03036098. 2. van der Heijden MS et al. *N Engl J Med*. 2023;389:1778-1789.

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Ongoing Phase 3 NILE: IO Plus Chemo in 1L mUC[1,2]



- **Co-primary endpoint:** OS in PD-L1+ (arm 1 vs arm 3)
- **Select secondary endpoints:** OS, OS 24 mo, PFS, ORR

1. https://clinicaltrials.gov/study/NCT03682068. 2. Galsky MD et al. ASCO GU 2021. Abstract TPS504.

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Importance of Discussing Genomic Testing With Patients

Eligibility for FGFR inhibition requires patients to undergo testing for genomic alterations



Testing ideally occurs at the time of diagnosis of metastatic disease

Flatiron Database analysis of >700 eligible patients showed that fewer than half had undergone testing[1]



Of those who were tested, 21% had an *FGFR* alteration but only 42% received erdafitinib[1]

Both urologists and oncologists have important roles in educating patients on the importance of genomic testing so they can be offered the full range of available therapeutic options to ensure the best possible outcome

1. Nimgaonkar N et al. *JAMA Oncol*. 2022;8:1070-1072.

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Erdafitinib in *FGFR*-Altered Metastatic or Unresectable UC

2019: accelerated FDA approval of erdafitinib monotherapy for mUC with an *FGFR3*- or *FGFR2*-activating mutation or fusion after progression on ≥1 line of platinum-containing chemotherapy[1-3]

Phase 3 THOR[4]:
Where should FGFR3 inhibitors be integrated into the treatment regimens of patients with mUC?

Key Eligibility Criteria

- Patients with metastatic or unresectable locally advanced UC
- **Cohort 1:** prior treatment with an anti–PD-L1 agent as monotherapy or as combination therapy; ≤2 prior lines of systemic treatment
- **Cohort 2:** no prior treatment with an anti–PD-L1 agent; only 1 line of prior systemic treatment
- ECOG PS 0-2

Central screening for *FGFR* fusions or mutations

Cohort 1
n = 266

- **Erdafitinib** 8 mg orally once daily for 21 d in a 21-d cycle
- **Vinflunine** 320 mg/m^2 IV Q3W **+ docetaxel** 75 mg/m^2 IV Q3W

Cohort 2
n = 351

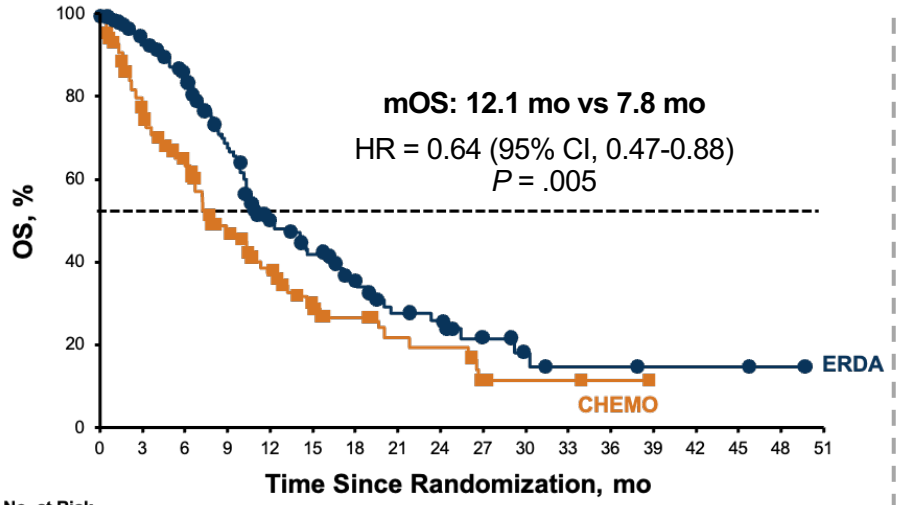
- **Erdafitinib** 8 mg orally once daily for 21 d in a 21-d cycle
- **Pembrolizumab** 200 mg IV Q3W

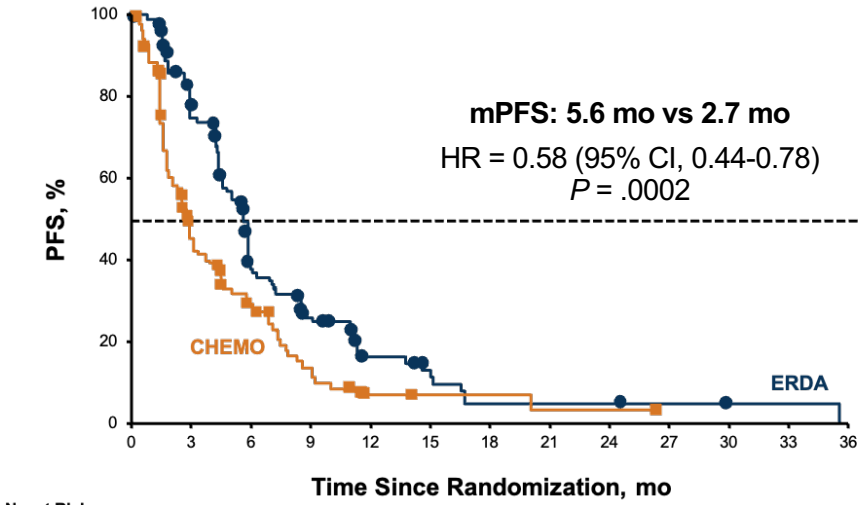
- **Primary endpoint:** OS
- **Secondary endpoints:** PFS, ORR, PROs, DOR, safety

1. Loriot Y et al. *N Engl J Med*. 2019;381:338-348. 2. Necchi A et al. *Ann Oncol*. 2020;31(suppl 4):s550.
3. Siefker-Radtke et al. *Lancet Oncol*. 2022;23:248-258. 4. Loriot T et al. *N Engl J Med*. 2023;389:1961-1971.

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Phase 3 THOR: Cohort 1 (Erdafitinib Versus Chemotherapy)[1,a]





January 2024

Full FDA Approval for locally advanced or mUC with select FGFR3 alterations progressing on ≥1 PD-1/PD-L1 inhibitor[2]

[a] Median follow-up: 15.9 months.

1. Loriot T et al. *N Engl J Med.* 2023;389:1961-1971.
2. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-erdafitinib-locally-advanced-or-metastatic-urothelial-carcinoma.

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DESTINY-PanTumor02: T-DXd in HER2-Expressing Solid Tumors[1-5]

Key Eligibility Criteria

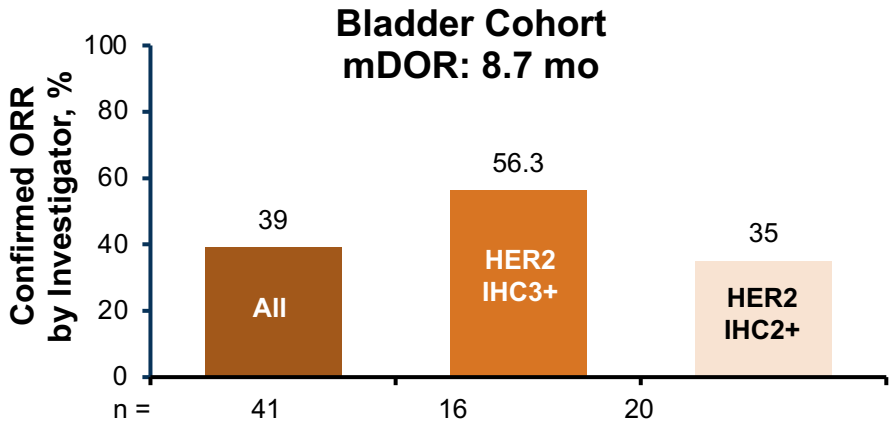
- Advanced solid tumors not eligible for curative therapy
- 2L+ patient population
- HER2 expression (IHC 3+ or 2+)
  - Local test or central test by HercepTest if local test not feasible (ASCO/CAP gastric cancer scoring)
- Prior HER2-targeting therapy allowed
- ECOG/WHO PS 0-1

T-DXd
5.4 mg/kg
Q3W

40 per cohort

- Endometrial cancer
- Cervical cancer
- Ovarian cancer
- **Bladder cancer**
- Other tumors
- Biliary tract cancer
- Pancreatic cancer

- **Primary endpoint:** confirmed ORR (investigator)
- **Secondary endpoints:** DOR, DCR, PFS, OS, safety
- **Exploratory analysis:** subgroup analysis by HER2 status



mPFS 7.0 mo
- 7.8 mo for IHC2+
- 7.4 mo for IHC3+

mOS 12.8 mo
- 13.1 mo for IHC2+
- 13.4 mo for IHC3+

1. https://clinicaltrials.gov/study/NCT04482309. 2. Hofmann M et al. *Histopathol*. 2008;52:797-805. 3. Meric-Bernstam F et al. ESMO 2023. Abstract LBA34. 4. Meric-Bernstam F et al. *J Clin Oncol*. 2024;42:47-58. 5. Wysocki et al. ASCO 2024. Abstract 4565.

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Tumor-Agnostic FDA Approval for T-DXd[1-3]

Updated NCCN Guidelines for Bladder Cancer[1]

Second- or subsequent-line therapy:
T-DXd added for HER2+ tumors (IHC 3+ or 2+)
Useful in certain circumstances

Accelerated FDA Approval[2]

For adult patients with unresectable or metastatic HER2+ (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options

1. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.
2. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2.
3. Enhertu (fam-trastuzumab deruxtecan-nxki) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761139s032s035lbl.pdf.

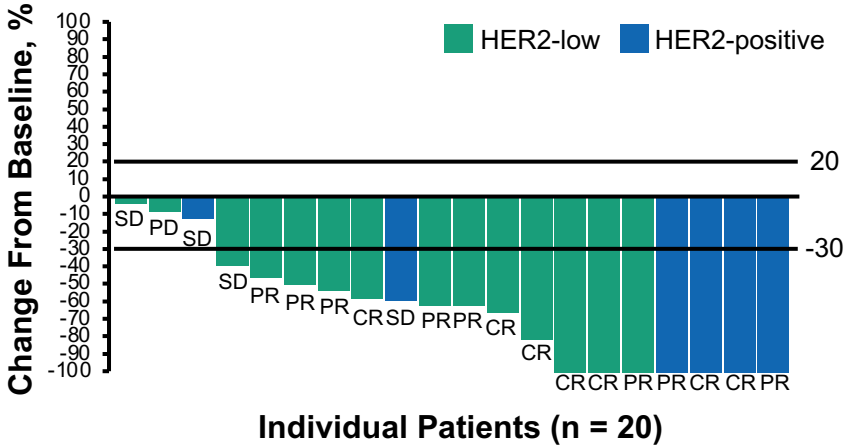
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Anti-HER2 ADCs in Biomarker-Selected mUC[1-3]

1L mUC: Disitamab Vedotin (Anti-HER2) + Pembrolizumab in HER2-Expressing mUC[1]

Phase 2

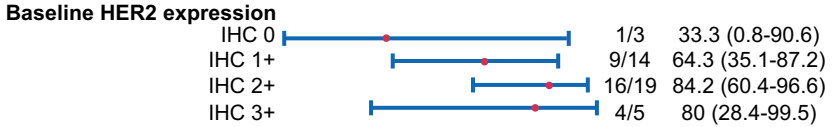
Best Change in Sum of Diameters From Baseline per BICR, %

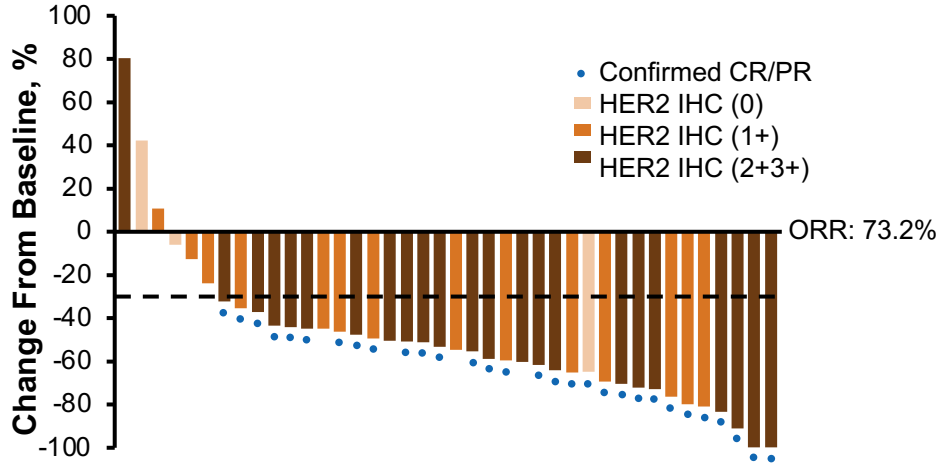


Individual Patients (n = 20)

- **Phase 3 study underway[2]**

≥1L mUC: Disitamab Vedotin + Toripalimab





mPFS: 9.3 mo **mOS: 33.1 mo**

1. Galsky MD et al. ESMO 2024. Abstract 1967MO. 2. https://clinicaltrials.gov/study/NCT05911295.
3. Zhou L et al. *Ann Oncol*. 2025;36:331-339.

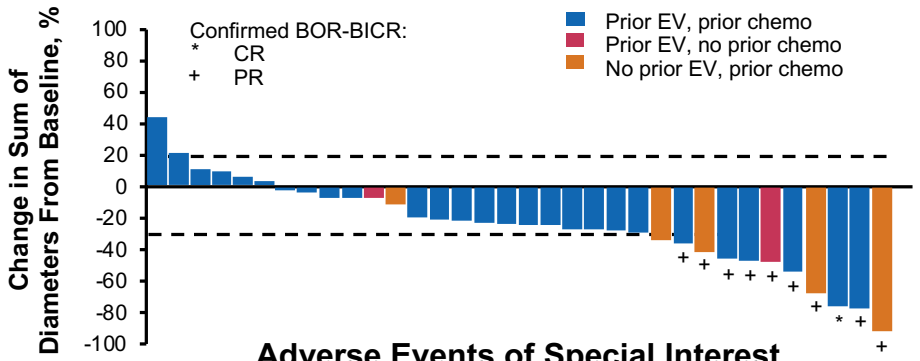
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Anti-Trop2 ADC: Datopotamab Deruxtecan (Dato-DXd) in Pretreated mUC[1-5]

TROPION-PanTumor01[1,2]

Response by BICR	Dato-DXd (N = 40)
ORR, n (%) [95% CI]	10 (25) [12.7-41.2]
DCR, n (%) [95% CI]	31 (77.5) [61.5-89.2]
BOR, n (%)	
CR	1 (2.5)
PR	9 (22.5)
SD	20 (50)
Non-CR/non-PD	1 (2.5)
PD	5 (12.5)
NE	4 (10)
DOR, median (95%CI), month	NE (2.6-NE)
6-month **DOR** rate, % (95% CI)	76.2 (33.2-93.5)

ORR by investigator was 30% (n =12); all were PR



Adverse Events of Special Interest

AESI, n (%)	AESIs				AESIs Associated With		
	Any Grade	Grade 1	Grade 2	Grade 3	Dose Reduction	Dose Delay	Treatment Discontinuation
Oral mucositis/ stomatitis	22 (55)	11 (28)	9 (23)	2 (5)	3 (8)	1 (3)	0
Ocular surface events	7 (18)	4 (10)	3 (8)	0	1 (3)	2 (5)	0
Adjudicated drug-related ILD	2 (5)	0	1 (3)	1 (3)	0	1 (3)	1 (3)

Dato-DXd is being further evaluated as a monotherapy and in combination in patients with UC in the phase 1/2 TROPION-PanTumor02[3] and the phase 2 TROPION-PanTumor03[4] studies

1. Lisberg A et al. ASCO GU 2024. Abstract 603. 2. https://www.clinicaltrials.gov/study/NCT03401385.
3. https://clinicaltrials.gov/study/NCT05460273. 4. https://www.clinicaltrials.gov/study/NCT05489211. 5. Meric-Bernstam F et al. ASCO GU 2025. Abstract 663.

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Targeted Agents Have Distinct AE Profiles[1-4]

Be prepared for potential toxicity, variable onset timing, and dose adjustment needs

Erdafitinib:
rash, hyperphosphatemia, ocular disorders

EV:
rash, peripheral neuropathy, ocular disorders, hyperglycemia

T-DXd:
pneumonitis, ILD

Dato-DXd:
oral mucositis, stomatitis

Ask your patients:

- ❑ Are you having any joint pain, muscle aches, or changes in your strength?
- ❑ Are you having any changes in your gait, mobility, or balance?
- ❑ Have you had a rash?
- ❑ Are you using your eye drops?
- ❑ How is your oral hygiene?
- ❑ Any cough?

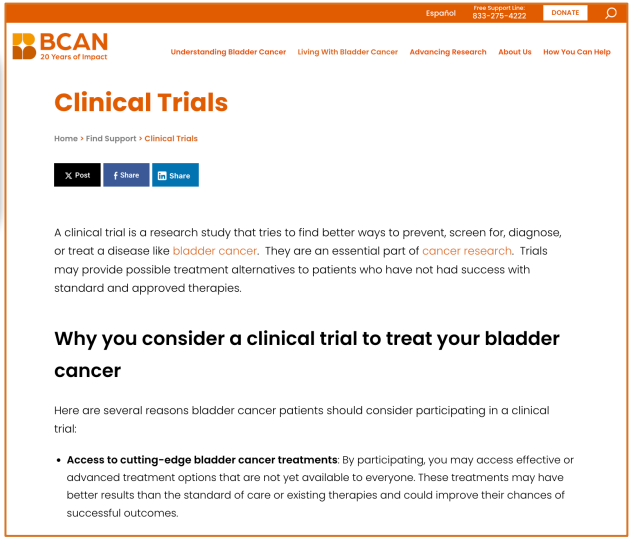
1. Balversa (erdafitinib) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212018s010lbl.pdf. 2. Padcev (enfortumab vedotin) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761137s029lbl.pdf. 3. Enherti (fam-trastuzumab deruxtecan-nxki) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761139s032s035lbl.pdf. 4. Heist RS et al. *Cancer Treat Rev*. 2024;125:102720.

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Tool to Support Patients Searching for Clinical Trials in Bladder Cancer

BCAN
20 Years of Impact

The BCAN Clinical Trials dashboard can be used to find a trial that fits an individual patient's needs



- Healthcare professionals can save trials and email them to patients for further discussion at their next visit
- Patients can search by geographic area and find trials close to/convenient for them

See the BCAN Practice Aid for full details on the BCAN website, a QR code for professionals to download resources for patients, and more!



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Let's Review a Patient Case: MIBC

Charles

- 68-year-old
- Cystoscopy and imaging consistent with a sessile mass at the anterior bladder wall
- Diagnosis of clinically localized MIBC
- CrCl: 45 mL/min
- History of T2DM
- No hydronephrosis on imaging
- Clinical T3N0

Panel Discussion

- Would neoadjuvant IO be appropriate before RC?
- How do you counsel Charles? What are important patient discussion points?
- What AEs do you and your team look out for, and when should patients call in?
- Would you order ctDNA testing?
- How can urologists and oncologists coordinate to support patients?

Visit us at PeerView.com/Bladder2025

- Complete and submit your post-test and evaluation for credit
- Download the slides and Practice Aids
- Watch the replay of this event in the next 24 hours and the online activity in the coming weeks

Thank you for joining us!

Join the conversation on
𝕏 @PeerView

Abbreviations

1L: first line
ADC: antibody–drug conjugate
ASCO: American Society of Clinical Oncology
ASCO GU: American Society of Clinical Oncology, Genitourinary Cancers
AUA: American Urological Association
BCAN: Bladder Cancer Advocacy Network
BCG: Bacillus Calmette-Guérin
BICR: blinded independent central review
BL: baseline
BOIN: Bayesian optimal interval design
cCR: clinical complete response
CIS: carcinoma in situ
CR: complete response
CrCl: creatinine clearance
CSR: central serous retinopathy
CTCAE: Common Terminology Criteria for Adverse Events
DFS: disease-free survival
DOR: duration of response
DSS: disease-specific survival
ECOG PS: Eastern Cooperative Oncology Group performance status
EFS: event-free survival
EMA: European Medicines Agency
ERDA: erdafitinib
ESMO: European Society for Medical Oncology
EV: enfortumab vedotin
FGFR: fibroblast growth factor receptor
FPI: first patient in
Gem/cis: gemcitabine/cisplatin
HR: hormone receptor
HRQOL: health-related quality of life
IL-15: interleukin 15
IR NMIBC: intermediate risk nonmuscle invasive bladder cancer
irAE: immune-related adverse event
LPI: last patient in
MCBS: Medicare Current Beneficiary Survey
mDFS: median disease-free survival

MFS: metastasis-free survival
MIBC: muscle-invasive bladder cancer
mOS: median overall survival
mPFS: median progression-free survival
mUC: metastatic urothelial carcinoma
MVAC: methotrexate, vinblastine sulfate, doxorubicin hydrochloride, and cisplatin
NCCN: National Comprehensive Cancer Network
NE: not evaluable
NGS: next-generation sequencing
NIVO: nivolumab
NMIBC: non-muscle invasive bladder cancer
NR: not reached
NUTRFS: non–urothelial tract recurrence free survival
ORR: overall response rate
P: pembrolizumab
pCR: pathologic complete response
PD: progressive disease
PD-1: programmed cell death protein 1
PD-L1: programmed death-ligand 1
PRO: patient-reported outcome
Q12W: every 12 weeks
Q3W: every 3 weeks
QW: every week
RC: radical cystectomy
RECIST: Response Evaluation Criteria in Solid Tumors
RFS: recurrence-free survival
RPED: retinal pigment epithelial detachment
RR: response rate
RT-PCR: reverse transcriptionpolymerase chain reaction
SAE: severe adverse event
SG: sacituzumab govitecan
TEAE: treatment-emergent adverse event
TRAE: treatment-related adverse event
TTP: time to progression
TURBT: transurethral resection of a bladder tumor
UC: urothelial cancer
VH: variant histology

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