TAR-200 Monotherapy in Patients With Bacillus Calmette-Guérin–Unresponsive Papillary Disease–Only High-Risk Non–Muscle-Invasive Bladder Cancer: First Results From Cohort 4 of SunRISe-1

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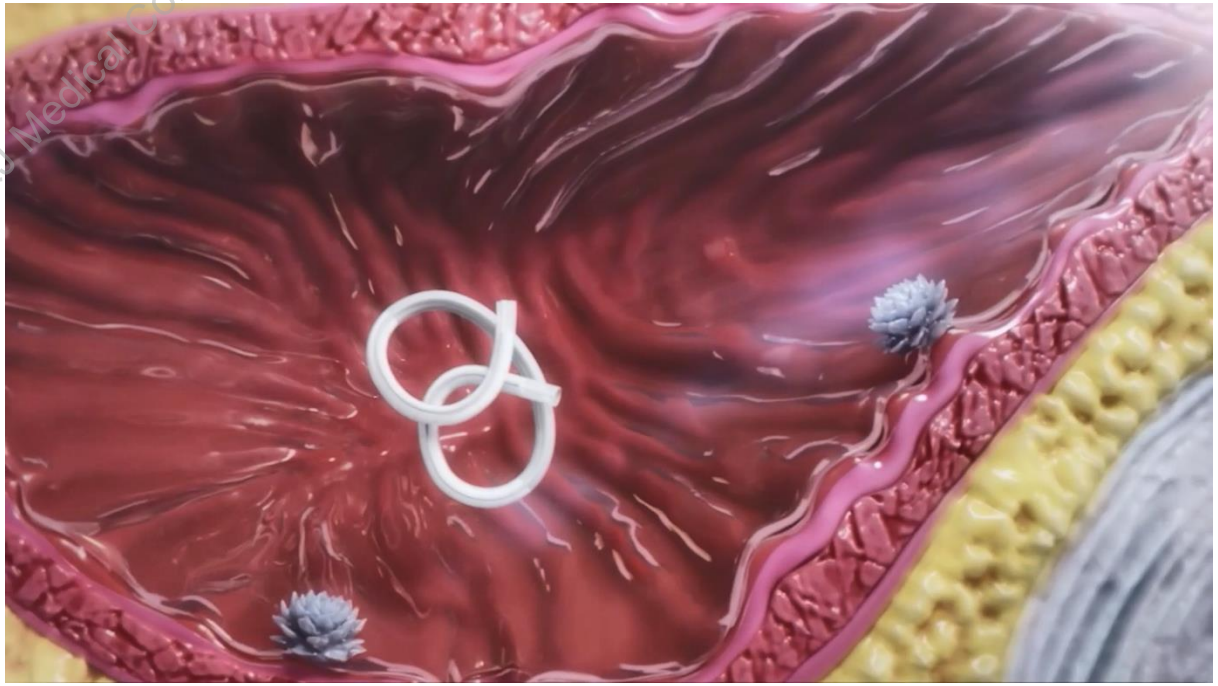
High Unmet Medical Need in BCG-Unresponsive HR NMIBC

- Worldwide, there are >650,000 newly diagnosed cases of bladder cancer annually. 75% of all bladder cancer patients have NMIBC, of which **nearly 50% are classified as HR**[1-3]
- New treatments are needed for the patients with HR NMIBC who experience disease recurrence or progression on BCG in ~50% of the cases, with RC being the standard of care[3-8]
  - RC is a life-altering surgery with a high degree of morbidity and impact on QOL, and has a post surgery mortality rate of 3% to 8%[3,9]
- For patients with BCG-unresponsive HR NMIBC with only papillary disease, ***there are no approved treatments***
  - 12-month DFS/RFS rates for investigational treatments being explored range from 44% to 55%[10-12]
- Here we report the **first results of TAR-200 monotherapy** in patients with **BCG-unresponsive HR NMIBC with only papillary disease** (*Cohort 4 of SunRISe-1*)

TAR-200: Novel Intravesical Drug Releasing System (iDRS)

TAR-200 provides sustained delivery of gemcitabine through all layers of the bladder wall. TAR-200 received FDA Breakthrough Therapy designation in 2023[13-16]



BCG, bacillus Calmette-Guérin; DFS, disease-free survival; FDA, United States Food and Drug Administration; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; RFS, recurrence-free survival.
1. GLOBOCAN. Cancer Tomorrow (https://gco.iarc.fr/tomorrow/en/dataviz/isotype?cancers=30&single_unit=50000&years=2025). 2. Based on 8 studies.* 3. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 4. Babjuk M, et al. *Eur Urol.* 2022;81:75-94. 5. AUA/SUO Guidelines. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. 6. Grimm MO *Eur Urol.* 2020;78(5):690-698. 7. Ritch CR, et al. *J Urol.* 2020;203(3):505-511. 8. Sylvester RJ, et al. *Eur Urol.* 2006;49(3):466-5. 9. Marqueen KE, et al. *JNCI Cancer Spectr.* 2018;2:pky075. 10. Necchi A, et al. *Lancet Oncol.* 2024;25:720-730. 11. Boorjian SA, et al. *Lancet Oncol.* 2021;22:107-117. 12. Chamie K, et al. *NEJM Evid.* 2023;2(1):EVIDoa2200167. 13. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 14. Tyson MD, et al. *J Urol.* 2023:209:890-900. 15. van Valenberg FJP, et al. *Eur Urol Open Sci.* 2024;62:8-15. 16. Daneshmand S, et al. *Urol Oncol.* 2025;S1078-1439(24)01044-5.

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Phase 2b SunRISe-1 Study: Cohort 4 Papillary Disease–Only HR NMIBC

NCT04640623

Population:
- Aged ≥18 years
- Histologically confirmed HR NMIBC CIS (+/-papillary disease)
- ECOG PS of 0-2
- Persistent or recurrent disease within 12 months of completion of BCG
- Unresponsive to BCG[1,2] and not receiving RC

R

- TAR-200 + Cetrelimab[b] *Cohort 1* (N=53)[c] — *Cohort 1 was closed*
- TAR-200 Monotherapy *Cohort 2* (N=85) — *Enrollment completed*
- Cetrelimab[b] Monotherapy *Cohort 3* (N=28) — *Cohort 3 was closed*

Population:
- Papillary-only HR NMIBC (no CIS)[a]

TAR-200 Monotherapy *Cohort 4* (N=52) — *Enrollment completed*

TAR-200 dosing: Q3W (indwelling) for the first 24 weeks; then Q12W through Week 96

Cohorts 1-3:
Primary end point
- Overall CR rate

Key secondary end points
- DOR
- Overall survival
- Safety
- Tolerability

Cohort 4:
Primary end point
- DFS

Key secondary end points
- Safety
- Tolerability

- Response is determined by quarterly cystoscopy, quarterly central cytology, local imaging Q24W, and bladder biopsy by central assessment as clinically indicated
- The **study protocol did not allow re-induction for nonresponders**, consistent with US FDA guidance[2]

The clinical data cutoff was March 31, 2025.
CIS, carcinoma in situ; CR, complete response; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; Q3W, every 3 weeks; Q12W, every 12 weeks; Q24W, every 24 weeks; R, randomization.
[a]Patients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment 4. [b]Cetrelimab is an anti–programmed cell death-1[3,4]; cetrelimab dosing was Q3W through Week 78. [c]Number of patients enrolled in Cohort 1 was N=55 and number of patients treated was N=53.
1. Lerner SP, et al. *Urol Oncol*. 2009;27:155-159. 2. US Food and Drug Administration. Available at: 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.

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Baseline Characteristics: Cohort 4 Papillary Disease–Only HR NMIBC

Characteristics	TAR-200 Monotherapy *Cohort 4* (N=52)[a]
Age, years, median (range)	71.0 (42-88)
Sex, male, %	71.2
Race, %	
White	86.5
Asian	11.5
Black or African American	1.9
Nicotine use, %	
Current	13.5
Former	55.8
Never	30.8
ECOG PS 0, %	94.2

Characteristics	TAR-200 Monotherapy *Cohort 4* (N=52)[a]
Tumor stage, %[b]	
Papillary disease	100.0
Ta	59.6
T1	**40.4**
Total doses of prior BCG, n, median (range)	12 (8-45)
Time from last BCG to high-grade papillary disease diagnosis, months, median (range)	2.8 (0.3-9.9)
Reason for not receiving RC, %[c]	
Declined	**82.4**
Ineligible	17.6

[a]Patient characteristics are shown for all patients who received at least 1 dose of study drug in the full analysis set of Cohort 4 (N=52).
[b]Tumors confined to the mucosa and invading the lamina propria are classified as stage Ta and T1, respectively.[1]
[c]Percentages are based on number of patients with available data (n=51).
1. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5.

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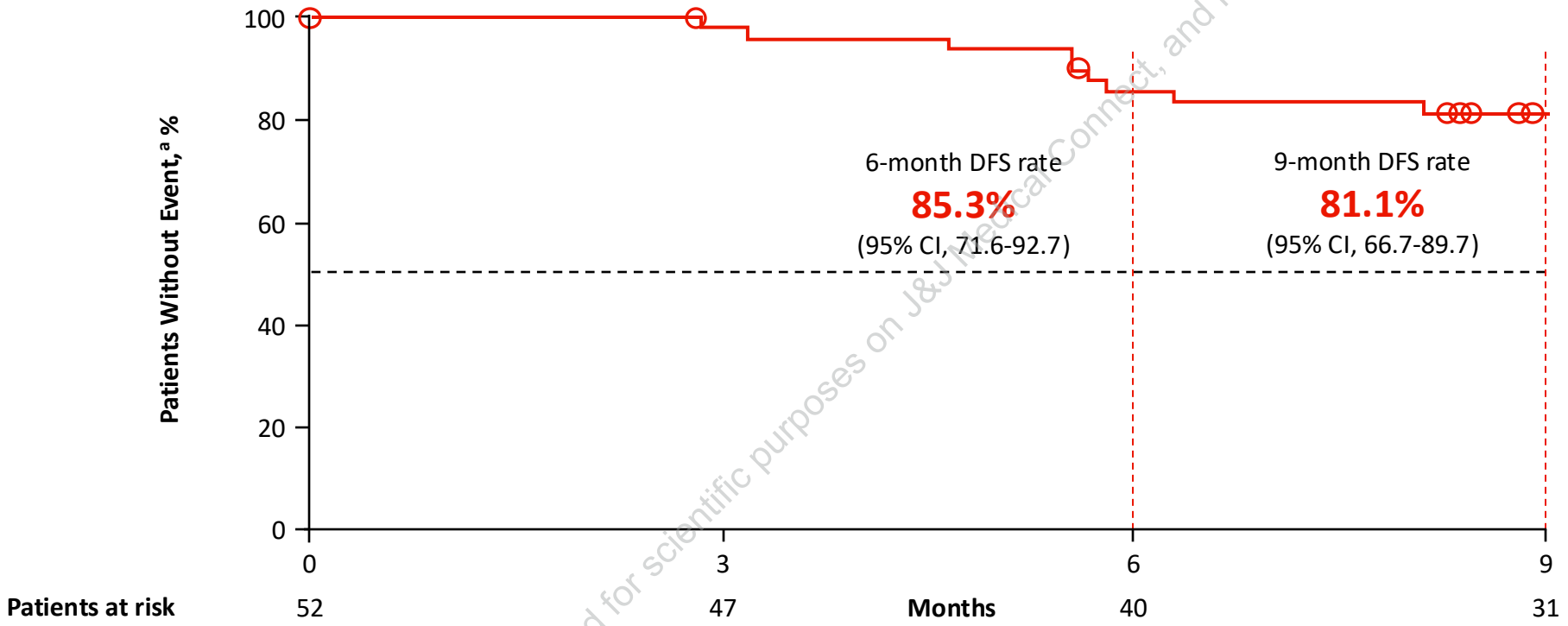
6- and 9-Month DFS Rates With TAR-200 Monotherapy in Papillary Disease–Only HR NMIBC



- Median follow-up was 12.8 months
- **Median DFS was not reached** (95% CI, 12.1-NE)
- Overall, only **5.8%** (3 of 52) of patients had **RC**

NE, not estimable.

[a]**An event is defined as recurrence, progression, or death.**

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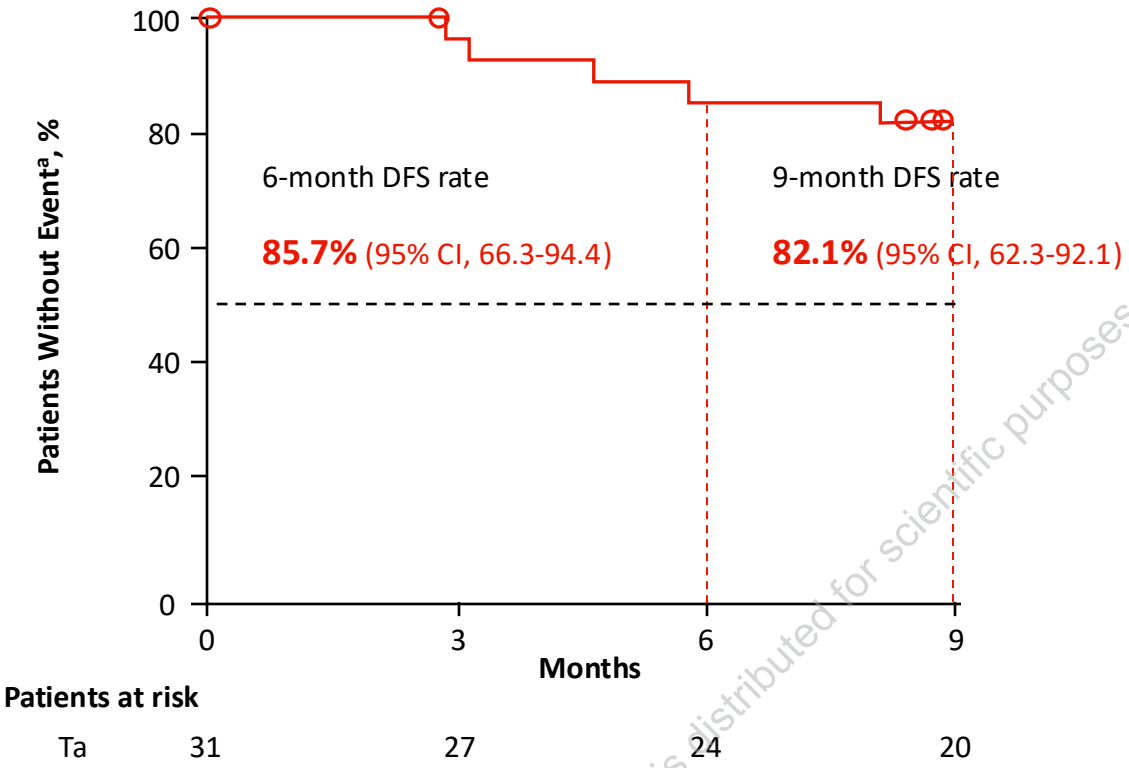
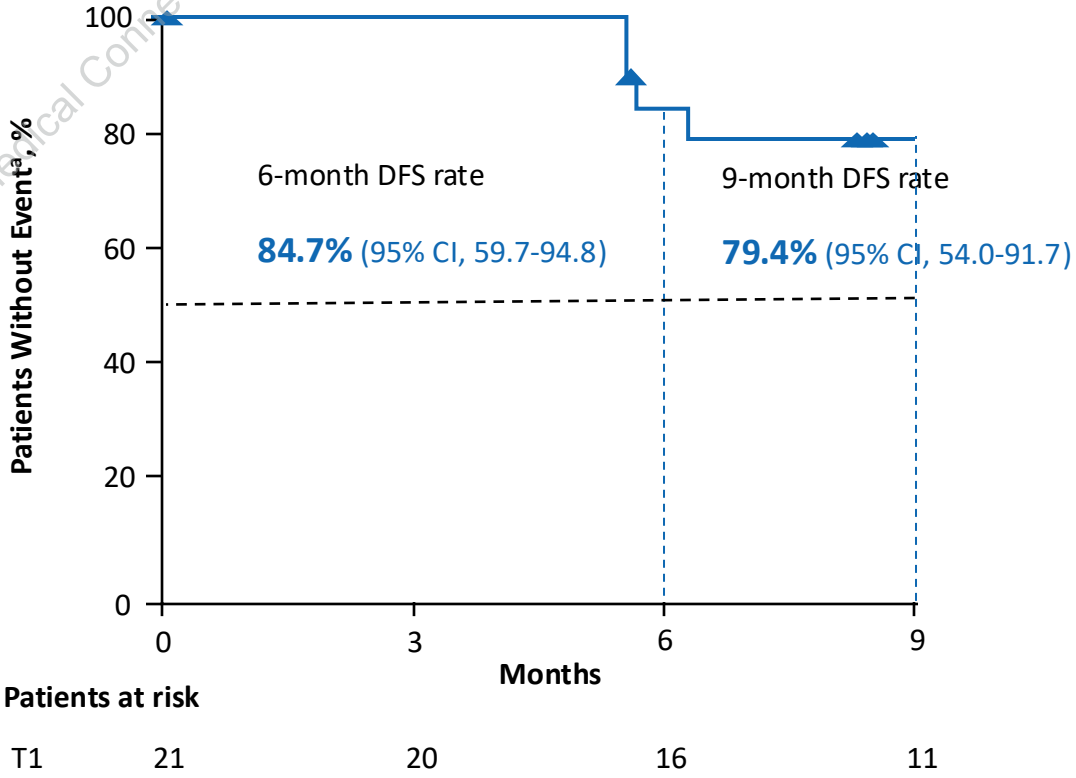
Consistently High DFS Rates With TAR-200 Monotherapy Across High-Grade Ta and T1 Disease

Patients with high-grade Ta disease



Patients with T1 disease



[a]An event is defined as recurrence, progression, or death.

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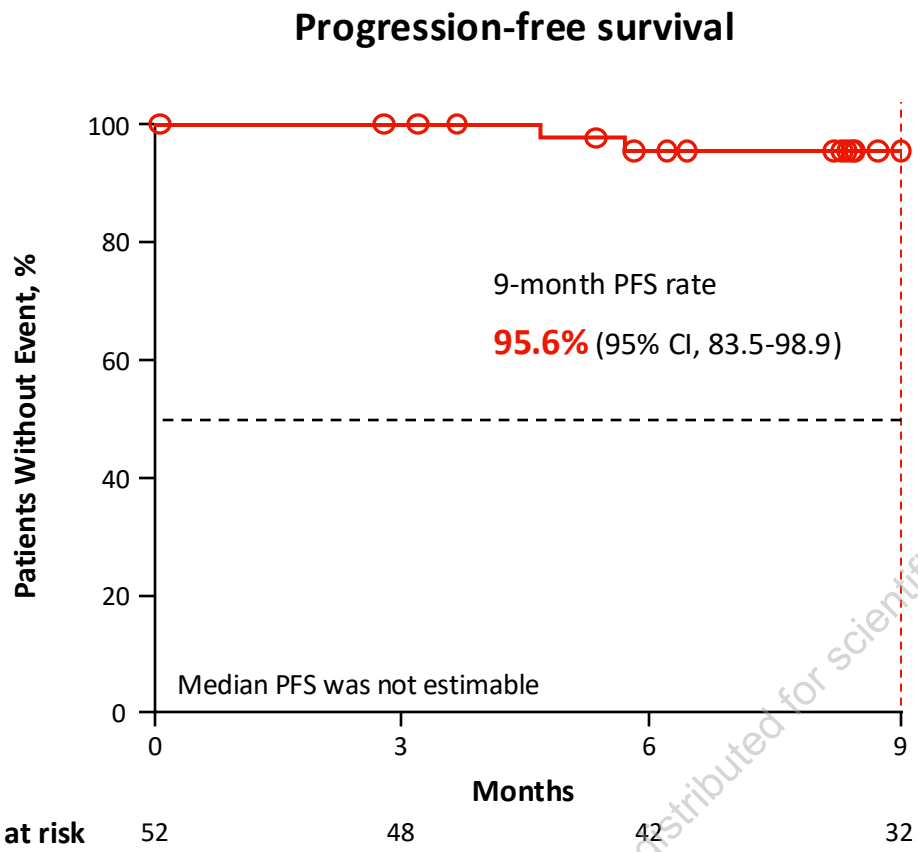
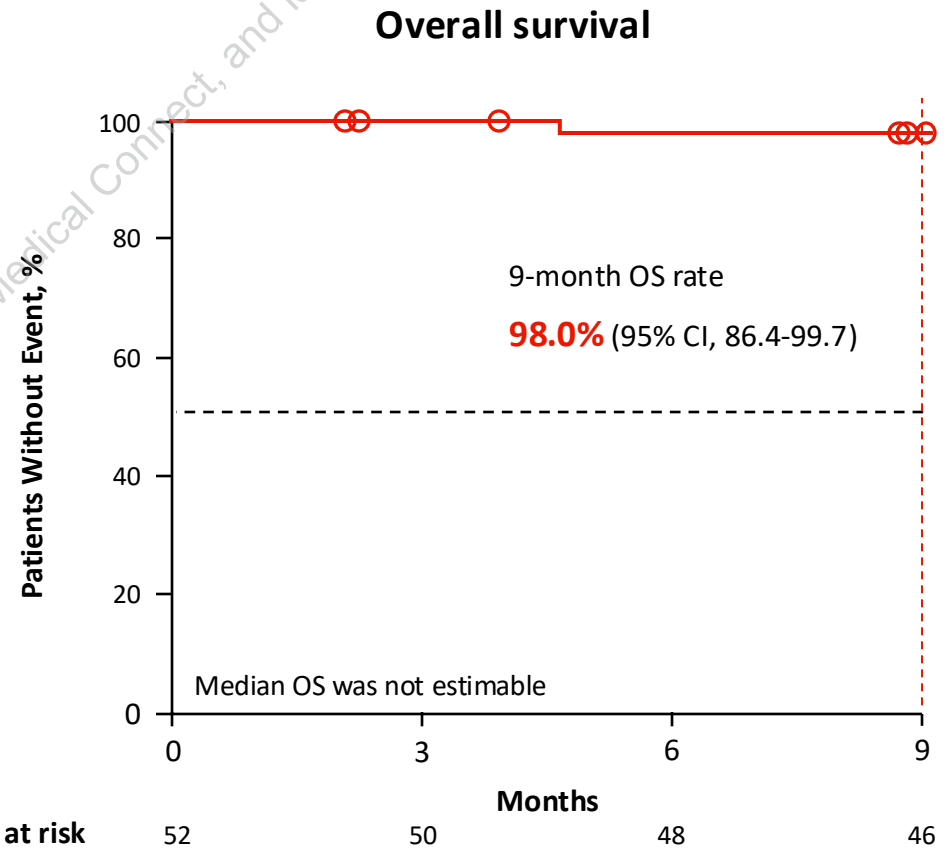
TAR-200 Monotherapy Resulted in 9-Month OS Rate of 98% in Papillary Disease–Only HR NMIBC





- **Among 52 patients, only 1 case of progression (1.9%)[a,b] to MIBC was reported**

MIBC, muscle-invasive bladder cancer; OS, overall survival. PFS, progression-free survival.
[a]Progression is defined as advancing to muscle-invasive bladder cancer, [T≥2], lymph node [N+] or distant disease [M+], or death due to any cause. [b]2 deaths (3.8%; unrelated to treatment) were reported. These deaths were due to renal failure and cardiac arrest.

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Safety: Cohort 4 Papillary Disease–Only HR NMIBC

- **Most TEAEs were grade 1 or 2**
  - The majority of TEAEs resolved quickly, after a median of 3.7 weeks
- **99.5%** (387 of 389) **insertion success rate**
- 3 patients (5.8%) had ≥1 serious TRAEs[a]
- 4 patients (7.7%) discontinued treatment due to TRAEs[b]
- **No treatment-related deaths** were reported

Patients With Events, n (%)	TAR-200 Monotherapy *Cohort 4* (N=52)[c]	
	Any Grade	Grade ≥3
≥1 TRAE[d]	42 (80.8)	7 (13.5)
Most frequent TRAEs[e,f]		
Dysuria	21 (40.4)	0
Pollakiuria	16 (30.8)	0
Micturition urgency	14 (26.9)	0
Urinary tract infection	12 (23.1)	1 (1.9)
Hematuria	7 (13.5)	0
Bladder pain	5 (9.6)	2 (3.8)
Nocturia	5 (9.6)	0
Bladder spasm	4 (7.7)	0
Noninfective cystitis	4 (7.7)	0
Pruritus	4 (7.7)	0
Asthenia	3 (5.8)	0
Bladder irritation	3 (5.8)	0
Pelvic pain	3 (5.8)	1 (1.9)
Urinary incontinence	3 (5.8)	1 (1.9)
Urinary tract pain	3 (5.8)	0

TEAE, treatment emergent adverse event; TRAE, treatment-related adverse event.

[a]Included 1 event each of sepsis, urinary tract infection, and spinal fracture. [b]TRAEs leading to discontinuation were micturition urgency (n=4), pollakiuria (n=2), dysuria (n=2) and bladder spasm, urinary incontinence, and urinary tract infection in 1 patient each. Note, patients who discontinued may have had ≥1 TRAE. [c]Safety is shown for all patients who received at least 1 dose of TAR-200 in the safety analysis set (N=52). [d]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. [e]Reported in ≥5% of patients. [f]TRAEs of grade ≥3 reported in ≥2% of patients. All other TRAEs of grade ≥3 were reported in only 1 patient each and included sepsis and spinal fracture. Note, patients may have had ≥1 grade ≥3 TRAE.

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Conclusions: SunRISe-1 TAR-200 Monotherapy (Cohort 4)

- **First results** of TAR-200 monotherapy in SunRISe-1 Cohort 4 showed **impressive DFS rates** in patients with BCG-unresponsive **papillary disease–only HR NMIBC**
  - DFS rates at **6 and 9 months** were **85.3%** and **81.1%**, respectively
  - DFS rates **were consistently high across both high-grade Ta and T1 disease**, indicative of how the iDRS delivers sustained tissue penetration with TAR-200
  - Only 5.8% of patients underwent subsequent RC
- High rates of **OS (98.0%)** and **PFS (95.6%)** were observed at 9 months
- No new safety signals were observed, with most TEAEs being grade 1 or 2 lower urinary tract symptoms, and with low rates of serious TRAEs and TAR-200 treatment discontinuations due to TRAEs
- The currently ongoing phase 3 SunRISe-5 study (NCT06211764) comparing TAR-200 monotherapy versus intravesical chemotherapy in patients with BCG-unresponsive/experienced papillary-only HR NMIBC will provide further evidence of the potential of TAR-200 in this setting

iDRS, intravesical drug releasing system.

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https://www.congresshub.com/Oncology/AUA2025/TAR-200/Guerrero-Ramos

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Ongoing studies of TAR-200:

- **SunRISe-1**
  BCG-unresponsive HR NMIBC
  (Cohorts 1-3: CIS; Cohort 4: papillary only)
  NCT04640623
  Cohort 4 presented here
  Cohort 2 already presented in P2 Plenary Session
- **SunRISe-3**
  BCG-naive HR NMIBC
  NCT05714202
- **SunRISe-4**
  Neoadjuvant MIBC
  NCT04919512
- **SunRISe-5**
  Papillary-only, BCG-exposed,
  RC-ineligible/-refusing, recurrent HR NMIBC
  NCT06211764

Additional AUA 2025 presentations on TAR-200:

- **SunRISe-1 Cohort 2, 1-Year Durability and PRO Results**
  Venetian Ballroom, April 26, 2025; 10:50 AM - 11:00 AM; Plenary Session
- **SunRISe-5 Clinical Trials in Progress, Bladder Cancer**
  April 28, 2025; 9:56 AM - 10:04 AM; Learning Lab

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