Gemcitabine Intravesical System (Gem-iDRS) Monotherapy in Patients With Bacillus Calmette-Guérin–Unresponsive Papillary Disease–Only High-Risk Non–Muscle-Invasive Bladder Cancer: 1-Year Disease-Free Survival Results From SunRISe-1

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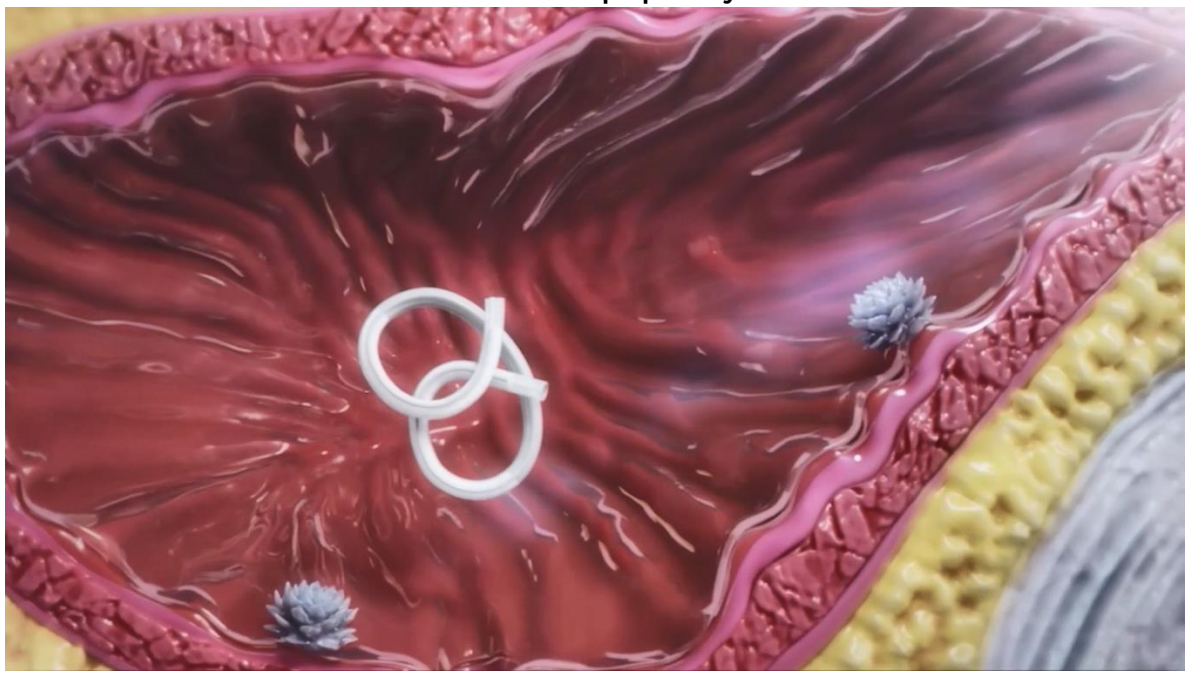
High Unmet Medical Need in BCG-Unresponsive Papillary Disease–Only HR NMIBC

- 75% of all patients with bladder cancer have NMIBC, of which **nearly 50% of cases are classified as HR**[1,2]
- Disease recurrence or progression on BCG treatment is observed in ~50% of the HR NMIBC cases, and RC is the standard of care[2-7]
  - RC is a life-altering surgery with a high degree of morbidity and impact on QoL, and has a postsurgery mortality rate of 3% to 8%[2,8]
- There are no approved treatments for BCG-unresponsive HR NMIBC with only papillary disease
  - 12-month DFS/RFS rates for investigational treatments being explored range from 44% to 55%[9-11]
- Here we report **1-year DFS results** from **Gem-iDRS monotherapy** in patients with **BCG-unresponsive HR NMIBC with only papillary disease** (*Cohort 4 of SunRISe-1*)

Gem-iDRS (Gemcitabine intravesical system; TAR-200)

provides sustained delivery of gemcitabine through all layers of the bladder wall. Gem-iDRS was recently approved for BCG-unresponsive NMIBC with CIS with or without papillary tumors[12-17]



BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; DFS, disease-free survival; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; RFS, recurrence-free survival.

1. Based on 8 studies.* 2. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 3. Babjuk M, et al. *Eur Urol.* 2022;81:75-94. 4. AUA/SUO Guidelines. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. 5. Grimm M-O, et al. *Eur Urol.* 2020;78:690-698. 6. Ritch CR, et al. *J Urol.* 2020;203:505-511. 7. Sylvester RJ, et al. *Eur Urol.* 2006;49:466-475. 8. Marqueen KE, et al. *JNCI Cancer Spectr.* 2018;2:pky075. 9. Necchi A, et al. *Lancet Oncol.* 2024;25:720-730. 10. Boorjian SA, et al. *Lancet Oncol.* 2021;22:107-117. 11. Chamie K, et al. *NEJM Evid.* 2023;2:EVIDoa2200167. 12. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 13. Tyson MD, et al. *J Urol.* 2023:209:890-900. 14. van Valenberg FJP, et al. *Eur Urol Open Sci.* 2024;62:8-15. 15. Daneshmand S, et al. *Urol Oncol.* 2025;S1078-1439(24)01044-5. 16. Daneshmand S, et al. *J Clin Oncol.* 2025:10.1200/JCO-25-01651. 17. INLEXZO™ (gemcitabine intravesical system) [prescribing information]. Janssen Products, LP, Horsham PA; 2025.

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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

- Gem-iDRS + Cetrelimab[b] *Cohort 1* (N=53)[c] — *Cohort 1 was closed*
- Gem-iDRS 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]

Gem-iDRS Monotherapy *Cohort 4* (N=52) — *Enrollment completed*

Gem-iDRS 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
- HRQoL

Cohort 4:
Primary end point
- DFS

Key secondary end points
- Safety
- Tolerability
- HRQoL

- 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 July 03, 2025.
CR, complete response; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FDA, United States Food and Drug Administration; HRQoL, health-related quality of life; 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	Gem-iDRS 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	Gem-iDRS 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] Patients with Ta have papillary disease only and T1 includes papillary and T1 stage of disease.
[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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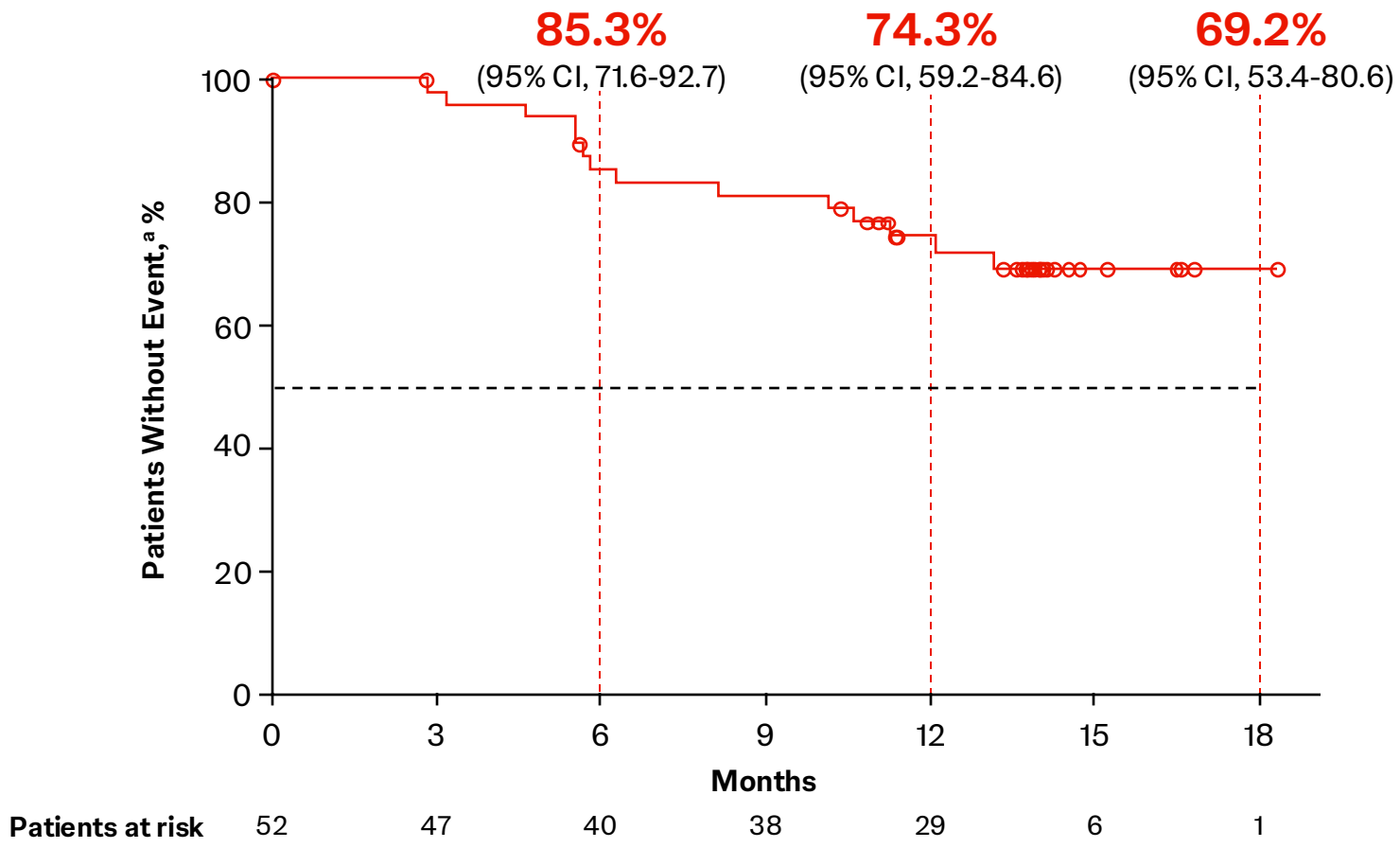
6- and 12-Month DFS Rates With Gem-iDRS Monotherapy in Papillary Disease–Only HR NMIBC



- With a median follow-up of 15.9 months (range 4-20), **median DFS was not reached** (95% CI, NE-NE)

NE, not estimable.
[a]An event is defined as recurrence, progression, or death.

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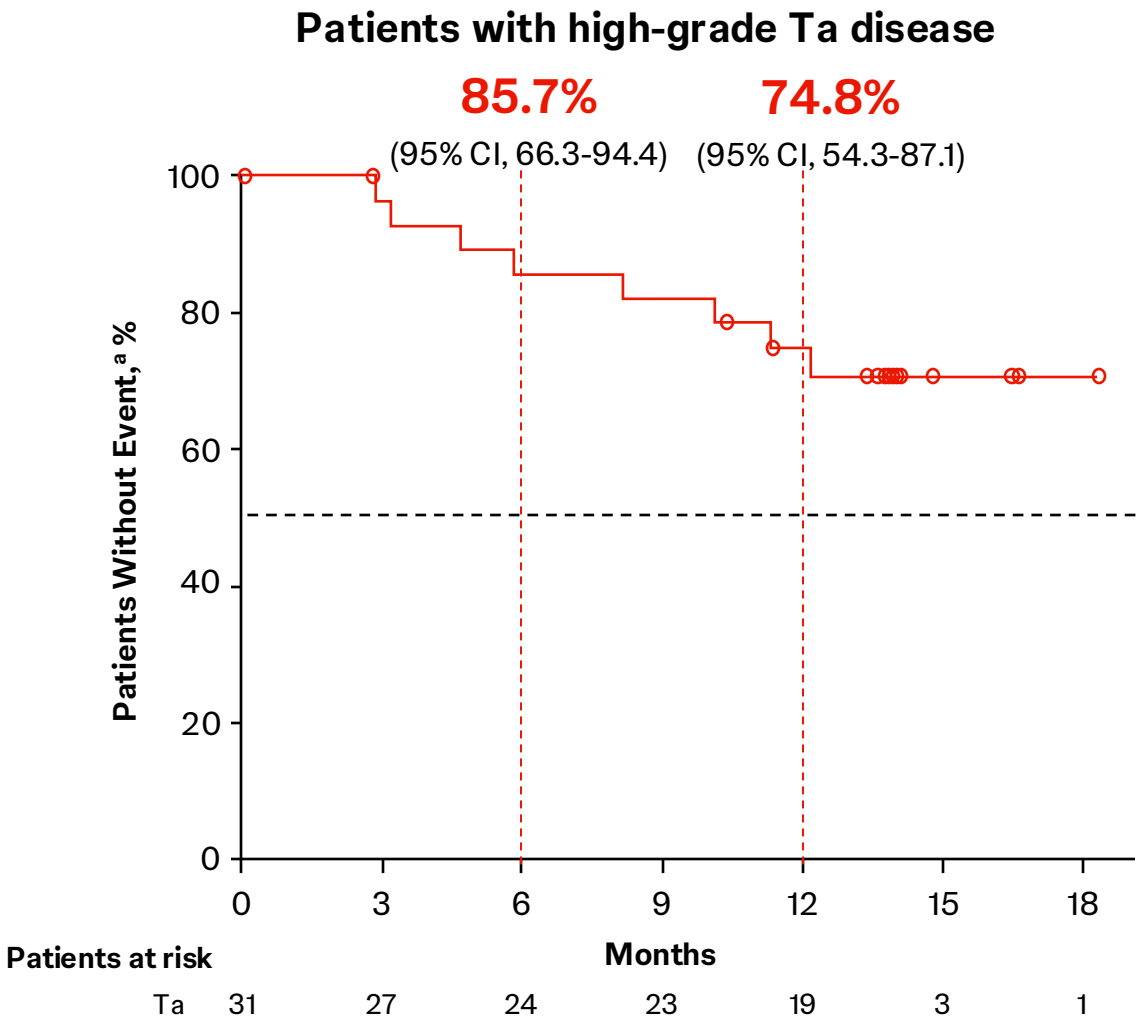
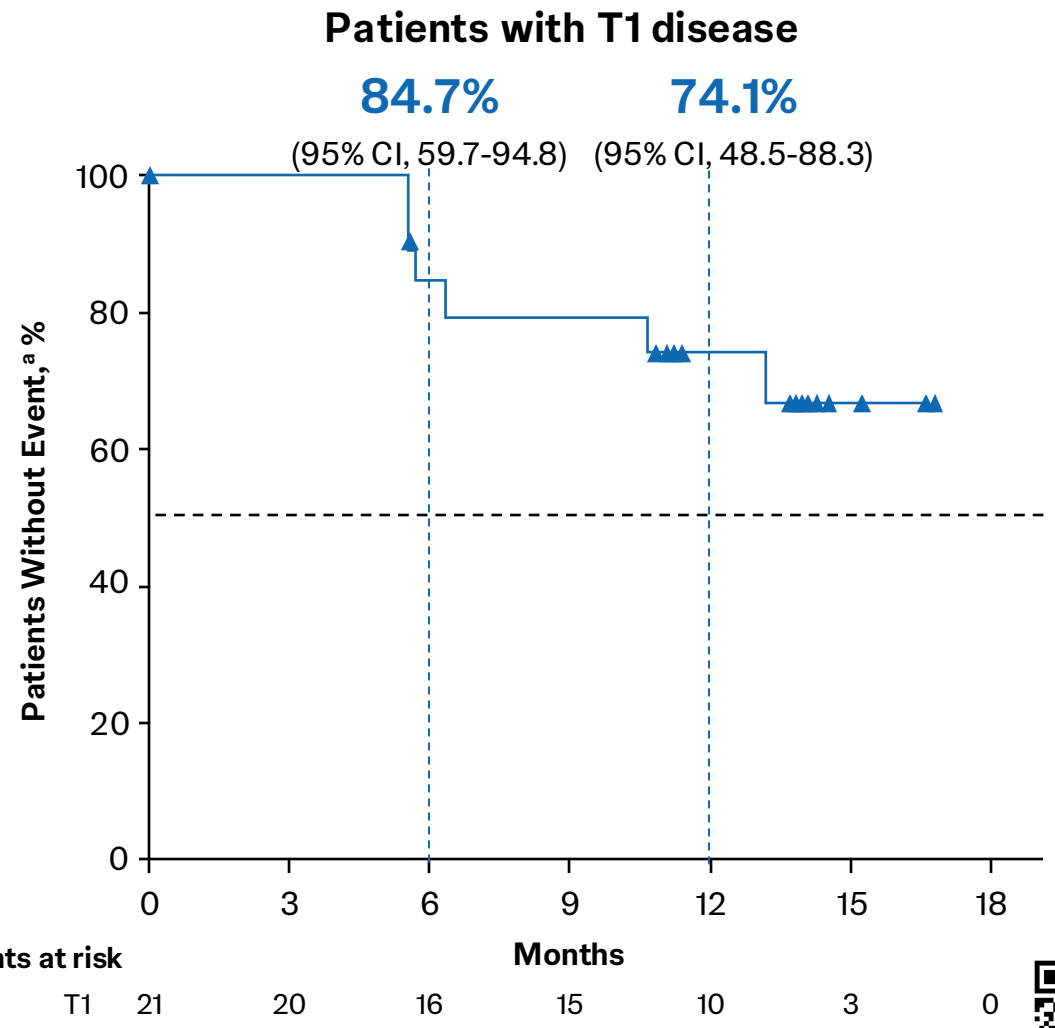
Consistently High DFS Rates With Gem-iDRS Monotherapy Across High-Grade Ta and T1 Disease





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

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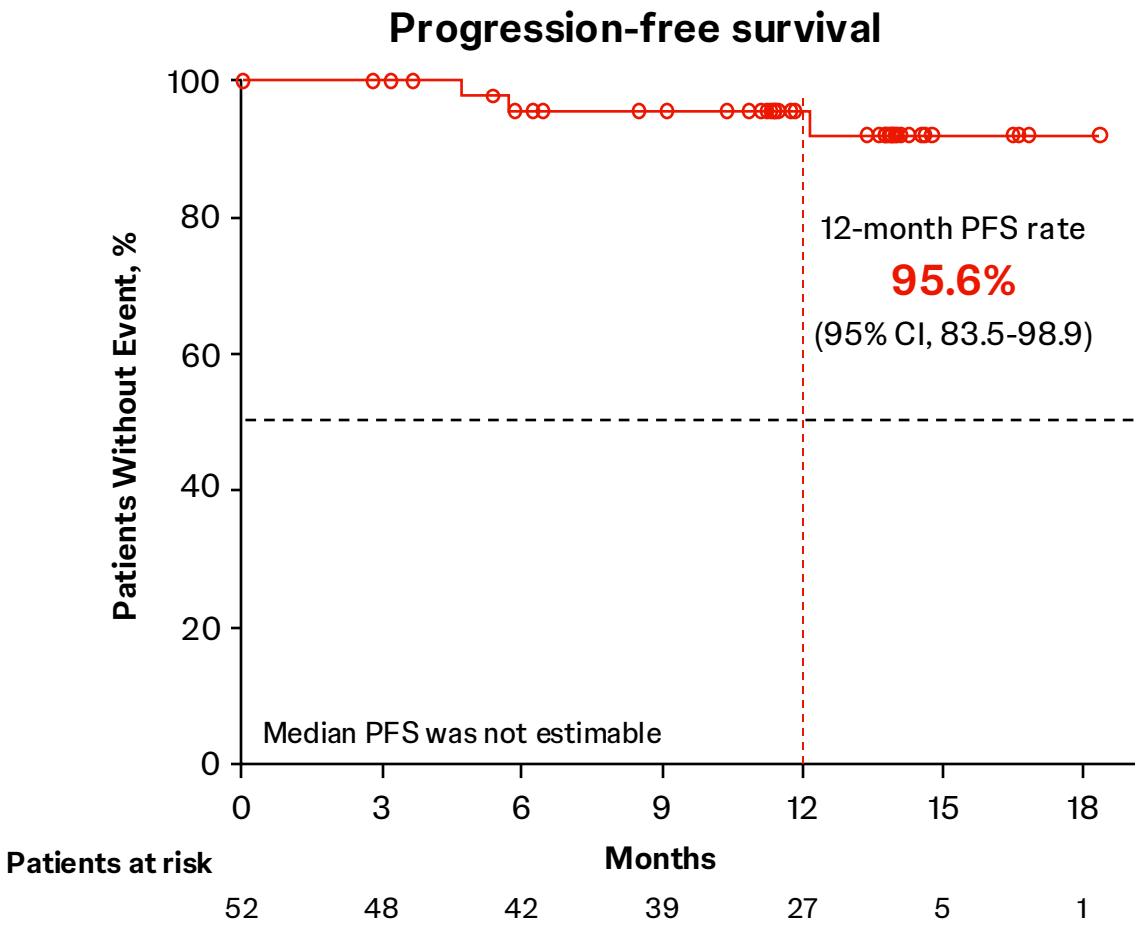
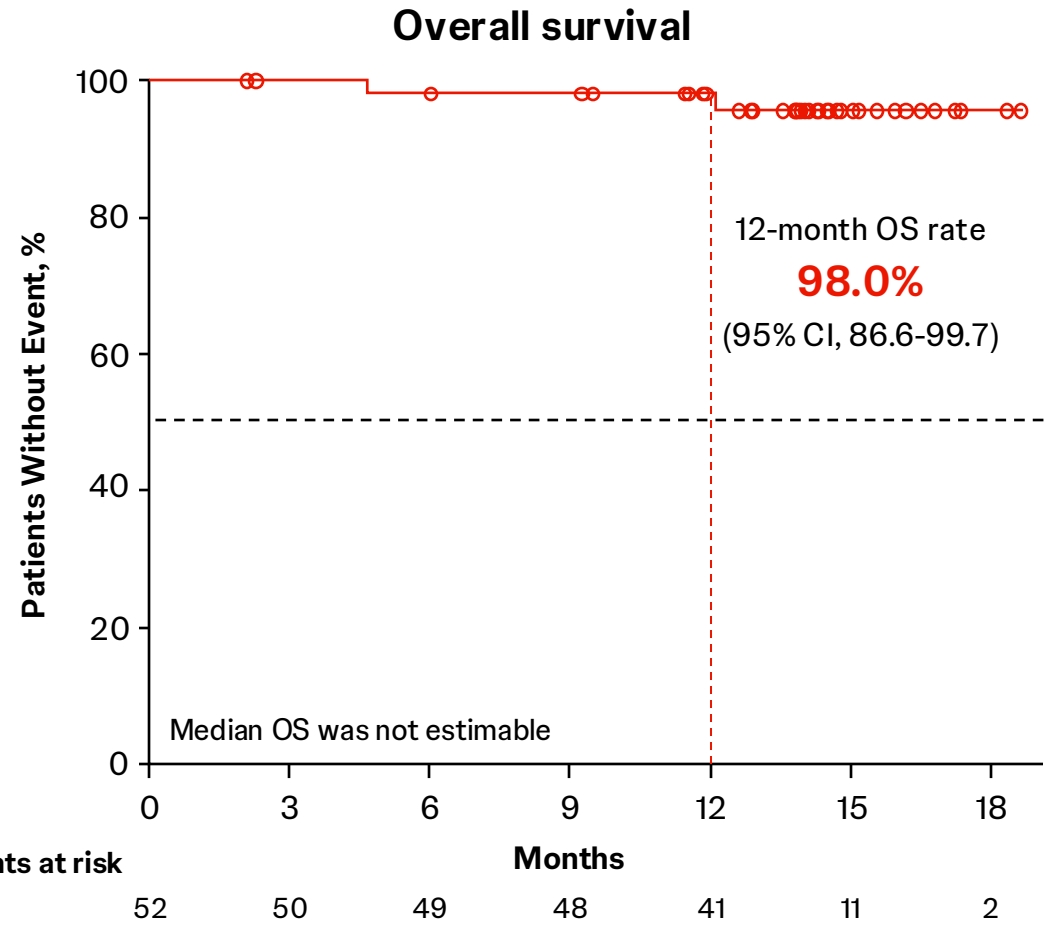
Gem-iDRS Monotherapy Resulted in 12-Month OS Rate of 98% in Papillary Disease–Only HR NMIBC





- **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 MIBC, [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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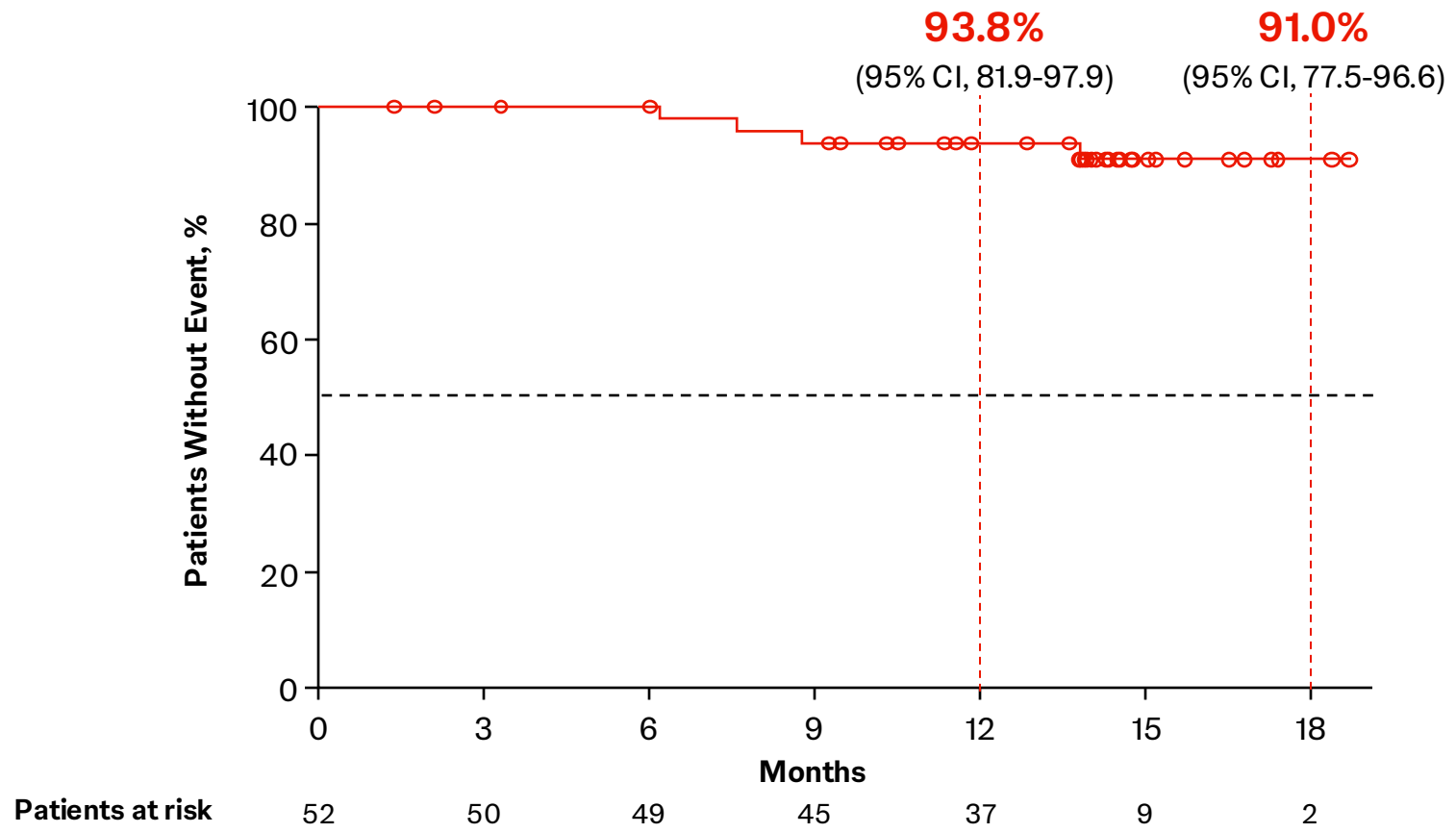
Time to Cystectomy With Gem-iDRS Monotherapy in Papillary Disease–Only HR NMIBC



- Overall, only **7.7%** (4 of 52) of patients had RC

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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 3.3 weeks
- 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
- **99.8%** (419 of 420) **insertion success rate**

Patients With Events, n (%)	Gem-iDRS 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	15 (28.8)	0
Urinary tract infection	14 (26.9)	1 (1.9)
Hematuria	8 (15.4)	0
Bladder pain	5 (9.6)	2 (3.8)
Bladder spasm	5 (9.6)	0
Nocturia	5 (9.6)	0
Noninfective cystitis	4 (7.7)	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 Gem-iDRS 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 study drug/procedure. [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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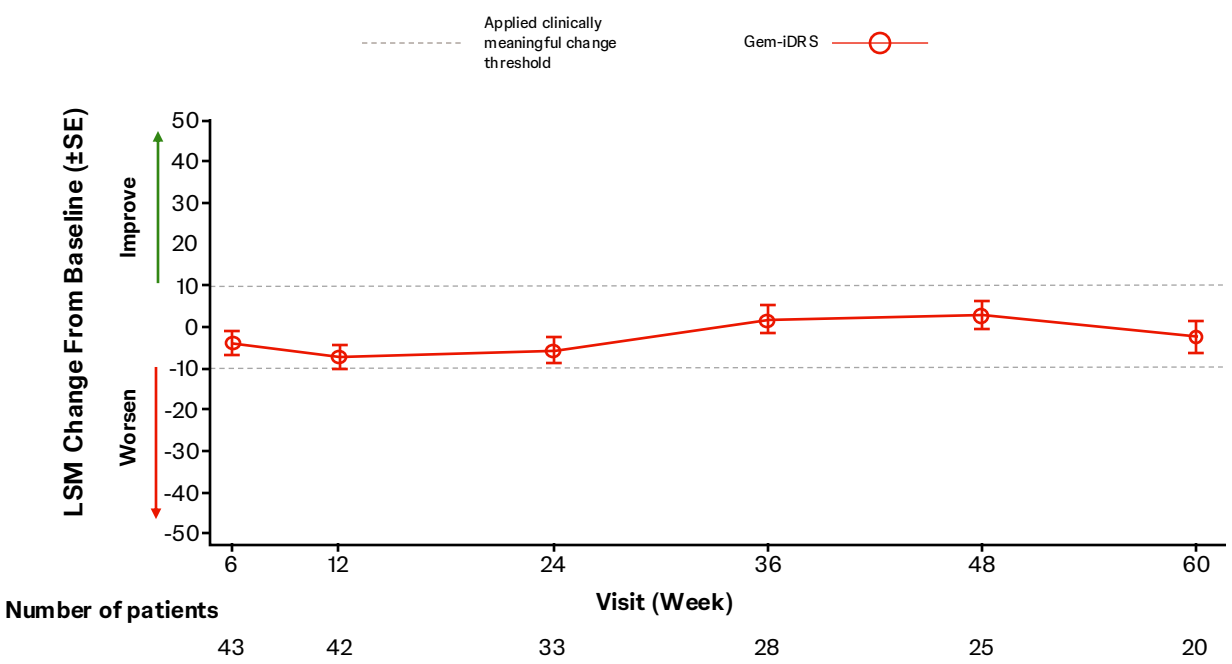
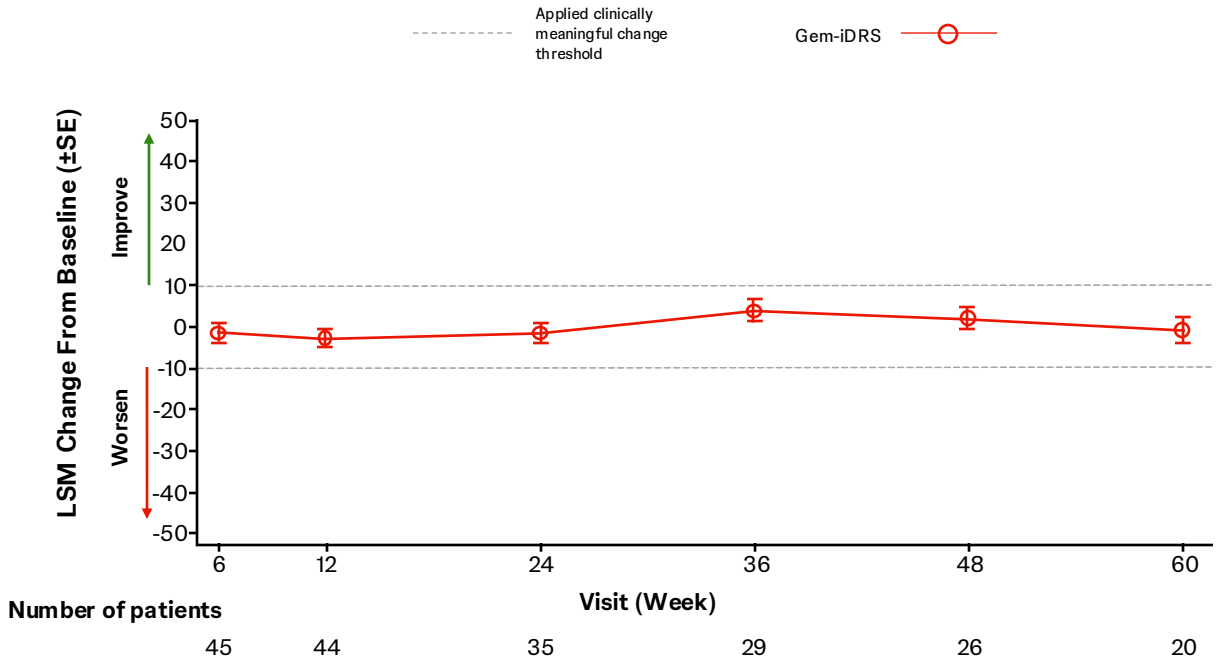
Patient Quality of Life Was Maintained on Gem-iDRS

EORTC QLQ-C30: Global Health Status



EORTC QLQ-C30: Physical Functioning



- Mean EORTC QLQ-C30 GHS (77.1 [SD, 18.7]) and PF (85.4 [SD, 16.8]) scores were high at baseline and stable on treatment (did not exceed clinically meaningful change threshold of 10 points[1-3])

EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core Questionnaire; GHS, global health status; LSM, least square means; PF, physical functioning; SD, standard deviation; SE, standard error.

1. Osoba D, et al. *J Clin Oncol*. 1998;16:139-144. 2. Musoro JZ, et al. *Eur J Cancer*. 2023;188:171-182. 3. Aaronson NK, et al. *J Natl Cancer Inst*. 1993;85:365-376.

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Conclusions: SunRISe-1 Gem-iDRS Monotherapy (Cohort 4)

- Gem-iDRS monotherapy demonstrated a high 12-month **DFS rate** in BCG-unresponsive **papillary disease–only HR NMIBC**
  - 12-month DFS rate was **74.3%**
  - DFS rates **were consistently high across both high-grade Ta and T1 disease**
- High rates of **OS (98.0%)** and **PFS (95.6%)** were observed at 12 months
- Only 7.7% of patients underwent subsequent RC
- Gem-iDRS was well tolerated, with low rates of serious TRAEs and Gem-iDRS discontinuations due to TRAEs
- Overall health status and high physical functioning were maintained while on Gem-iDRS treatment
- The phase 3 SunRISe-5 study (NCT06211764) of Gem-iDRS vs intravesical chemotherapy is continuing to investigate Gem-iDRS's potential in BCG-unresponsive/-experienced papillary-only HR NMIBC

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