Periprocedural Prophylactic Antibiotic Use With Gemcitabine Intravesical System (Gem-iDRS) Monotherapy: Analysis of Data From SunRISe-1

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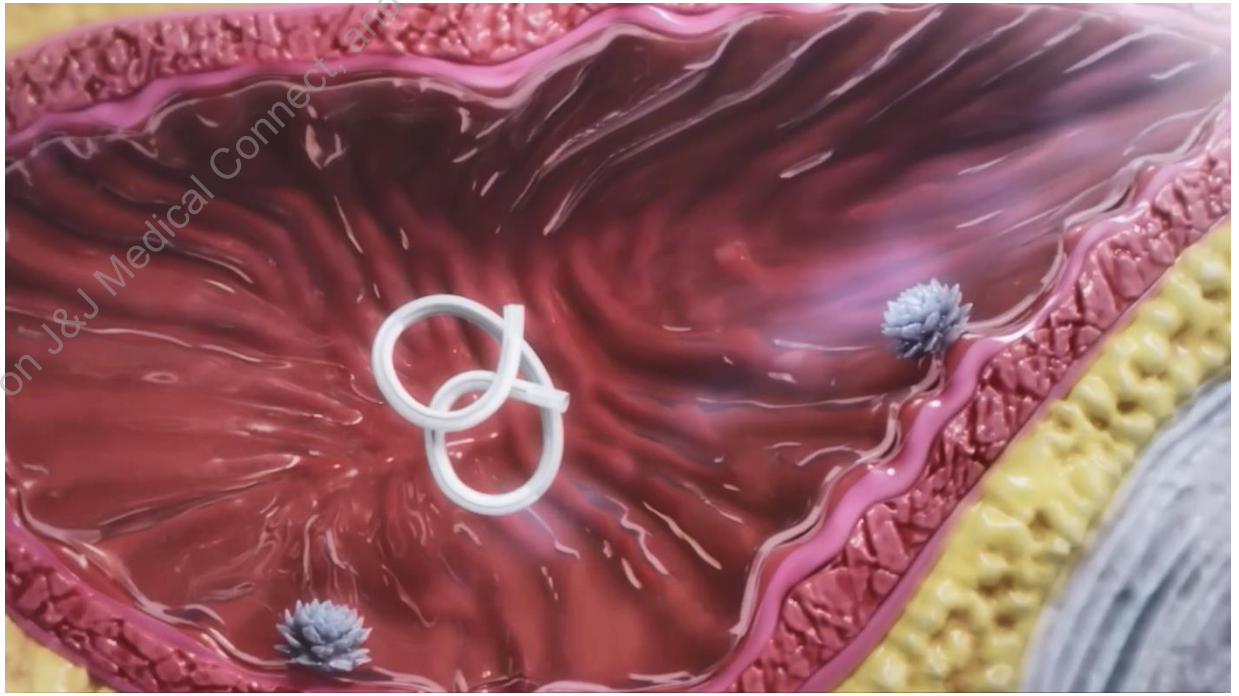
Gemcitabine Intravesical System (Gem-iDRS)

- **Gem-iDRS is a novel intravesical drug-releasing system designed to provide prolonged delivery of gemcitabine in the bladder[1]**
- Gem-iDRS monotherapy is approved in the United States for BCG-unresponsive HR NMIBC CIS with or without papillary disease, based on the phase 2b SunRISe-1 study[2,3]
- In this analysis of data from SunRISe-1, we examined the rate of periprocedural prophylactic antibiotic use and the rate of infectious AEs in patients who received gem-iDRS monotherapy



- **Gem-iDRS is inserted via urinary placement catheter and removed from the bladder via cystoscopy.[1] Removal and new insertion are often completed during the same visit**

AE, adverse event; BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer.

1. Daneshmand S, et al. *Urol Oncol*. 2025;43:286-296. 2. Daneshmand S, et al. *J Clin Oncol*. 2025;43:3578-3588. 3. INLEXZO™ (gemcitabine intravesical system) [prescribing information]. Janssen Products, LP, Horsham PA; 2025.

Phase 2b SunRise-1 Study for HR NMIBC

NCT04640623

Population:
- Aged ≥18 years
- Histologically confirmed HR NMIBC CIS (with or without 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

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

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

Gem-iDRS Monotherapy Cohort 2 (N=85)
Enrollment completed

Cetrelimab[b] Monotherapy Cohort 3 (N=28)
Cohort 3 was closed

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
- Duration of response
- Overall survival
- Safety
- Tolerability
- HRQoL

Cohort 4:
Primary end point
- DFS

- **Periprocedural prophylactic antibiotic use**: Administered ≤2 days before/after a gem-iDRS insertion or removal procedure
- **Infectious AEs**: Any urinary tract infection, cystitis, or other plausibly related infections occurring ≤14 days after an insertion or removal procedure
- Descriptive analyses, no statistical hypotheses

The clinical data cutoff was March 31, 2025.
CR, complete response; DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; Q3W, every 3 weeks; Q12W, every 12 weeks; R, randomization; RC, radical cystectomy.
[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 antibody[3,4]; cetrelimab dosing was Q3W through Week 78.
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.

Summary of Periprocedural Prophylactic Antibiotics Used in Gem-iDRS Insertions or Removals

	Gem-iDRS Monotherapy *Cohort 2* (N=85)	Gem-iDRS Monotherapy *Cohort 4* (N=52)
Patients with use of ≥1 periprocedural prophylactic antibiotic, n (%)	79 (92.9)	47 (90.4)
Most common periprocedural prophylactic antibiotics used, n (%)[a]		
Ciprofloxacin	19 (22.4)	16 (30.8)
Levofloxacin	8 (9.4)	6 (11.5)
Fosfomycin trometamol	15 (17.6)	4 (7.7)
Cefalexin	9 (10.6)	6 (11.5)
Sulfamethoxazole; trimethoprim	9 (10.6)	7 (13.5)
Nitrofurantoin	9 (10.6)	3 (5.8)

Prophylactic Antibiotic Use	Gem-iDRS Monotherapy *Cohort 2* (N=85)	Gem-iDRS Monotherapy *Cohort 4* (N=52)
Total **insertions**, n	755	389
Prophylactic antibiotics given, n (%)[b]	616 (81.6)	317 (81.5)
Prophylactic antibiotics not given, n (%)[b]	139 (18.4)	72 (18.5)
Total **removals**, n[c]	735	378
Prophylactic antibiotics given, n (%)[b]	570 (77.6)	293 (77.5)
Prophylactic antibiotics not given, n (%)[b]	165 (22.4)	85 (22.5)

[a]Reported in ≥10% of patients in either cohort. Type of antibiotic was per institutional guidelines, not specified in protocol.[b]Percentages are based on the number of insertions/removals. [c]Patients who had gem-iDRS indwelling on the clinical data cutoff do not have a removal.

Rates of Infectious AEs Were Similar Following Gem-iDRS Insertion or Removal Regardless of Periprocedural Prophylactic Antibiotics Use

Infectious AEs, n (%)[a,b]	Gem-iDRS Monotherapy *Cohort 2* (N=85)	Gem-iDRS Monotherapy *Cohort 4* (N=52)
Infectious AEs following insertion		
With antibiotics	46 (7.5)	18 (5.7)
Without antibiotics	10 (7.2)	4 (5.6)
Infectious AEs following removal		
With antibiotics	28 (4.9)	18 (6.1)
Without antibiotics	11 (6.7)	8 (9.4)
Infectious AEs resolved, n/n (%)	90/92 (97.8)	44/44 (100.0)
Duration of infectious AEs, median (range), weeks	1.9 (0.1-61.0+)	1.7 (0.4-25.1)

- Most infectious AEs following insertions and removals were grade 1-2
  - AEs were managed per institutional standard of care
  - In Cohort 2, 97.8% of infectious AEs resolved after a median of 1.9 weeks, and in Cohort 4, 100% resolved after a median of 1.7 weeks
- Rates of infectious AEs were consistent with those typically observed with urethral catheterization (≈9%)[1,2]

+ indicates censored. [a]Infectious AEs were defined as any urinary tract infection, cystitis, or other plausibly related infections occurring ≤14 days after an insertion or removal procedure. [b]Percentages are based on the number of procedures in which prophylactic antibiotics were given or not given.

1. Gambrill B, et al. *BMC Urol.* 2024;24(1):186. 2. Li F, et al. *J Adv Nurs.* 2019;75(3):517-527.

Conclusions

- The use of periprocedural prophylactic antibiotics in SunRISe-1 was not associated with a difference in rates of infectious AEs following gem-iDRS insertion or removal
- Incidence of infectious AEs following insertion or removal of gem-iDRS was low, and most AEs resolved quickly
- Similar rates of infectious AEs were reported previously with conventional urethral catheterization[1,2]
- For most patients undergoing gem-iDRS insertion or removal, routine periprocedural prophylactic antibiotics do not appear to be necessary, as infectious AE rates were low and similar with or without antibiotics

1. Gambrill B, et al. *BMC Urol.* 2024;24(1):186. 2. Li F, et al. *J Adv Nurs.* 2019;75(3):517-527.

https://www.congresshub.com/Oncology/EAU2026/Gem-iDRS/Zainfeld

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