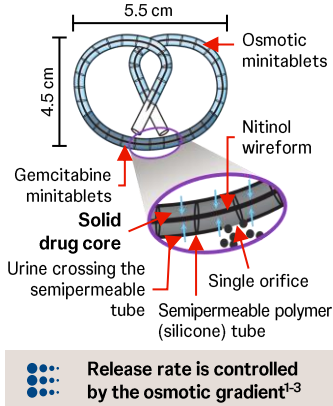


Gemcitabine Intravesical System (Gem-iDRS) Monotherapy in BCG-Unresponsive HR NMIBC With Papillary Only Disease: 1-year Disease-free Survival (DFS) Results From SunRISe-1 Cohort 4



Study Design^{4,5}

Key Eligibility Criteria

Cohort 4

- BCG-unresponsive, not receiving RC
- ECOG PS 0-2
- HR NMIBC papillary disease only (no CIS)*

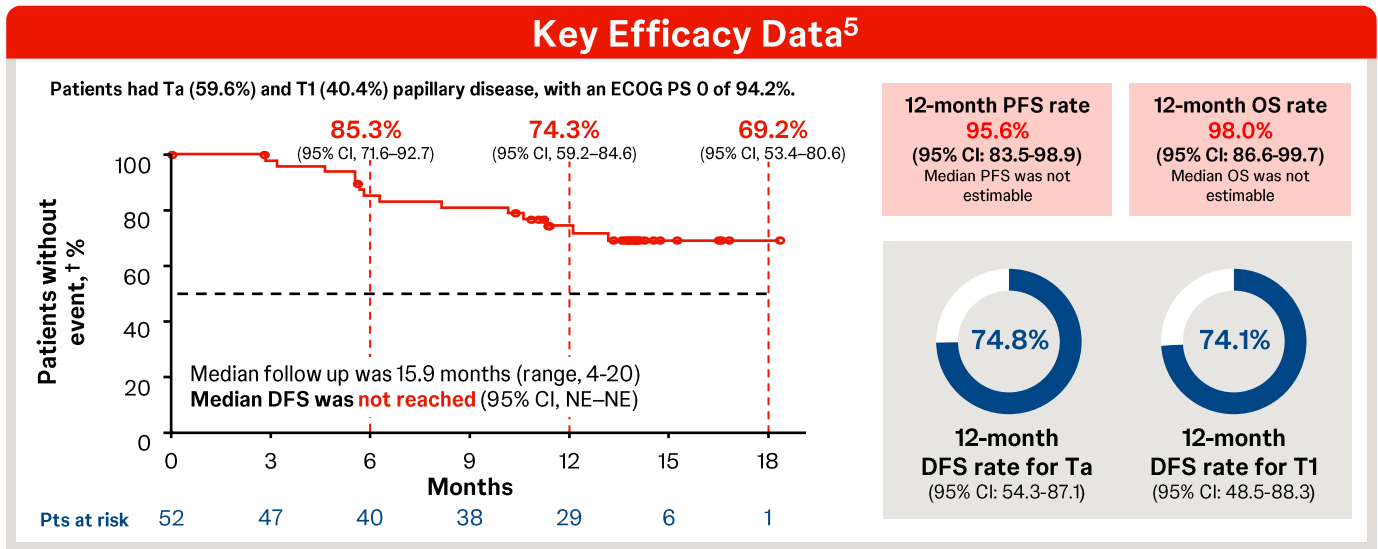
Study Endpoints

Cohort 4

- Primary endpoint
- DFS
- Key secondary endpoints
- OS, HRQoL
- Safety, tolerability

Cohort	Treatment	N
Cohort 1	Gem-iDRS + cetrelimab	53
Cohort 2	Gem-iDRS monotherapy	85
Cohort 3	Cetrelimab monotherapy	28
Cohort 4	Gem-iDRS monotherapy	52

Re-induction in nonresponders was not allowed



Safety Summary⁵

Patients with events, n (%)	Gem-iDRS Monotherapy (N=52) [‡]	
	Any grade	Grade ≥3
≥1 TRAE [§]	42 (80.8)	7 (13.5)
Most frequent TRAEs ^{¶,**}		
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

- Most TEAEs were **Grade 1 to 2**
- TEAEs resolved after a median of **3.3 weeks**
- **99.8%** (419/420) insertion success rate
- The most frequent **Grade ≥3** TRAE was bladder pain
- **5.8% (n=3)** had ≥1 serious TRAEs^{††}
- **7.7% (n=4)** had TRAEs that led to treatment discontinuation^{‡‡}
- No treatment-related deaths reported

*Patients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment 4. †An event is defined as recurrence, progression, or death. ‡Safety is shown for all patients who received at least 1 dose of Gem-iDRS in the safety analysis set (N=52). ††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. †††Reported in ≥5% of patients. **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. †††Included 1 event each of sepsis, urinary tract infection, spinal fracture. ††††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. AE, adverse event; BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; CI, confidence interval; DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; NE, not estimable; HR NMIBC, high risk non-muscle-invasive bladder cancer; OS, overall survival; PFS, progression-free survival; Pts, patients; RC, radical cystectomy; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.
1. Grimbberg DC, et al. *Eur Urol Focus*. 2020;6:620-622. Pons-Faudoa FP, et al. *Biomed Microdevices*. 2019;21:473. INLEXZO® (Gemcitabine intravesical system) [US Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2025. 4. Clinicaltrials.gov. Accessed April 27, 2026. <https://clinicaltrials.gov/ct2/show/NCT04640623>. Daneshmand S, et al. SUO 2025. Oral presentation. ©Johnson & Johnson and its affiliates 2026. This scientific information is provided by Johnson & Johnson Medical Affairs and is intended for non-promotional use. Do not alter, further disseminate, or distribute in any way. RP/RD. US-SFM-7800. 05/25.