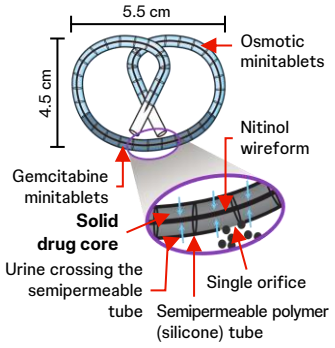
SunRISe-1 Cohort 4: A Phase 2, Randomized, Open-Label Study of TAR-200 Monotherapy in BCG-Unresponsive HR NMIBC Patients With Papillary Only Disease



Release rate is controlled by the osmotic gradient[1-3]

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)*

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Cohort 1	TAR-200 + cetrelimab (N=53)
Cohort 2	TAR-200 monotherapy (N=85)
Cohort 3	Cetrelimab monotherapy (N=28)

Reported here

Cohort 4	TAR-200 monotherapy (N=52)

Re-induction in nonresponders was not allowed

Study Endpoints

Cohort 4

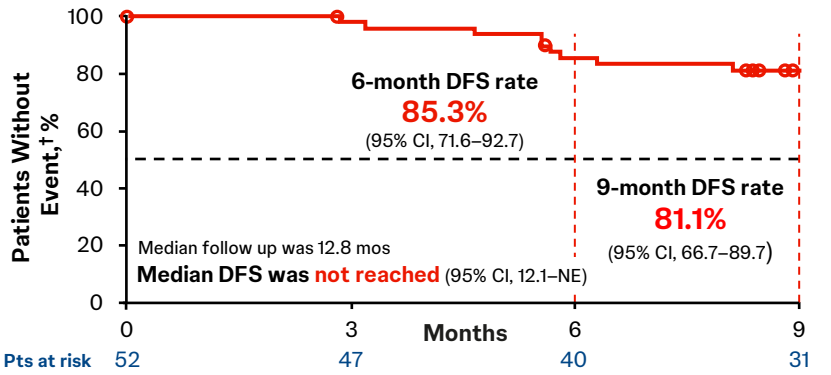
Primary endpoint

- DFS

Key secondary endpoints

- OS, HRQoL
- Safety, tolerability

Key Efficacy Data[5]



TAR-200 provided a high DFS rate in HR Ta/T1 BCG-unresponsive HR NMIBC (9-month DFS rate 81.1%), without the need for re-induction

DFS rates were consistent in patients with high-grade Ta and T1 disease

9-month PFS rate
(95% CI: 83.5–98.9)

Median PFS was not estimable

9-month OS rate
(95% CI: 86.4–99.7)

Median OS was not estimable

Safety Summary[5]

Patients with events, n (%)	TAR-200 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	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

- Most TEAEs were **Grade 1 to 2**
  - TEAEs resolved after a median of **3.7 weeks**
  - **99.5%** (387/389) 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 TAR-200 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 TAR-200 or the insertion or removal procedure or urinary placement catheter. ¶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. Grimberg DC, et al. *Eur Urol Focus*. 2020;6:620–622. **2.** Pons-Faudoa FP, et al. *Biomed Microdevices*. 2019;21:47. **3.** Data on File. Janssen Scientific Affairs, LLC. TAR-200 Draft Prescribing Information. **4.** Clinicaltrials.gov. Accessed April 22, 2025. https://clinicaltrials.gov/ct2/show/NCT04640623. 5. Guerrero-Ramos F, et al. AUA 2025. Oral presentation.

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