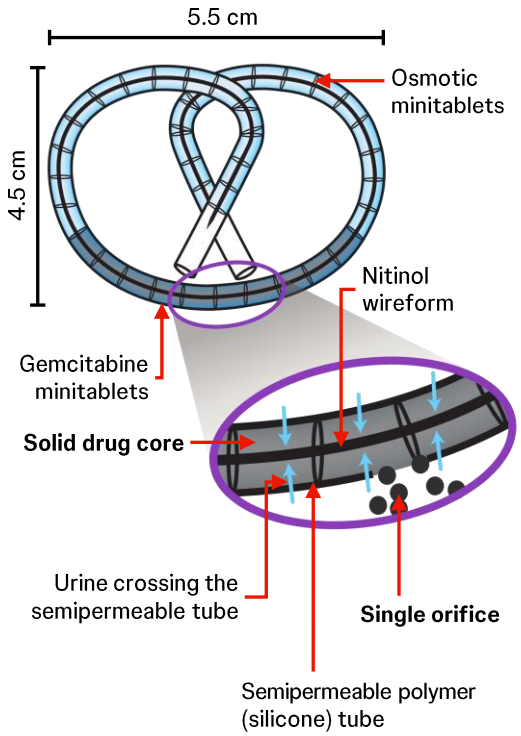
TAR-200: An intravesical gemcitabine releasing system

Please **scan to watch** an animation on insertion and removal of TAR-200

Drug Delivery Controlled via an Osmotic Pump[1–3]



Release rate is controlled by the osmotic gradient

Insertion and Removal Is an In-Office Procedure[4]

1. Insertion

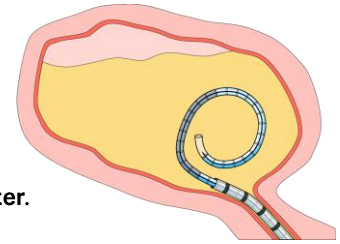
A. Gather supplies

B. Lubricate tip of catheter shaft and introduce it into the urethra

C. Inject lubricant into end of catheter shaft. Then, **load TAR-200 into the catheter**. Use the second syringe to inject lubricant into end of catheter shaft

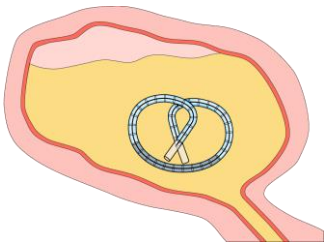
D. Insert stylet into catheter shaft until the stylet hub is flush with the proximal end of the catheter shaft

E. Remove catheter shaft and stylet as a single unit



2. Indwelling

A. TAR-200 is **freely mobile** within the bladder over the indwelling period



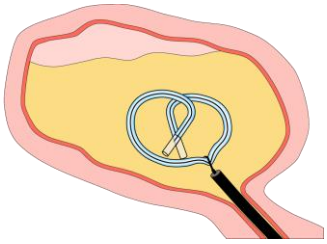
3. Removal

A. Removal is performed 3 weeks after insertion

B. Insert cystoscope into bladder. Then, introduce **non-cutting grasping forceps** through cystoscope's working channel

C. Grasp TAR-200 by silicone tubing and nitinol wireform. Do not grasp on or near ends of TAR-200

D. Remove the cystoscope and forceps together to remove TAR-200



Ease of Use and Seamless Integration Into Clinical Practice

- **Rapid in-office procedure*[3–5]**
- **Utilization of familiar catheterization procedure[4]**
- **Off-the-shelf room temperature storage and handling[4]**
- **No voiding restrictions post-insertion[3]**
- **99% (745/755) Insertion success rate[6]**
- **QoL measures remained stable throughout TAR-200 treatment[6]**

TAR-200 is an investigational product, and the safety and efficacy of the product have not yet been determined. There is no guarantee that TAR-200 will be filed with/or approved for marketing by the FDA or other Health Authorities. For additional information, you may visit www.clinicaltrials.gov. *Insertion/removal by trained personnel takes a few minutes and patients do not need to remain in the clinic after insertion to rotate sides or hold blader.

FDA, Food and Drug Administration.

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. Data on File. Janssen Scientific Affairs, LLC. TAR-200 Instructions for Use. 5. Danshmand S, et al. *Urol. Oncol.* 2025;S1078–1439. 6. Jacob JM, et al. AUA 2025. Oral presentation.

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US-SFM-7095 05/25

SunRISe-1 Cohort 2: A Phase 2, Randomized, Open-label Study of TAR-200 Monotherapy in Patients With BCG-Unresponsive HR-NMIBC

Please **scan to watch** an animation on insertion and removal of TAR-200

Study Design[1,2]

Key Eligibility Criteria

Cohorts 1–3
- CIS ± papillary disease
- BCG-unresponsive, not receiving RC
- ECOG PS 0–2

Cohort 4
- HR NMIBC papillary disease only (no CIS)*

R
- Cohort 1: TAR-200 + cetrelimab (N=53)
- *Reported here*
- **Cohort 2: TAR-200 monotherapy (N=85)**
- Cohort 3: Cetrelimab monotherapy (N=28)
- Cohort 4: TAR-200 monotherapy (N=52)

Re-induction in non-responders was not allowed

Study Endpoints

Cohorts 1–3
Primary endpoint
- Overall CR rate

Key secondary endpoints
- DOR, OS, HRQoL
- Safety, tolerability

Cohort 4
Primary endpoint
- DFS

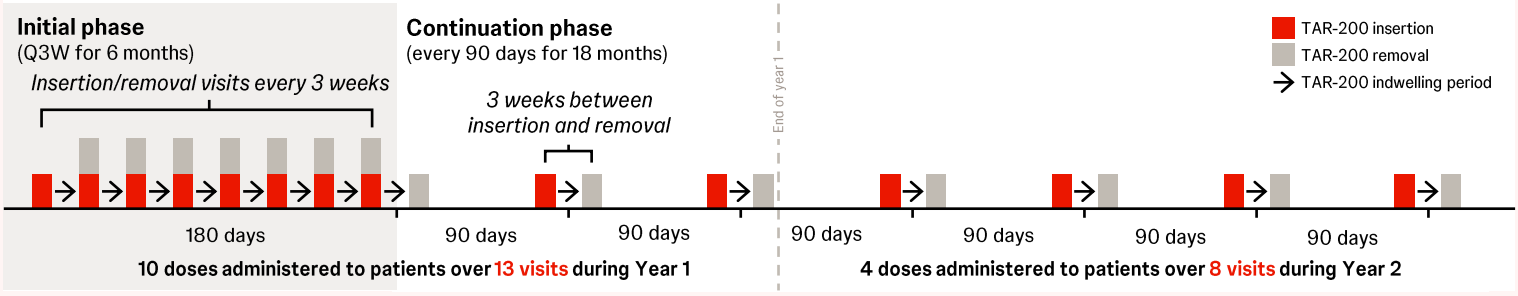
HR NMIBC Patient Journey[1]

Symptoms and initial diagnosis → Staging and risk assessment → Treatment of NMIBC → Response evaluation → BCG-unresponsiveness established

Includes cystoscopy, repeat biopsy, and potentially TURBT in cases of disease recurrence

Next steps are determined for BCG-unresponsive patients
- *In some cases, a community URO will refer patients to an academic URO*

Dosing schedule for BCG-unresponsive patients with HR NMIBC who receive TAR-200 monotherapy per SunRISe-1 protocol[1]

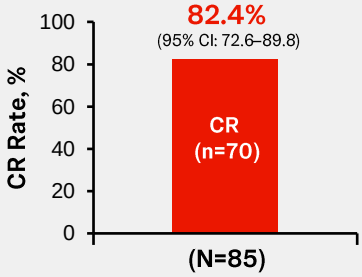


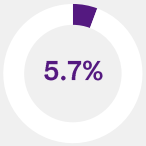
10 doses administered to patients over 13 visits during Year 1

4 doses administered to patients over 8 visits during Year 2

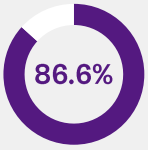
Key Efficacy Data[2]

Overall CR rate†

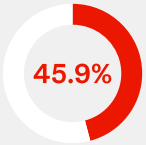




(n=4)
Had ≥T2 progression‡



(95% CI; 76.6-92.6)
Cystectomy-free at 12 mos



Observed CR rate at 12 mos (39/85)

52.9% (37/70)
Observed 12-mo DOR rate

25.8 mos
Median DOR
(95%CI: 8.3-NE)

Estimated 24-mo DOR probability:
51.8% (95% CI: 38.7–63.4)

Safety Summary[2]

Patients with events, n (%)	TAR-200 Monotherapy (N=85)¶¶	
	Any grade	Grade ≥3
≥1 TRAE**	71 (83.5)	11 (12.9)
Most frequent TRAEs††,‡‡		
Pollakiuria	37 (43.5)	0
Dysuria	34 (40.0)	0
Micturition urgency	21 (24.7)	0
Urinary tract infection	19 (22.4)	1 (1.2)
Hematuria	14 (16.5)	0
Urinary tract pain	9 (10.6)	4 (4.7)

- Most TEAEs were **Grade 1 to 2**
  - TEAEs resolved after a median of **3.1 weeks**
- **5.9% (n=5)** had ≥1 serious TRAEs§§
- **3.5% (n=3)** 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. †Response is based on centrally reviewed urine cytology, local cystoscopy, and central biopsy (if available). CRs do not have to be confirmed. A CR is defined as having a negative cystoscopy and negative (including atypical) centrally read urine cytology, or positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative (including atypical) centrally read cytology at any time point. ‡Stage based on investigator assessment. Three patients with no evidence of disease had recurrence/progression based on central review but was not indicated by local assessment. §Median follow-up in responders was 20.2 months (range, 5 to 48). ¶Safety is shown for all patients who received at least 1 dose of TAR-200 in the safety analysis set (N=85). **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 acute kidney injury, cystitis, urinary retention, cystitis pseudomonal, and urosepsis. Note, patients may have had ≥1 Grade ≥3 TRAE.§§1 event each of acute kidney injury, bladder pain, cystitis, cystitis pseudomonal, urinary tract infection, urinary tract pain, and urosepsis. Note, patients may have had ≥1 serious TRAE. ¶¶TRAEs leading to discontinuation were noninfective cystitis (n=2), bladder pain (n=1), pollakiuria (n=1), and urinary tract disorder (n=1). Note, patients who discontinued may have had ≥1 TRAE.

AE, adverse event; BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; CI, confidence interval; CR, complete response; DFS, disease-free survival; DOR, duration of response; 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; MIBC, muscle invasive bladder cancer; Mo, month; OS, overall survival; RC, radical cystectomy; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; TURBT; transurethral resection of the bladder tumor; URO, urologist.

1. Clinicaltrials.gov. Accessed April 23, 2025. https://clinicaltrials.gov/ct2/show/NCT04640623. 2. Jacob JM, et al. AUA 2025. Oral presentation.

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