SunRISe-1 Cohort 2: A Phase 2, randomized, single-arm study of TAR-200 monotherapy in patients with BCG-unresponsive HR-NMIBC

Please **scan to view** additional data from SunRISe-1

Study Design[1,2]

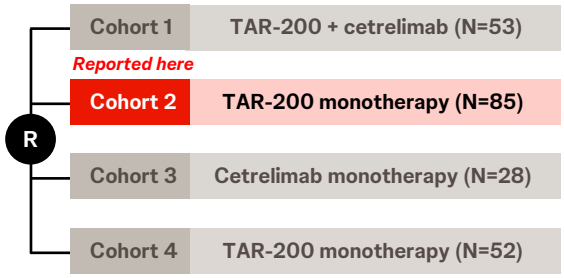
Key Eligibility Criteria

Cohorts 1–3

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

Cohort 4

- HR NMIBC papillary disease only (no CIS)*



Re-induction in non-responders was not allowed

Study Endpoints

Cohorts 1–3

Primary endpoint

- Overall CR rate

Key secondary endpoints

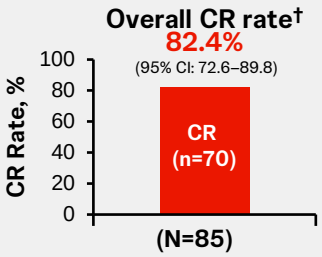
- DOR, OS, HRQoL
- Safety, tolerability

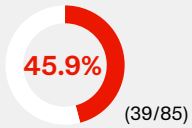
Cohort 4

Primary endpoint

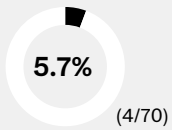
- DFS

Key Efficacy Data[2]

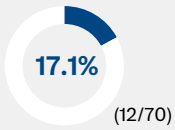




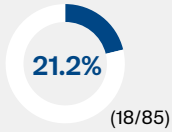
Observed CR rate at 12 months



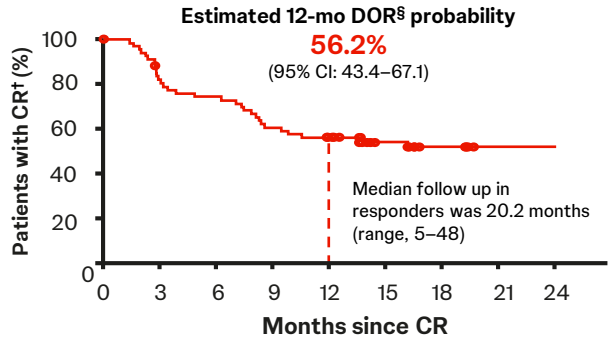
Of responders had ≥T2 progression‡



Of responders underwent cystectomy



Of all patients underwent cystectomy



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

25.8 months (95% CI: 8.3–NE) **Median DOR**

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	18 (21.2)	1 (1.2)
Hematuria	14 (16.5)	0
Urinary tract pain	9 (10.6)	4 (4.7)
Bladder pain	7 (8.2)	2 (2.4)
Bladder spasm	7 (8.2)	0
Noninfective cystitis	6 (7.1)	0
Urinary incontinence	5 (5.9)	0

- Most TRAEs were **Grade 1 to 2**
  - TRAEs resolved after a median of **3.0 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

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Figure adapted with permission from Daneshmand S, et al. TAR-200 for Bacillus Calmette-Guérin-unresponsive high-risk non-muscle-invasive bladder cancer: Results from the phase IIb SunRISe-1 study. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. Available at: https://ascopubs.org/doi/10.1200/JCO-25-01651. *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). 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. §Kaplan-Meier estimates. ¶Safety data are shown for all patients who received at least 1 dose of study drug in the full analysis set of the TAR-200 monotherapy in CIS with or without papillary disease cohort (N=85). **An AE was categorized as related if the investigator determines that there is a relationship between the AE and study drug/procedure. Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. ††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, pseudomonal cystitis, urinary retention, and urosepsis. Patients may have had ≥1 Grade ≥3 TRAE. §§1 event each of bladder pain, pseudomonal cystitis, urinary tract infection, urosepsis with acute kidney injury, and urinary tract pain. ¶¶TRAEs leading to TAR-200 discontinuation included two patients (2.4%) with noninfective cystitis and one (1.2%) with pollakiuria and urinary tract disorder. 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; Mo, month; OS, overall survival; RC, radical cystectomy; TRAE, treatment-related adverse event.

1. Clinicaltrials.gov. Accessed September 15, 2025. https://clinicaltrials.gov/ct2/show/NCT04640623. **2.** Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.