

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}

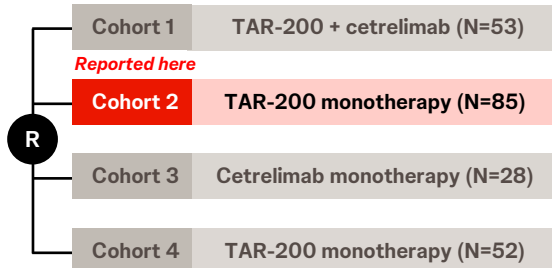
Key Eligibility Criteria

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

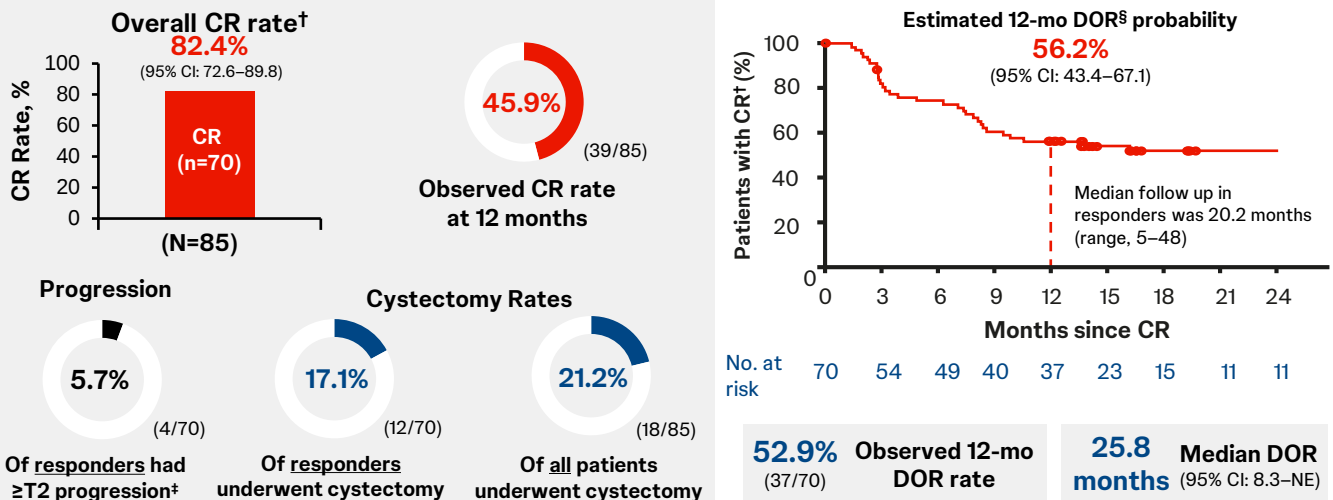
- DOR, OS, HRQoL
- Safety, tolerability

Cohort 4

Primary endpoint

- DFS

Key Efficacy Data²



Safety Summary²

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

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;101200/JCO2501651. 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 urine 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.