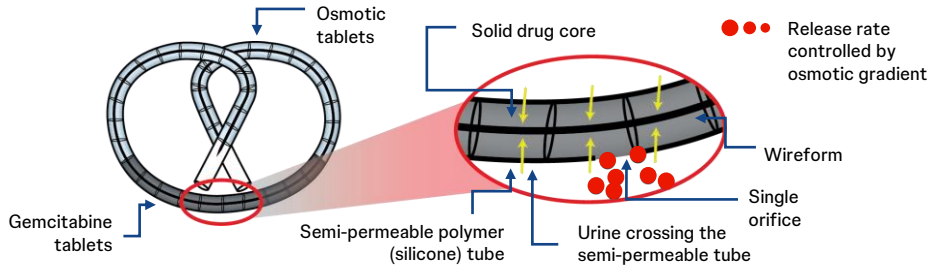
Results From SunRISe-1: A Phase 2, Randomized, Open-Label Study of TAR-200 ± Cetrelimab to Assess Efficacy and Safety in BCG-Unresponsive Patients With NMIBC

TAR-200 Overview[1-3]

TAR-200 is an investigational intravesical system that is designed to provide sustained, local release of gemcitabine in the bladder



SunRISe-1: Study Design[3-6]

Randomization 2:1:1 N≈200

Cohort 1	TAR-200 doses Q3W [24 weeks], then Q12W through Week 96 + cetrelimab* Q3W [18 months] (N=55)†	*Not reported here*
Cohort 2	**TAR-200 doses Q3W [24 weeks], then Q12W through Week 96 (N=85)**	***Reported here***
Cohort 3	Cetrelimab* doses Q3W [18 months] (N=28)‡	*Not reported here*
Papillary-only HR NMIBC (no CIS)§		
Cohort 4	TAR-200 doses Q3W [24 weeks], then Q12W through Week 96 (N≈50)	*Not reported here*

Key Inclusion Criteria

Cohorts 1-3
- Age ≥18 years
- Histologically confirmed CIS ± papillary disease (high-grade Ta, any T1)
- Unresponsive to BCG and not receiving RC
- ECOG PS 0-2

Cohort 4
- Age ≥18 years
- HR NMIBC papillary disease only (no CIS)

Key Exclusion Criteria

Cohorts 1-3
- Muscle-invasive, locally advanced, nonresectable, or metastatic UC (T2, T3, T4, and/or Stage IV)
- Prior therapy with anti-PD-1 or anti-PD-L2

Cohort 4
- CIS

Study Endpoints

Cohorts 1-3¶

Primary endpoint
- Overall CR rate‖

Key secondary endpoints
- DOR
- OS
- Safety, tolerability

Cohort 4

Primary endpoint
- DFS rate at 12 months

SunRISe-1 (Cohort 2): Baseline Characteristics[3,7#]

Characteristics	TAR-200 (N=85)**
Age, years, median (range)	71 (40-88)
Sex, male, %	80.0
Race, %	
White	72.9
Asian	9.4
Black or African American	2.4
Not reported/unknown	15.3
Nicotine use, %	
Current	9.4
Former	57.6
Never	32.9

Characteristics	TAR-200 (N=85)**
ECOG PS 0, %	91.8
Tumor stage, %	
CIS only	67.1
CIS + papillary disease	32.9
Total doses of prior BCG, n, median (range)	12 (7-42)
Time from last BCG to CIS diagnosis, months, median (range)	3.4 (0-22)††
Reason for not receiving RC, %	
Declined	96.5
Ineligible	3.5

BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; CR, complete response; CT, computerized tomography; DFS, disease-free survival; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, high risk; MRI, magnetic resonance imaging; NMIBC, non–muscle-invasive bladder cancer; OS, overall survival; PD-1, programmed cell death protein 1; PD-L2, programmed cell death-ligand 2; Q3W, every 3 weeks; Q12W, every 12 weeks; RC, radical cystectomy; UC, urothelial carcinoma. *Cetrelimab dosing was through Week 78. †55 patients were randomized and 53 were treated in Cohort 1. ‡28 patients were randomized and treated in Cohort 3. §Patients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment 4. ¶Imaging (CT/MRI) was performed every 24 weeks through Year 3. ‖Response is determined by quarterly cystoscopy, quarterly central cytology, and central pathology at Weeks 24 and 48 and as clinically indicated. #Data for Cohorts 1 and 3 are available upon request. **Patient characteristics are shown for all patients who received at least one dose of TAR-200 in the full analysis set (N=85). ††1 patient had 22.4 months from last BCG dose to CIS diagnosis (protocol deviation); all other patients had ≤12 months from last BCG dose to CIS diagnosis (per protocol).

1. Grimberg DC, et al. *Eur Urol Focus*. 2020;6(4):620-622. 2. Pons-Faudoa FP, et al. *Biomed Microdevices*. 2019;21(2):47. 3. Jacob JM, et al. AUA 2024. Oral presentation. Abstract P2-01. 4. NCT04640623. Clinicaltrials.gov. Accessed April 9, 2024. https://clinicaltrials.gov/ct2/show/NCT04640623 5. Necchi A, et al. ESMO 2023. Oral presentation. Abstract LBA105. 6. Daneshmand S, et al. AUA 2023. Oral presentation. Abstract LBA02. 7. van der Heijden MS, et al. ESMO 2024. Oral presentation. Abstract LBA85.

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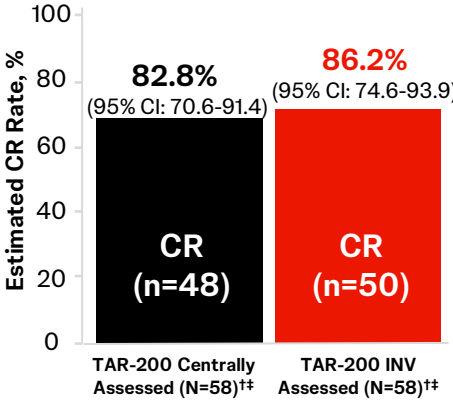
SunRISe-1 (Cohort 2, HR NMIBC CIS): Estimated CR Rate[1,2]

Estimated CR rate* (clinical data cutoff: January 2, 2024)[1]

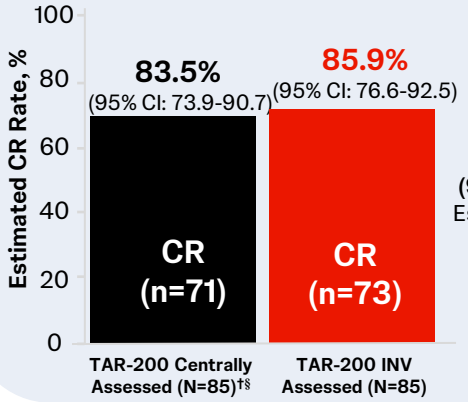


98%
47 of 48
CRs achieved at 1st disease assessment at Week 12[1]

75.7%
(95% CI: 59.1-86.3)
Estimated CR rate at 6 months (KM estimate)[1]

61.9%
(95% CI: 41.4-77.1)
Estimated CR rate at 12 months (KM estimate)[1]

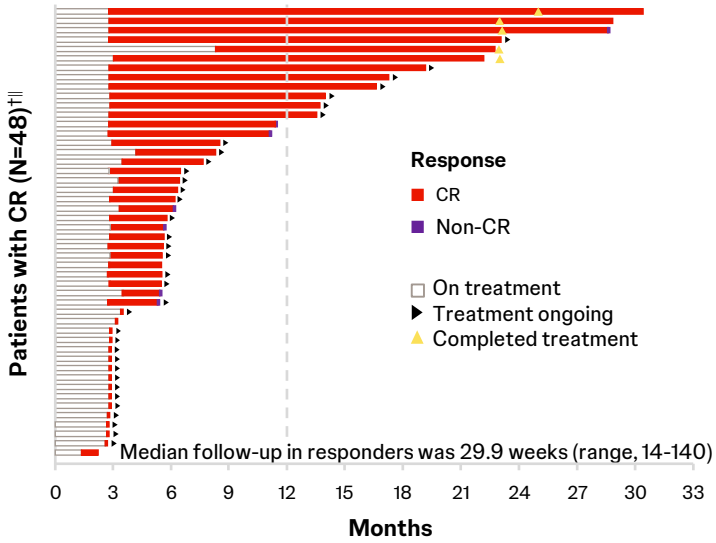
Estimated CR rate* (clinical data cutoff: May 13, 2024)[2]



57.4%
(95% CI: 40.6-71.0)
Estimated CR rate at 12 months (KM estimate)[2]

SunRISe-1 (Cohort 2): Duration of Response[1,2]

Duration of Response (clinical data cutoff: January 2, 2024)[1]



Durability of Response (clinical data cutoff: January 2, 2024)[1]

30 weeks
(95% CI: 3.7-36.6)
Median follow-up in responders

74.6%
(95% CI: 49.8-88.4)
12-month DOR rate (KM estimate)

85.0%
(41/48)
Patients remaining in response

Durability of Response (clinical data cutoff: May 13, 2024)[2]

9.2 months
(95% CI: 3.7-36.6)
Median follow-up in responders

65.7%
(95% CI: 45.2-80.1)
12-month DOR rate (KM estimate)

82.0%
(58/71)
Patients remaining in response

SunRISe-1 (Cohort 2): Safety Profile[1,2]

Safety Profile (clinical data cutoff: May 13, 2024)[2]

Adverse events	TAR-200 (N=85)**	
	Any grade	Grade ≥3
≥1 TRAEs¶	71 (83.5)	8 (9.4)
≥1 Most frequent TRAEs		
Pollakiuria	33 (38.8)	-
Dysuria	30 (35.3)	-
Urinary tract infection	17 (20.0)	1 (1.2)
Hematuria	12 (14.1)	-
Urinary tract pain	-	3 (3.5)
Pruritus	1 (1.2)	-
Hypothyroidism	0	-
AST increased	-	0

Grade, Onset, Resolution of AEs

Most AEs were Grade 1 or 2[1,2]

Onset of most AEs: Within 12 weeks of treatment initiation[1]

Resolution of most AEs: Within 2 weeks of onset[1]

- 5 patients (5.9%) had ≥1 serious TRAEs[2]
- 5 patients (5.9%) discontinued treatment due to TRAEs[2††]
- No treatment-related deaths were reported[2]

AE, adverse event; AST, aspartate aminotransferase; CI, confidence interval; CIS, carcinoma in situ; CR, complete response; DOR, duration of response; HR, high risk; INV, investigator; KM, Kaplan-Meier; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event. *Estimated CR rate is based on CR at any time. †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. ‡The efficacy analysis was performed on all treated patients who had active disease at baseline and adequate disease assessment postbaseline, or who progressed, died, had been withdrawn from treatment due to the recurrence of high-risk or progressive disease, or discontinued the study (N=58). 2 patients discontinued the study before having a disease evaluation but were included in the denominator of the evaluation of CR rate. §Response is based on centrally reviewed urine cytology, local cystoscopy, and central biopsy (if available). CRs do not have to be confirmed. ‖The efficacy analysis was performed on all treated patients who had active disease at baseline and adequate disease assessment postbaseline, or who progressed, died, had been withdrawn from treatment due to the recurrence of high-risk or progressive disease, or discontinued the study. Response duration shown for patients with CR (N=48). ¶TRAEs of any grade by preferred term are listed if they were reported in ≥20% of patients. **Safety data are shown for all patients who received at least 1 dose of study drug in the full analysis set (N=85). ††TRAEs leading to discontinuation were noninfective cystitis (n=3), dysuria (n=1), pollakiuria (n=1), and urinary retention (n=1). Note, patients who discontinued may have had ≥1 TRAE.

1. Jacob JM, et al. AUA 2024. Oral presentation. Abstract P2-01. 2. van der Heijden MS, et al. ESMO 2024. Oral presentation. Abstract LBA85.

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