TAR-200 Monotherapy in Patients With Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer Carcinoma in Situ: 1-Year Durability and Patient-Reported Outcomes From SunRISe-1

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Disclosures

- JM Jacob has received consultant fees and served as an advisory board member for Janssen, Aura Biosciences, and Pfizer

- This study is sponsored by Janssen Research & Development, LLC, a Johnson & Johnson company

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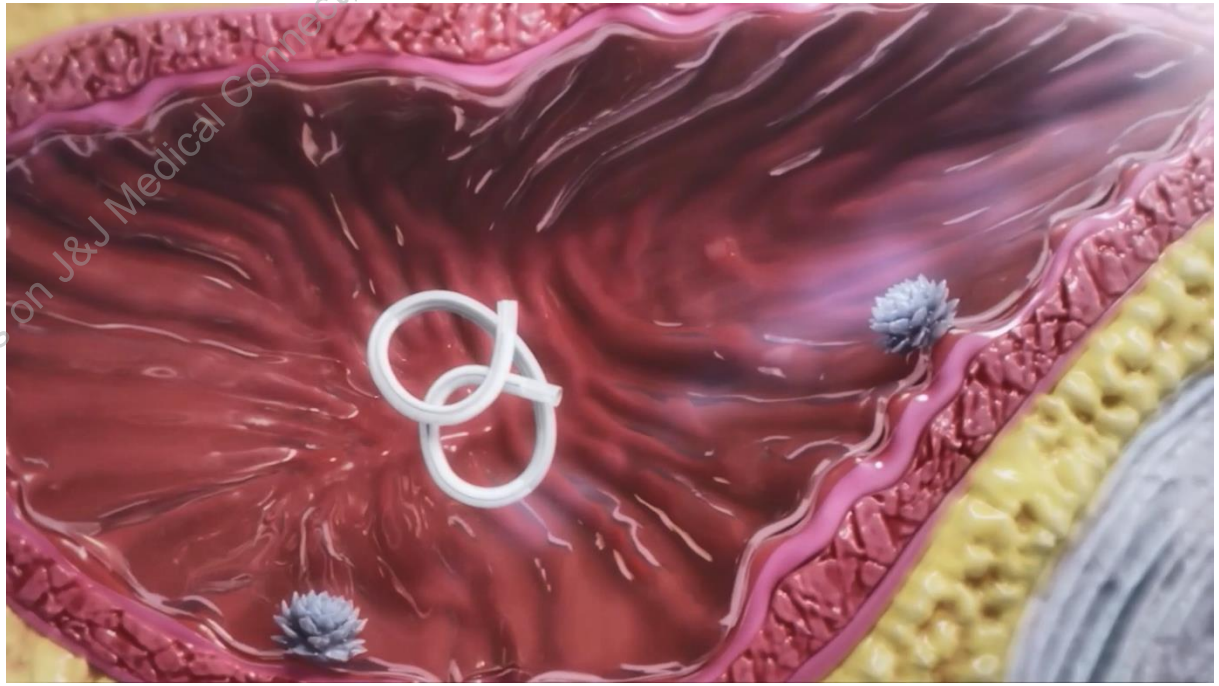
TAR-200 and Addressing Unmet Needs in Patients With HR NMIBC Unresponsive to BCG Treatment

- Standard of care for BCG-unresponsive HR NMIBC is RC[1,2]
  - RC is a life-changing operation associated with considerable morbidity and impact on QoL and a 90-day mortality risk of up to 8%[3]
  - Many patients are unable or unwilling to undergo RC[2]
  - In real-world studies, <20% of patients with HR NMIBC that recurred after BCG treatment underwent RC[4]
- Limited US FDA–approved treatment options are available to treat BCG-unresponsive HR NMIBC CIS; overall CR rates are:
  - 41% with pembrolizumab[5]
  - 51% with nadofaragene firadenovec[6]
  - 62% with nogapendekin alfa inbakicept + BCG[7]

TAR-200 is a novel intravesical drug releasing system designed to provide sustained delivery of gemcitabine in the bladder[8-11]



TAR-200, which has been granted FDA Breakthrough Therapy Designation, is placed using a urinary placement catheter in a **brief in-office procedure**

BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; CR, complete response; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; US FDA, United States Food and Drug Administration.

1. Holzbeierlein JM, et al. *J Urol.* 2024;211:533-538. 2. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 3. Marqueen KE, et al. *JNCI Cancer Spectr.* 2018;2:pky075. 4. Musat MG, et al. *Clinicoecon Outcomes Res.* 2022;14:35-48. 5. ADSTILADRIN® (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 2024. 6. ANKTIVA® (nogapendekin alfa inbakicept-pmln) [prescribing information]. Culver City, CA, USA: Altor BioScience; 2024. 7. KEYTRUDA® (pembrolizumab) [prescribing information]. Rahway, NJ, USA: Merck & Co., Inc.; 2024. 8. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 9. Tyson MD, et al. *J Urol.* 2023:209:890-900. 10. van Valenberg FJP, et al. *Eur Urol Open Sci.* 2024;62:8-15. 11. Daneshmand S, et al. *Urol Oncol.* 2025;S1078-1439(24)01044-5.

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Phase 2b SunRISe-1 Study: Cohort 2 BCG-Unresponsive HR NMIBC CIS ± Papillary Disease

NCT04640623

Population:
- Aged ≥18 years
- Histologically confirmed HR NMIBC CIS (with or without papillary disease)
- ECOG PS of 0-2
- Persistent or recurrent disease within 12 months of completion of BCG
- Unresponsive to BCG[1,2] and not receiving RC

R

- TAR-200 + Cetrelimab[b] *Cohort 1* (N=53)[c] — *Cohort 1 was closed*
- **TAR-200 Monotherapy *Cohort 2* (N=85)** — ***Enrollment completed***
- Cetrelimab[b] Monotherapy *Cohort 3* (N=28) — *Cohort 3 was closed*
- TAR-200 Monotherapy *Cohort 4* (N=52) — *Enrollment completed*

Population:
- Papillary-only HR NMIBC (no CIS)[a]

TAR-200 dosing:
Q3W (indwelling) for the first 24 weeks; then Q12W through Week 96

Cohorts 1-3:
Primary end point
- Overall CR rate

Key secondary end points
- Duration of response
- Overall survival
- Safety
- Tolerability
- HRQoL

Cohort 4:
Primary end point
- DFS

- **Here we report *1-year durability data from the TAR-200 monotherapy cohort (Cohort 2) of SunRISe-1***
- Response is determined by quarterly cystoscopy, quarterly central cytology, **mandated bladder biopsy by central assessment at Weeks 24 and 48**, and local imaging Q24W
- The study protocol did not allow re-induction for nonresponders, consistent with US FDA guidance[2]
- As of June 2023, Cohorts 1 and 3 were closed for enrollment, and Cohort 2 enrollment continued to achieve N=85, per protocol amendment

The clinical data cutoff was March 31, 2025.

DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; Q3W, every 3 weeks; Q12W, every 12 weeks; Q24W, every 24 weeks; R, randomization.

[a]Patients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment 4. [b]Cetrelimab is an anti–programmed cell death-1[3,4]; cetrelimab dosing was Q3W through Week 78. [c]Number of patients enrolled in Cohort 1 was N=55 and number of patients treated was N=53.

1. Lerner SP, et al. *Urol Oncol*. 2009;27:155-159. 2. US Food and Drug Administration. Available at: https://www.fda.gov/media/101468/download. 3. DeAngelis N, et al. *Cancer Chemother Pharmacol*. 2022;89:515-527.
4. Felip E, et al. *Cancer Chemother Pharmacol*. 2022;89:499-514.

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Baseline Characteristics: Cohort 2 BCG-Unresponsive HR NMIBC CIS ± Papillary Disease

Characteristics	TAR-200 Monotherapy *Cohort 2* (N=85)[a]
Age, years, median (range)	71.0 (40-88)
Sex, male, %	80.0
Race, %	
White	87.1
Asian	9.4
Black or African American	2.4
Not reported/unknown	1.2
Nicotine use, %	
Current	8.2
Former	58.8
Never	32.9

Characteristics	TAR-200 Monotherapy *Cohort 2* (N=85)[a]
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)	3.2 (0-22)[b]
Reason for not receiving RC, %	
Declined	96.5
Ineligible	3.5

[a]Patient characteristics are shown for all patients who received at least 1 dose of study drug in the full analysis set of Cohort 2 (N=85).
[b]2 patients had >12 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).

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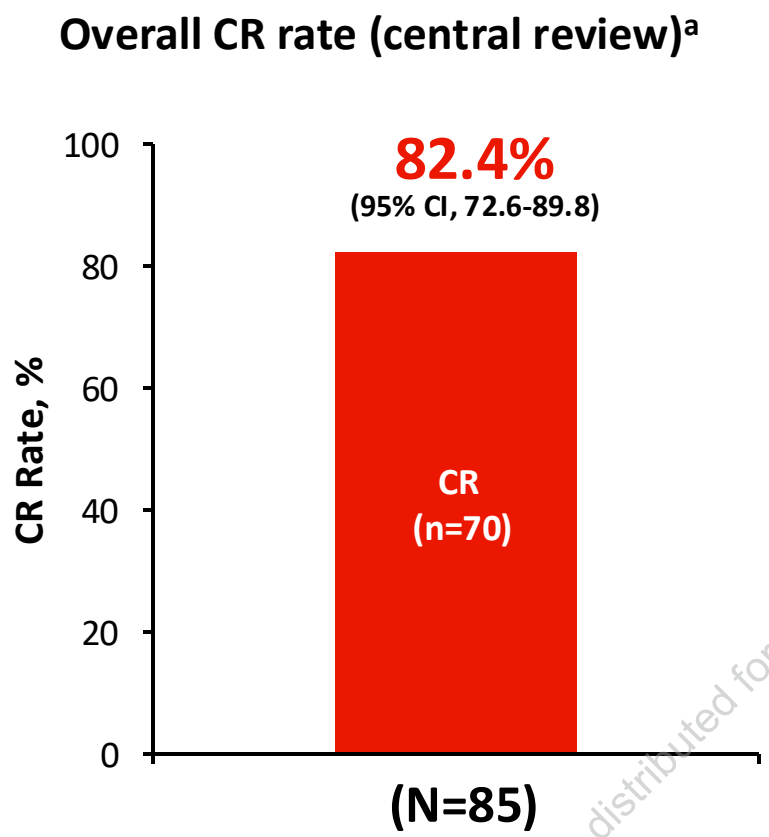
Highest CR Rate to Date With Rapid Onset After TAR-200 Monotherapy in BCG-Unresponsive HR NMIBC CIS ± Papillary Disease



CR Rate From Treatment Initiation	Observed Overall CR Rate, % (n/N)
12 months[b]	**45.9** (39/85)

	KM Estimated Overall CR Rate, % (95% CI)
12 months	**52.4** (40.7-62.8)
24 months	**44.7** (33.1-55.7)

- Rapid onset of response: median time to onset, **2.8 months** (range, 2.1-8.3)
- **95.7%** (67 of 70) CRs achieved at the first (3 month) disease assessment

CI, confidence interval; KM, Kaplan-Meier.
[a]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. [b]The CR rate at 12 months is represented by disease evaluation occurring at 48 weeks from first dose.

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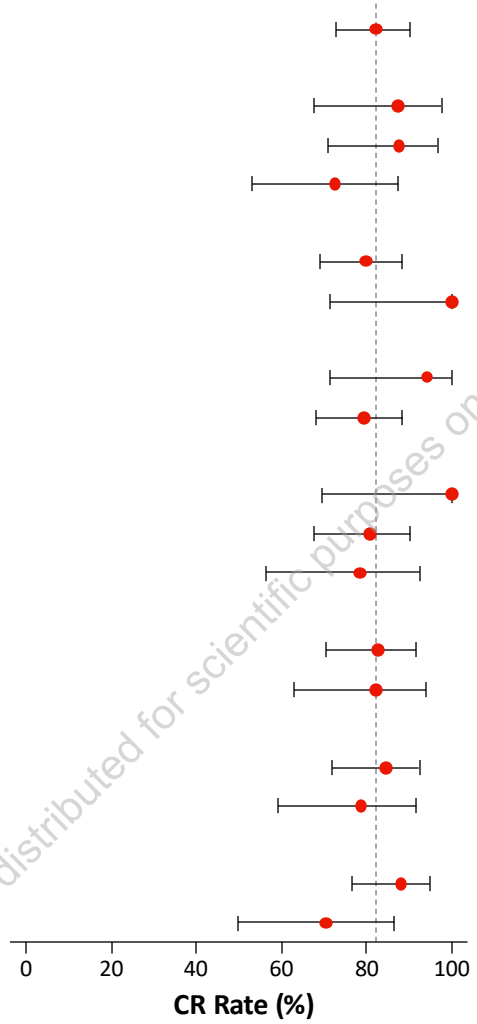
Forest Plot: Consistent CR Rate Across Patient Subgroups



	CR Rate n/N (%)	95% CI
Overall	70/85 (82.4)	72.6-89.8
Age group, years		
<65	21/24 (87.5)	67.6-97.3
65-<75	28/32 (87.5)	71.0-96.5
≥75	21/29 (72.4)	52.8-87.3
Race		
White	59/74 (79.7)	68.8-88.2
Non-White	11/11 (100.0)	71.5-100.0
Sex		
Female	16/17 (94.1)	71.3-99.9
Male	54/68 (79.4)	67.9-88.3
Region[a]		
Asia Pacific	10/10 (100.0)	69.2-100.0
EMEA	42/52 (80.8)	67.5-90.4
America	18/23 (78.3)	56.3-92.5
Tumor stage		
CIS (Tis)	47/57 (82.5)	70.1-91.3
CIS + papillary disease	23/28 (82.1)	63.1-93.9
Nicotine use		
Current/Former	48/57 (84.2)	72.1-92.5
Never	22/28 (78.6)	59.0-91.7
BCG strain		
TICE	51/58 (87.9)	76.7-95.0
Non-TICE	19/27 (70.4)	49.8-86.2

EMEA, Europe, Middle East, and Africa.

[a]America includes Canada, USA; Asia Pacific includes Australia, Japan, South Korea; EMEA includes Belgium, France, Germany, Greece, Italy, Netherlands, Portugal, Russia, Spain, United Kingdom.

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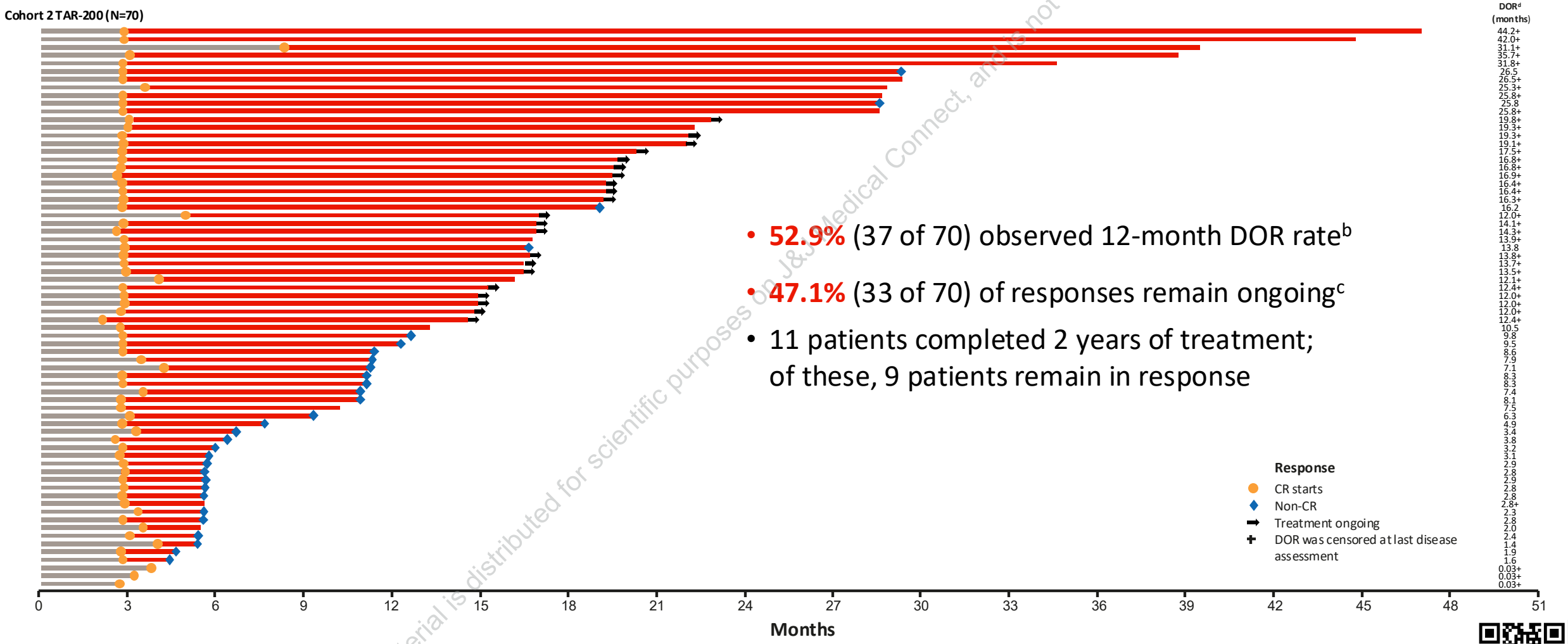
52.9% of the Responses[a] Lasted for ≥1 Year



- **52.9%** (37 of 70) observed 12-month DOR rate[b]
- **47.1%** (33 of 70) of responses remain ongoing[c]
- 11 patients completed 2 years of treatment; of these, 9 patients remain in response

DOR, duration of response.

[a]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. [b]12-month assessment indicates 365 days of DOR, represented by 52 weeks/12 months. [c]33 of 70 responders (47.1%) were censored and had ongoing response with no event as of the clinical data cutoff. [d]DOR was defined as the time from first complete response to first evidence of recurrence or progression or death, whichever occurs first.

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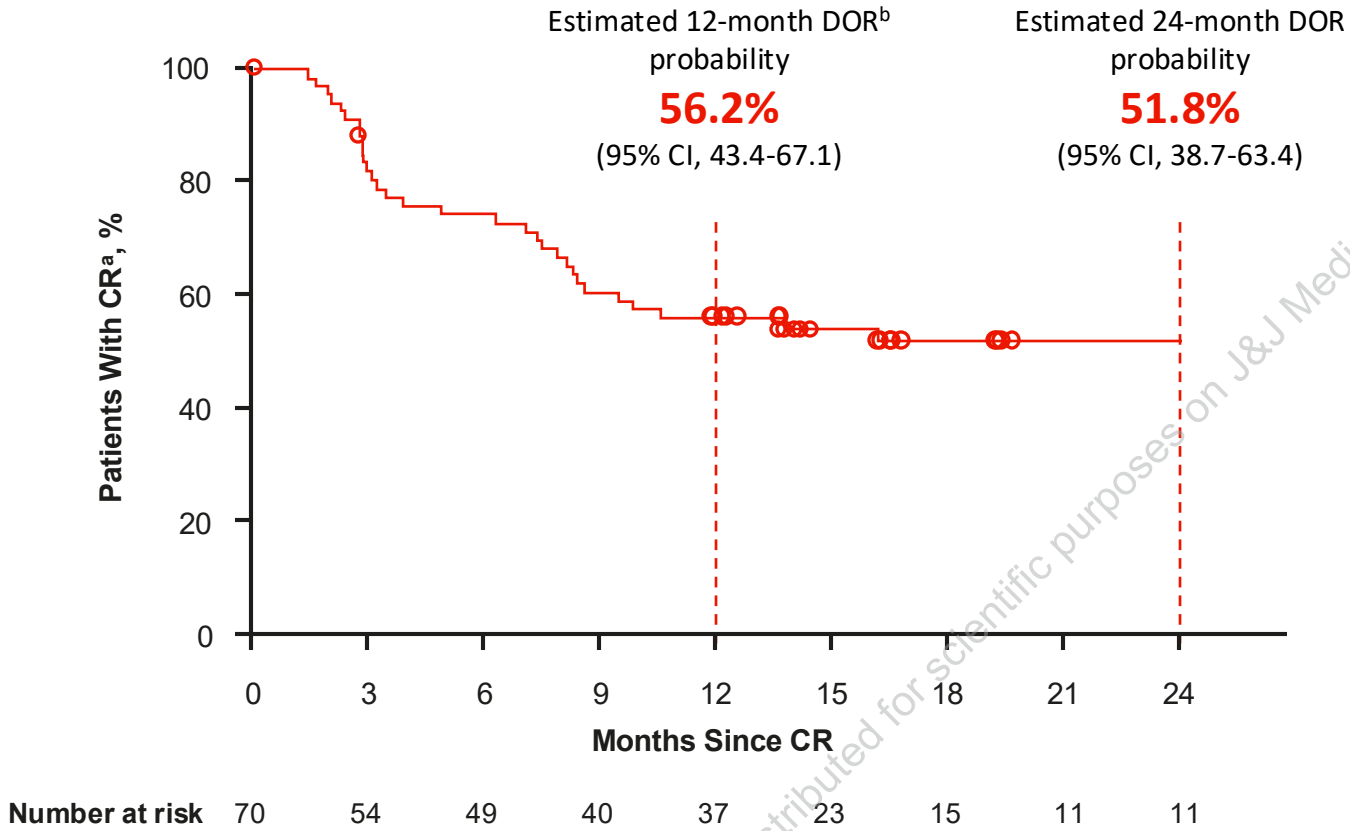
Durable Responses With TAR-200 Monotherapy



- **25.8 months** (95% CI, 8.3-NE) median DOR
- Of 70 responders, few experienced disease progression
  - 23 (32.9%) had HR NMIBC recurrence[c]
  - 4 (5.7%) had ≥T2 progression[c]
- **86.6%** (95% CI, 76.6-92.6) cystectomy-free rate at 12 months

DOR, duration of response; MIBC, muscle-invasive bladder cancer; NE, not estimable.
[a]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. [b]Median follow-up in responders was 20.2 months (range, 5-48). [c]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.

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Clinical Outcomes in HR NMIBC Unresponsive to BCG

SunRISe-1 results for patients with HR NMIBC BCG-unresponsive CIS ± papillary disease

Product	TAR-200	Adstiladrin	Anktiva + BCG (With Reinduction)	Keytruda
CR rate (primary end point)	82%[1]	51%[2]	62%[3]	41%[4]
≥12-month DOR (secondary end point)	53%[1]	46%[2]	58%[3]	46%[4]
Proportion of all patients who achieved and maintained CR for ≥12 months	44% (37/85)	24% (23/98)	36% (28/77)	19% (18/96)

Table provides published results from each compound and are presented to show results and not be comparative in nature.

1. SunRISe-1 Cohort 2 data. 2. ADSTILADRIN® (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 2024. 3. ANKTIVA® (nogapendekin alfa inbakicept-pmln) [prescribing information]. Culver City, CA, USA: Altor BioScience; 2024. 4. KEYTRUDA® (pembrolizumab) [prescribing information]. Rahway, NJ, USA: Merck & Co., Inc.; 2024.

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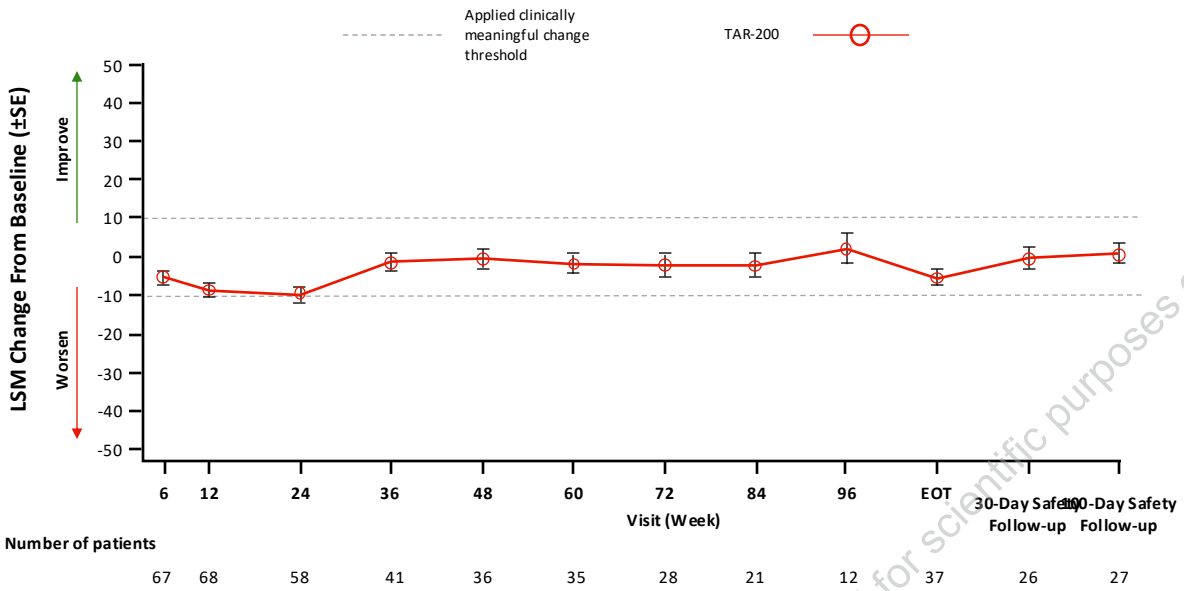
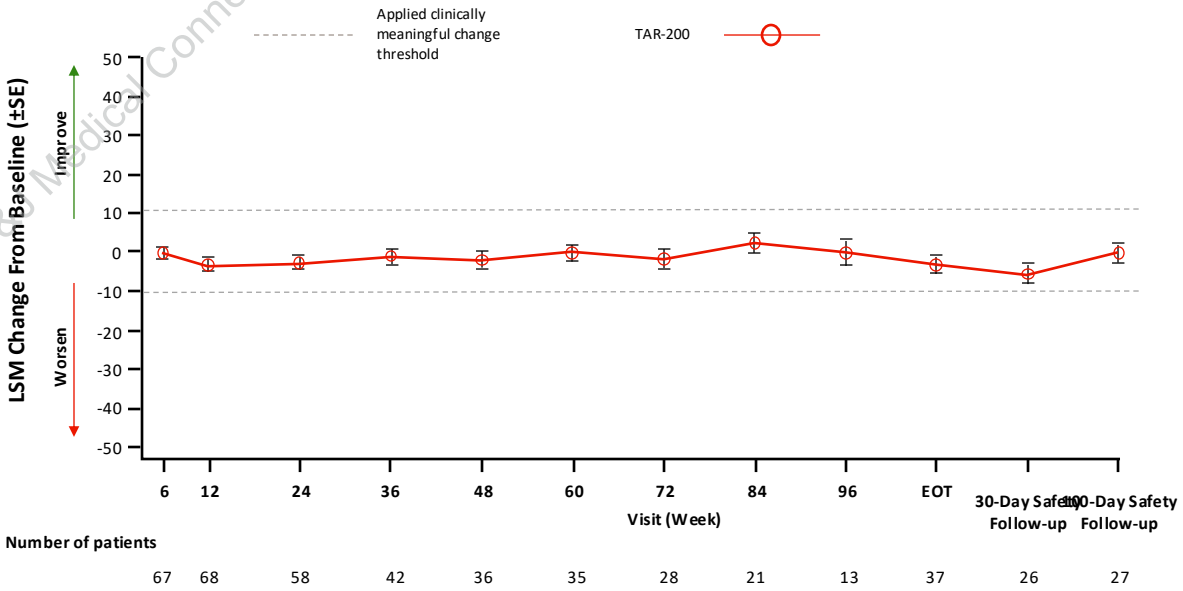
Patient Quality of Life Was Maintained on TAR-200

EORTC QLQ-C30: Global Health Status



EORTC QLQ-C30: Physical Functioning



- Mean EORTC QLQ-C30 GHS (75.0 [SD, 16.7]) and PF (86.2 [SD, 17.3]) scores were high at baseline and stable on treatment (did not exceed clinically meaningful change threshold of 10 points[1-3])

EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core Questionnaire; GHS, global health status; LSM, least square means; PF, physical functioning; SD, standard deviation; SE, standard error.

1. Osoba D, et al. *J Clin Oncol.* 1998;16:139-144. 2. Musoro JZ, et al. *Eur J Cancer.* 2023;188:171-182. 3. Aaronson NK, et al. *J Natl Cancer Inst.* 1993;85:365-376.

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TAR-200 Monotherapy Safety Profile

- Most TEAEs were grade 1 or 2
  - TEAEs resolved after a median of 3.1 weeks
- 99% (745 of 755) insertion success rate
- 5 patients (5.9%) had ≥1 serious TRAEs[a]
- Few patients (n=3; 3.5%) discontinued treatment due to TRAEs[b]
- No treatment-related deaths were reported

Patients With Events, n (%)	TAR-200 Monotherapy *Cohort 2* (N=85)[c]	
	Any Grade	Grade ≥3
≥1 TRAE[d]	71 (83.5)	11 (12.9)
Most frequent TRAEs[e,f]		
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)
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

TEAE, treatment emergent adverse event; TRAE, treatment-related adverse event.

[a]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. [b]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. [c]Safety is shown for all patients who received at least 1 dose of TAR-200 in the safety analysis set (N=85). [d]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. [e]Reported in ≥5% of patients. [f]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.

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Conclusions: SunRISe-1 TAR-200 Monotherapy

- **TAR-200 monotherapy provides *the highest single-agent CR rate*** (**82.4%**) reported to date in patients with BCG-unresponsive HR NMIBC[1-5]
  - Onset of response was rapid, without the need for reinduction (95.7% of CRs achieved at the first disease assessment)
- **TAR-200 monotherapy responses were durable, with a median DOR of 25.8 months and *52.9% of the responses lasting for ≥1 year***
  - Few responders had disease progression
- **Overall health status and high physical functioning were maintained** while on TAR-200 treatment
- TAR-200 monotherapy was **well tolerated,** with serious TRAEs and TRAEs leading to discontinuation being rare
- **TAR-200 is under review by the US FDA following submission of a New Drug Application**

1. Balar AJ, et al. *Lancet Oncol.* 2021;22:919-930. 2. Black PC, et al. *Eur Urol.* 2023;84:536-544. 3. ADSTILADRIN® (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 2024.
4. UroToday. 2024. https://www.urotoday.com/conference-highlights/suo-2024/suo-2024-bladder-cancer/156717-suo-2024-topline-results-from-bond-003-a-phase-3-study-of-intravesical-cretostimogene-grenadenorepvec-for-the-treatment-of-high-risk-bcg-unresponsive-nmibc-with-cis.html. 5. Chamie K, et al. *NEJM Evid*. 2023;2:EVIDoa2200167.

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Ongoing studies of TAR-200:

- **SunRISe-1**
  BCG-unresponsive HR NMIBC
  (Cohorts 1-3: CIS; Cohort 4: papillary only)
  NCT04640623
  Cohort 2 presented here
  Cohort 4 to be presented in P2 Plenary Session
- **SunRISe-3**
  BCG-naive HR NMIBC
  NCT05714202
- **SunRISe-4**
  Neoadjuvant MIBC
  NCT04919512
- **SunRISe-5**
  Papillary-only, BCG-exposed,
  RC-ineligible/-refusing, recurrent HR NMIBC
  NCT06211764

Additional AUA 2025 presentations on TAR-200:

- **SunRISe-1 Cohort 4 Interim Analysis Results**
  Venetian Ballroom, April 26, 2025; 11:00 AM - 11:10 AM; Plenary Session
- **SunRISe-5 Clinical Trials in Progress, Bladder Cancer**
  April 28, 2025; 9:56 AM - 10:04 AM; Learning Lab

- We thank the patients who participated in the study, their families, and the investigators and clinical research staff from the study centers
- Editorial support was provided by Nicolisha Narainpersad, PhD, of Parexel, and funded by Janssen Global Services, LLC
- This study is sponsored by Janssen Research & Development, LLC, a Johnson & Johnson company

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