TAR-200 for Bacillus Calmette-Guérin–unresponsive high-risk non–muscle-invasive bladder cancer: Results from the Phase 2b SunRISe-1 study

Daneshmand S, et al. *J Clin Oncol*. 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

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Key takeaways

Key objective:

- To evaluate the efficacy and safety of TAR-200—an intravesical gemcitabine-releasing system—in patients with BCG-unresponsive high-risk NMIBC

Knowledge generated:

- TAR-200 monotherapy provided the highest CR rate of 82.4% to date and durable responses (median DOR, 25.8 months) in BCG-unresponsive CIS and showed prolonged DFS in high-risk papillary disease–only NMIBC
- TAR-200 monotherapy was well tolerated in both CIS and papillary disease–only NMIBC cohorts

BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CR, complete response; DFS, disease-free survival; DOR, duration of response; NMIBC, non–muscle-invasive bladder cancer.

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Background

- Many patients with high-risk NMIBC experience disease recurrence (12–60%) or progression (2–15%) within 1 year[1–4] after standard of care TURBT and intravesical BCG treatment,[5–7] often leading to BCG-unresponsive disease
- The current standard of care for BCG-unresponsive high-risk NMIBC is radical cystectomy,[5–7] which is a life-changing surgery associated with considerable morbidity and significant impact on quality of life[8,9]
- Limited US FDA–approved treatment options are available to treat BCG-unresponsive high-risk NMIBC CIS (pembrolizumab, nadofaragene firadenovec, nogapendekin alfa inbakicept + BCG), however, they are associated with limited CR rates (ranging from 41 to 62%) and response durability, systemic or immune-related toxicities, reliance on BCG as combination therapy, and limited physician adoption[10–16]
- **TAR-200 is a novel intravesical drug releasing system designed to provide sustained delivery of gemcitabine in the bladder**

BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CR, complete response; FDA, United States Food and Drug Administration; NMIBC, non–muscle-invasive bladder cancer; TURBT, transurethral resection of bladder tumor.
See Notes section for references.
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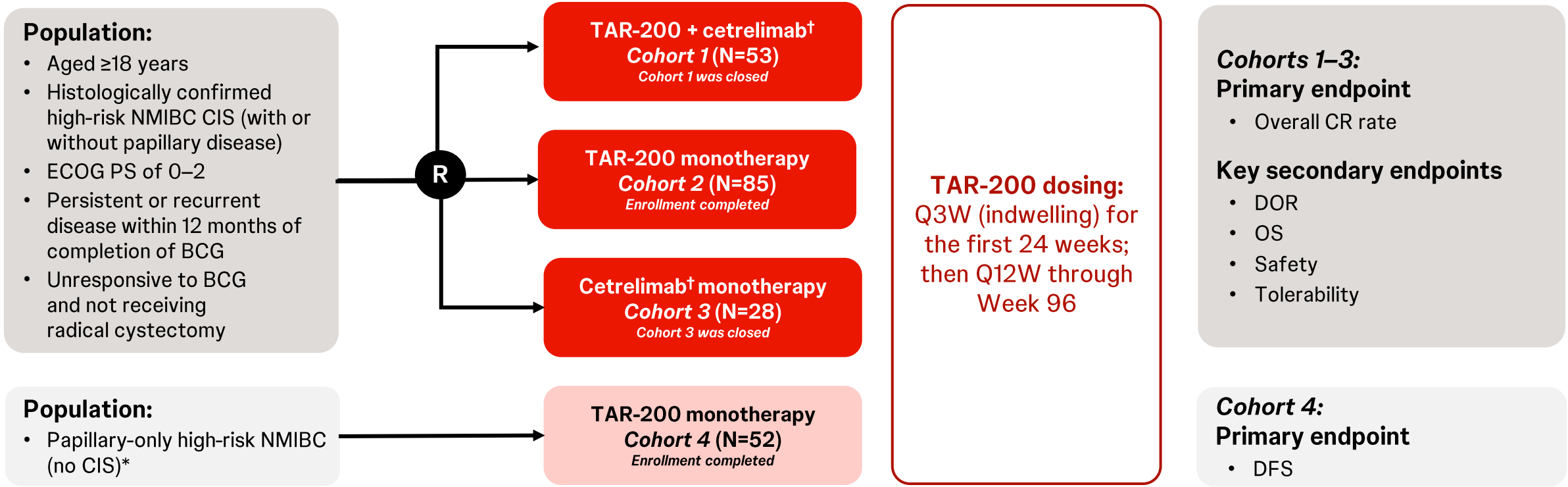
SunRISe-1 study design

Figure S1: Phase 2b parallel-cohort study evaluating TAR-200 monotherapy and in combination with cetrelimab in patients with BCG-unresponsive high-risk NMIBC

Clinical data cutoff: March 31, 2025



*Patients with BCG-unresponsive papillary disease-only high-risk NMIBC (high-grade Ta, any T1) per protocol amendment 4. †Cetrelimab is an anti-programmed cell death protein 1 agent; cetrelimab dosing was 360 mg intravenously Q3W through Month 18.

BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CR, complete response; DFS, disease-free survival; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; NMIBC; non–muscle-invasive bladder cancer; OS, overall survival; Q3W, every 3 weeks; Q12W, every 12 weeks; R, randomization.

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Cohort 2

TAR-200 monotherapy in patients with CIS ± papillary disease

Cohort 2: Baseline characteristics

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 1

Characteristic	TAR-200 monotherapy (N=85)*
Age, years, median (range)	71.0 (40–88)
Sex, n (%)	
Male	68 (80.0)
Female	17 (20.0)
Race, n (%)	
White	74 (87.1)
Asian	8 (9.4)
Black or African American	2 (2.4)
Not reported/unknown	1 (1.2)
Geographic region, n (%)†	
America	23 (27.1)
Asia Pacific	10 (11.8)
EMEA	52 (61.2)
Nicotine use, n (%)	
Current	7 (8.2)
Former	50 (58.8)
Never	28 (32.9)
ECOG PS, n (%)	
0	78 (91.8)
1	7 (8.2)
2	0

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of TAR-200 monotherapy in CIS with or without papillary disease cohort (N=85).
†America includes Canada, USA; Asia Pacific includes Australia, Japan, South Korea; EMEA includes Belgium, France, Germany, Greece, Italy, Netherlands, Portugal, Russia, Spain.
CIS, carcinoma *in situ*; ECOG PS, Eastern Cooperative Oncology Group performance status; EMEA, Europe, Middle East, and Africa.
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Cohort 2: Baseline characteristics (cont'd)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 1 (cont'd)

Characteristic	TAR-200 monotherapy (N=85)*
Tumor stage, n (%)	
CIS only	**57 (67.1)**
CIS + papillary disease	**28 (32.9)**
CIS + Ta	19 (22.4)
CIS + T1	9 (10.6)
PD-L1 status 1, n (%)†	
CPS ≥10	12 (32.4)
CPS ≤10	25 (67.6)
PD-L1 status 2, n (%)†	
CPS ≥1	23 (62.2)
CPS ≤1	14 (37.8)
No. of total doses of prior BCG, median (range)	**12 (7–42)**
Time from last BCG to CIS diagnosis, months, median (range)	**3.2 (0.1–21.7)‡**
Reason for not undergoing radical cystectomy, n (%)	
Declined	**82 (96.5)**
Preservation of bladder	50 (58.8)
Preservation of sexual function	1 (1.2)
Concern about quality of life after procedure	29 (34.1)
Concern about mortality and morbidity risk of procedure	2 (2.4)
Ineligible	**3 (3.5)**
Age	1 (1.2)
Medical and surgical comorbidities	2 (2.4)

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of TAR-200 monotherapy in CIS with or without papillary disease cohort (N=85). †Percentages are based on the number of patients with available data (n=37). ‡Two 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).
BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CPS, combined positive status; PD-L1, programmed death-ligand 1.
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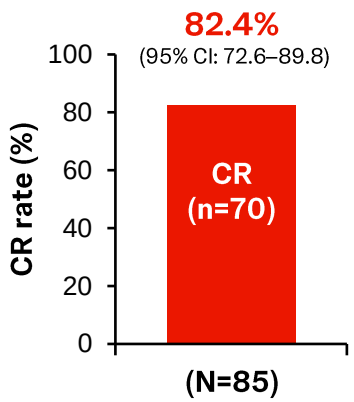
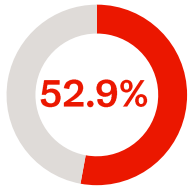
Cohort 2: Efficacy outcomes (CR rate and DOR)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 2

Overall CR rate*



Observed 12-month DOR rate



(37/70)

	TAR-200 monotherapy (N=85)
Overall CR rate, % (95% CI)*	
Centrally-assessed CR rate	**82.4 (72.6–89.8) [n=70]**
CR rate†	
3-month CR rate	78.8 (68.6–86.9)
6-month CR rate	58.8 (47.6–69.4)
12-month CR rate	45.9 (35.0–57.0)
DOR	
DOR of ≥12 months, n (%)	37 (52.9)
12-month DOR rate, % (95% CI)†	56.2 (43.4–67.1)
DOR, months, median (95% CI)†	25.8 (8.3–NE)
Follow-up in responders, months, median (range)	20.2 (5–48)
Patients with ongoing response, % (n/N)*	47.1 (33/70)‡

TAR-200 monotherapy provided a high overall CR rate (82.4%) in patients with high-risk NMIBC with CIS with or without papillary disease, and responses were durable, with a median DOR of 25.8 months and 52.9% of these patients having a DOR ≥12 months

*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 timepoint. †Kaplan–Meier estimates. ‡Thirty-seven of 70 responders (52.9%) were censored, including four (5.7%) who discontinued the study, started subsequent therapy, or missed ≥2 consecutive assessments. Thirty-three (47.1%) patients had an ongoing response with no event at clinical cutoff.

CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; DOR, duration of response; NE, not estimable; NMIBC, non–muscle-invasive bladder cancer.

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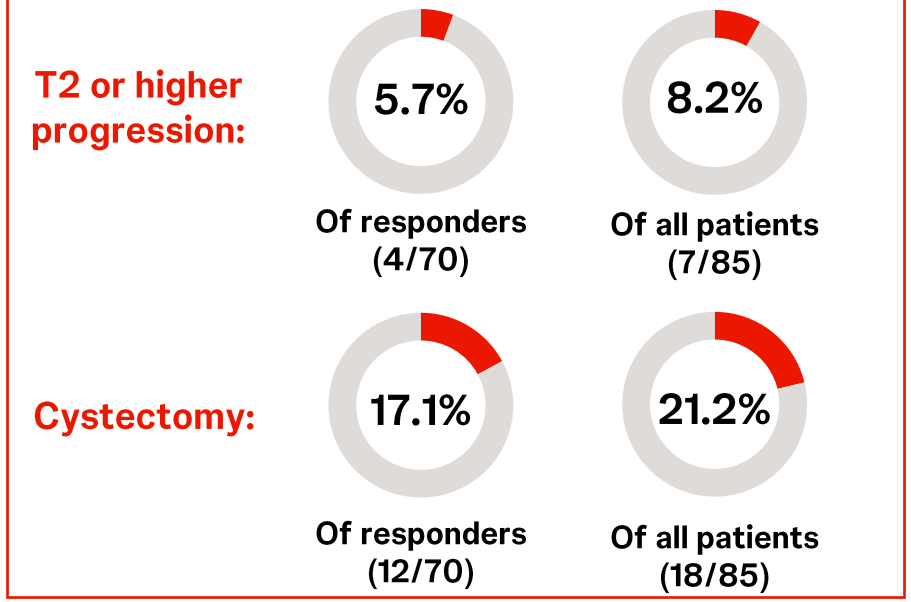
Cohort 2: Efficacy outcomes (disease persistence, recurrence, progression)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 2 (cont'd)

Rates of progression and cystectomy in Cohort 2 (N=85)



	Responders (n=70)	TAR-200 monotherapy (N=85)
Patients with disease persistence (non-responders only), recurrence, or progression, n (%)*	**30 (42.9)**	**41 (48.2)**
High-risk NMIBC†	**23 (32.9)**	**30 (35.2)**
Positive cytology only	1 (1.4)	2 (2.4)
CIS and/or Ta only	18 (25.7)	23 (27.1)
T1 (with or without CIS)	4 (5.7)	5 (5.9)
T2 or higher progression	**4 (5.7)**	**7 (8.2)**
T2–T4a	2 (2.9)	5 (5.9)
N1	1 (1.4)	1 (1.2)
M1a	1 (1.4)	1 (1.2)
No evidence of disease‡	**3 (4.3)**	**4 (4.7)**
Patients who underwent cystectomy, n (%)	**12 (17.1)**	**18 (21.2)**

Overall, patients with high-risk NMIBC with CIS with or without papillary disease receiving TAR-200 monotherapy had a low risk of progression (8.2%) and a low rate of radical cystectomy (21.2%)

*Disease persistence, recurrence, or progression event was based on positive central cytology, high-grade central pathology, or positive imaging. All results based on highest stage from local TURBT results, investigator-assessed clinical stage, and pathologic stage after cystectomy. Patients who discontinued study before disease evaluation are excluded. Note, upper tract urothelial carcinoma incident after treatment initiation was not included in assessment of CR; one case was reported in Cohort 2. †Includes patients with high-grade Ta, CIS, or T1 or patients with positive central cytology (n=5) or high-risk NMIBC from central pathology (n=2), but no evidence of high-risk NMIBC by investigator. Note, no cases of low-grade Ta recurrence were reported in Cohort 2. ‡Patients had positive central cytology or high-grade disease by central pathology, but no disease based on local assessment.
CIS, carcinoma *in situ*; CR, complete response; NMIBC, non–muscle-invasive bladder cancer; TURBT, transurethral resection of bladder tumor.
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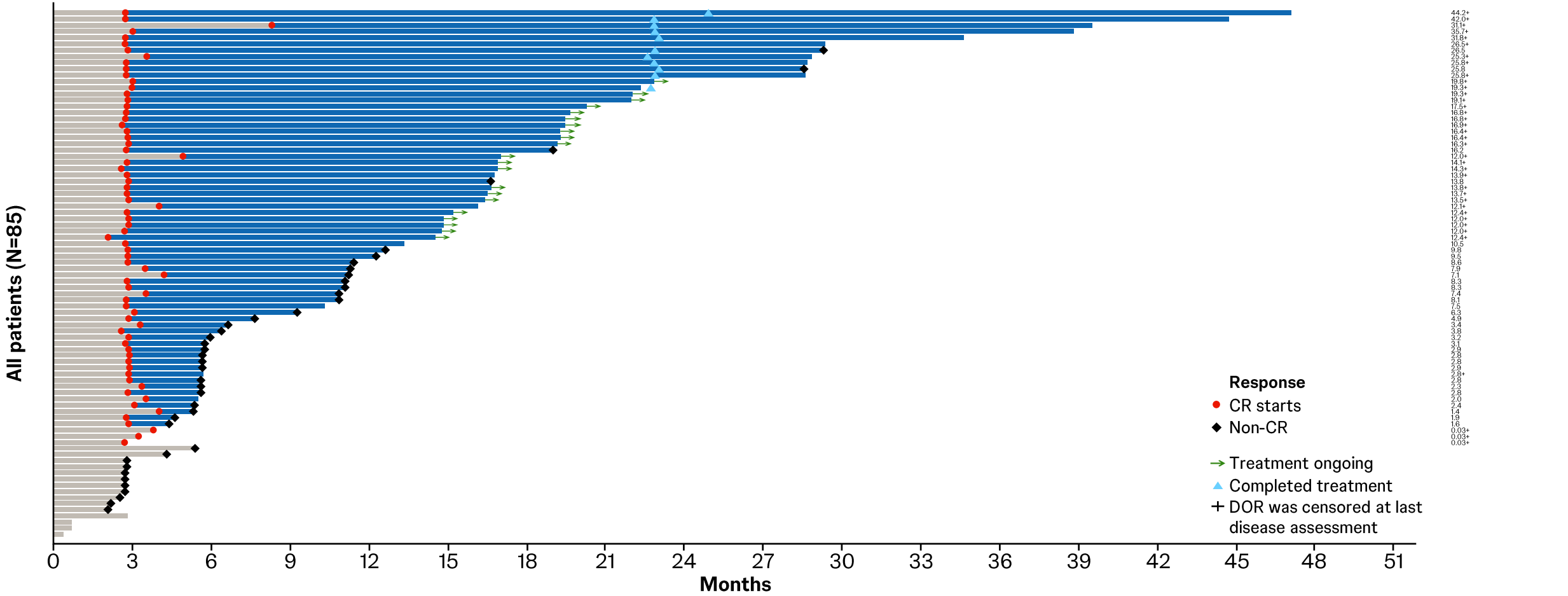
Cohort 2: Efficacy outcomes (durability of responses)

TAR-200 monotherapy in patients with CIS ± papillary disease: Figure 2A

Time to CR on non-CR in all patients (N=85), with DOR in individual responders (N=70)

Thirty-seven responders remained in CR at clinical cutoff, with 11 completing 2 years of treatment



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CIS, carcinoma *in situ*; CR, complete response; DOR, duration of response.

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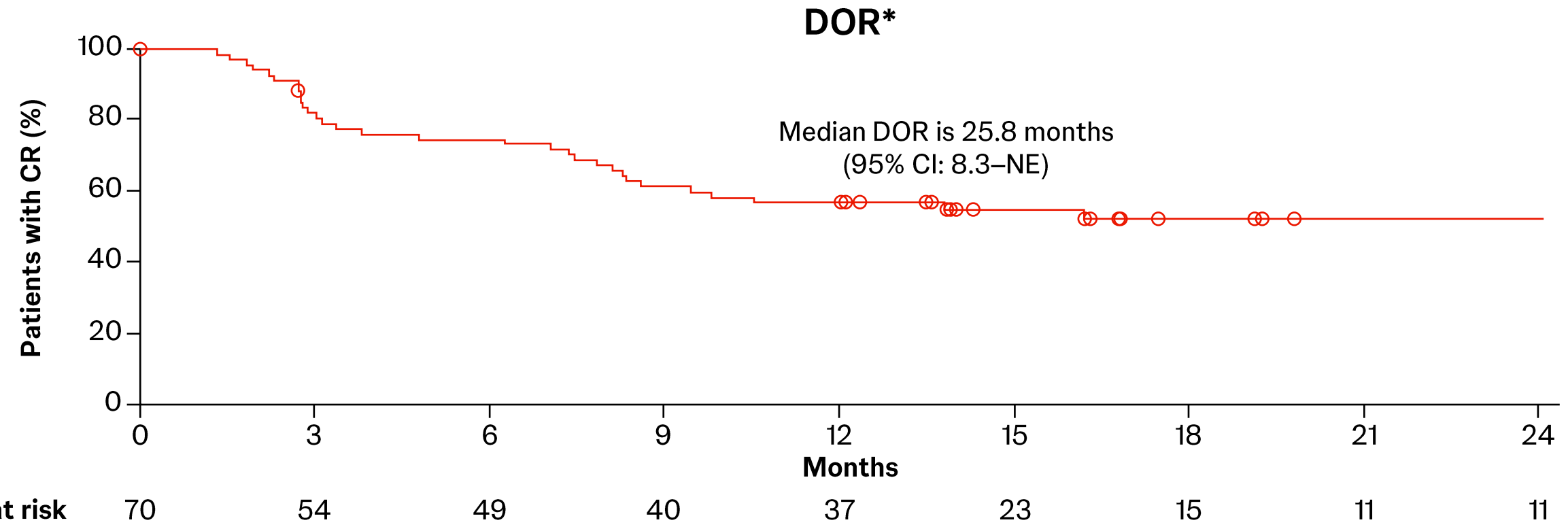
Cohort 2: Efficacy outcomes (durability of responses, cont'd)

TAR-200 monotherapy in patients with CIS ± papillary disease: Figure 2B



After a median follow-up in responders of 20.2 months, median DOR was 25.8 months. Among 70 responders, 37 (52.9%) had a DOR of ≥12 months

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*Timepoints with fewer than 10 patients at risk are excluded from the plot. DOR is a Kaplan–Meier estimate

CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; DOR, duration of response; NE, not estimable.

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Cohort 2: Efficacy outcomes (CR rate by subgroup)

TAR-200 monotherapy in patients with CIS ± papillary disease: Figure S2

	CR rate	(95% CI)
Overall	**70/85 (82.4%)**	(72.6–89.8)
Age group		
<65	**21/24 (87.5%)**	(67.6–97.3)
65 to <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		
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)
ECOG baseline		
0	**64/78 (82.1%)**	(71.7–89.8)
≥1	**6/7 (85.7%)**	(42.1–99.6)

CR rate with TAR-200 monotherapy was consistent across subgroups, including by age, presence of papillary disease, and PD-L1 status

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BCG, Bacillus Calmette-Guérin; CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; ECOG, Eastern Cooperative Oncology Group; EMEA, Europe, Middle East, and Africa; PD-L1, programmed death-ligand 1.

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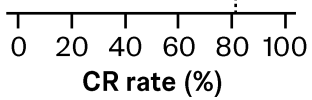
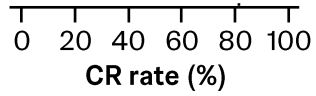
Cohort 2: Efficacy outcomes (CR rate by subgroup, cont'd)

TAR-200 monotherapy in patients with CIS ± papillary disease: Figure S2, cont'd

	CR rate	(95% CI)
Nicotine use		
Current/former	**48/57 (84.2%)**	(72.1–92.5)
Never	**22/28 (78.6%)**	(59.0–91.7)
PD-L1 status 1		
CPS <10 (negative)	**20/25 (80.0%)**	(59.3–93.2)
CPS ≥10 (positive)	**11/12 (91.7%)**	(61.5–99.8)
PD-L1 status 2		
CPS <1 (negative)	**13/14 (92.9%)**	(66.1–99.8)
CPS ≥1 (positive)	**18/23 (78.3%)**	(56.3–92.5)



	CR rate	(95% CI)
Reason for not receiving RC at screening		
Ineligible	**2/3 (66.7%)**	(9.4–99.2)
Elected not to undergo RC	**68/82 (82.9%)**	(73.0–90.3)
Prior intravesical BCG doses		
7–9	**23/25 (92.0%)**	(74.0–99.0)
10–14	**22/30 (73.3%)**	(54.1–87.7)
>14	**25/30 (83.3%)**	(65.3–94.4)
BCG strain		
TICE	**51/58 (87.9%)**	(76.7–95.0)
Non-TICE	**19/27 (70.4%)**	(49.8–86.2)



CR rate with TAR-200 monotherapy was consistent across subgroups, including by age, presence of papillary disease, and PD-L1 status

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BCG, Bacillus Calmette-Guérin; CI, confidence interval; CIS, carcinoma *in situ*; CPS, combined positive score; CR, complete response; PD-L1, programmed death-ligand 1; RC, radical cystectomy.

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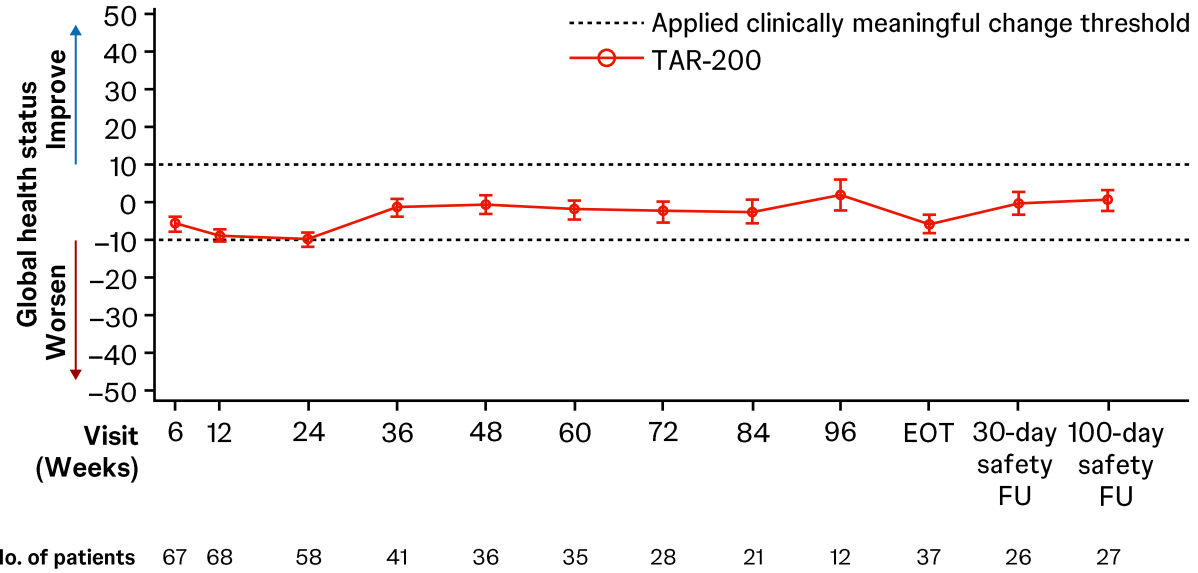
Cohort 2: Efficacy outcomes (EORTC QLQ-C30 PRO scores)

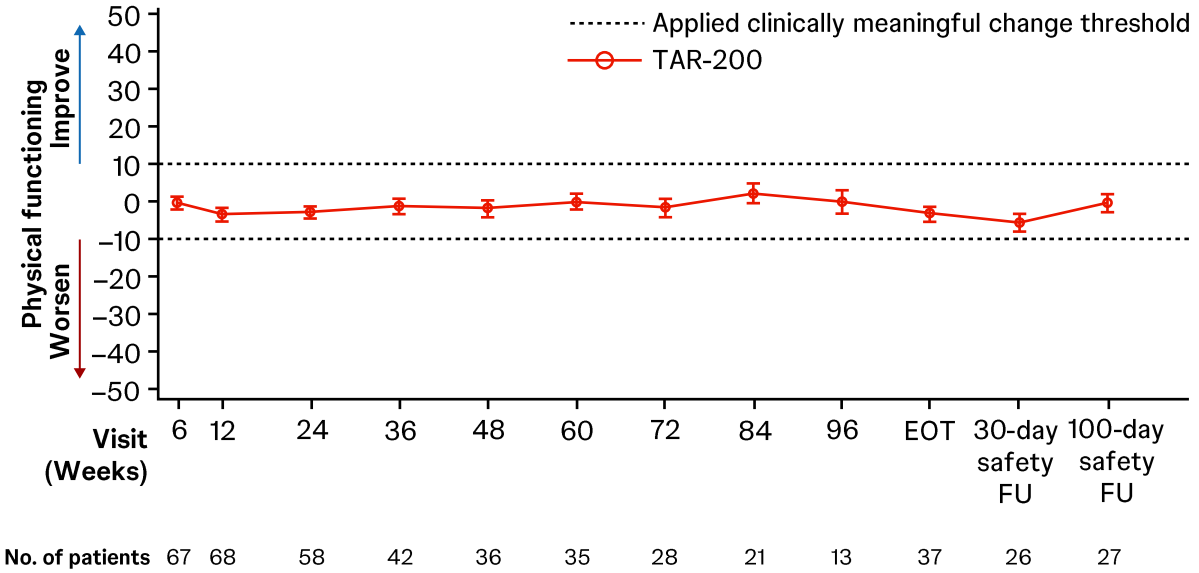
TAR-200 monotherapy in patients with CIS ± papillary disease: Figure S3

Global health status



No. of patients	67	68	58	41	36	35	28	21	12	37	26	27

Physical functioning over time*



No. of patients	67	68	58	42	36	35	28	21	13	37	26	27

Mean global health status and physical functioning scores were high at baseline and were maintained during treatment in patients with high-risk NMIBC with CIS with or without papillary disease treated with TAR-200 monotherapy†

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*Patients who had a baseline measurement and at least one post-baseline value were included in the analysis. Least squares means were derived based on the mixed-effects model with repeated measures, in which the dependent variable was change from baseline in score, and independent variables were baseline patient-reported outcome score and visit as fixed effects and individual subject as random effect. Global health status and physical functioning scores range from 0 (worse) to 100 (better). †Did not exceed clinically meaningful change threshold of ≥10 points.

CIS, carcinoma *in situ*; EORTC QLQ-C30, European Organisation For Research and Treatment of Cancer Core Quality of Life Questionnaire; EOT, end of treatment; FU, follow-up; NMIBC, non–muscle-invasive bladder cancer; PRO, patient-reported outcome.

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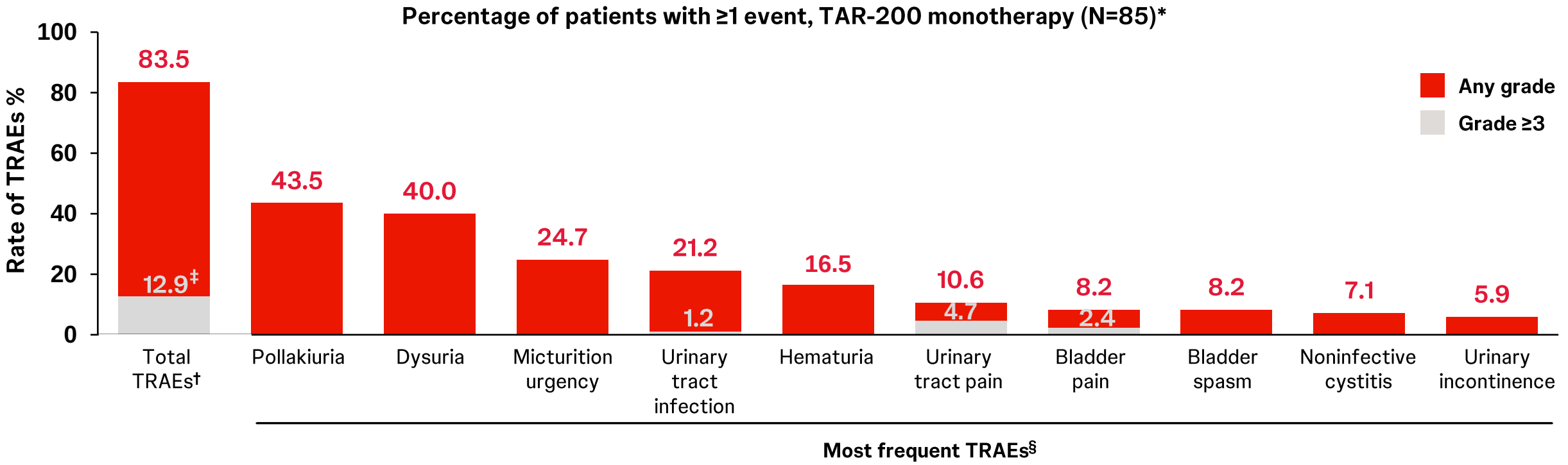
Cohort 2: Safety (TRAEs)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 3 (any grade AEs ≥5%)



TRAEs of any grade occurred in 83.5% of Cohort 2 patients, and the most frequent were low-grade lower urinary tract events, including pollakiuria (43.5%), dysuria (40.0%), micturition urgency (24.7%), and urinary tract infection (21.2%)

*Safety data are shown for all patients who received at least one 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 is 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. ‡In addition to the Grade ≥3 TRAEs shown by preferred term in the graph, all other Grade ≥3 TRAEs were reported in only one patient each and included acute kidney injury, pseudomonal cystitis, and urosepsis. Note, patients may have had one or more Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥2% of patients in the TAR-200 monotherapy in CIS with or without papillary disease cohort.
AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.
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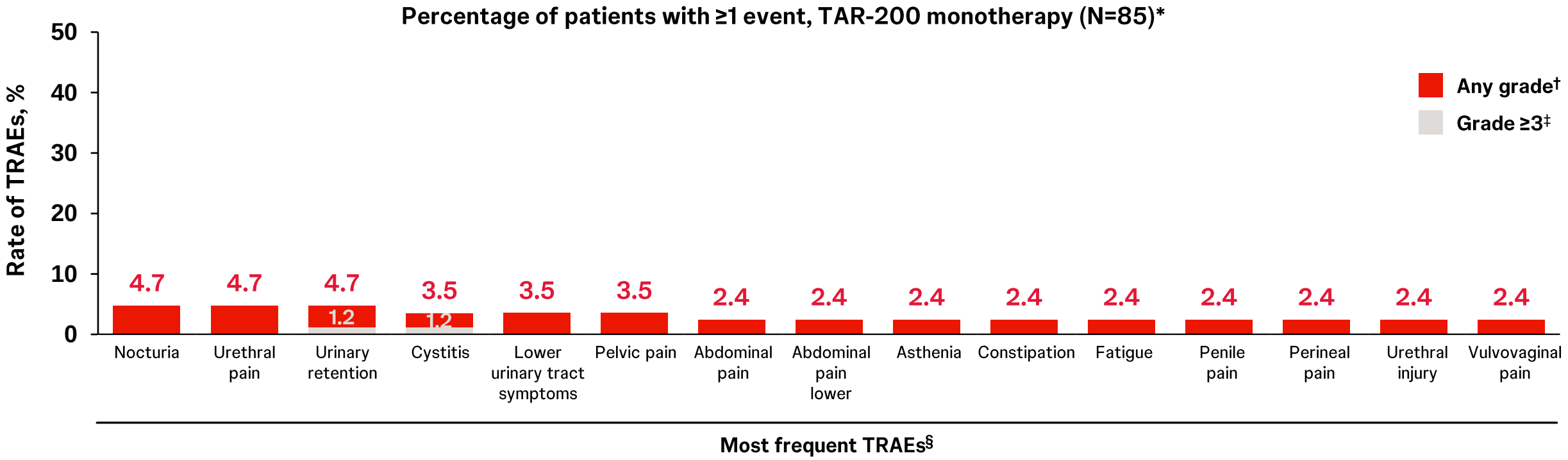
Cohort 2: Safety (TRAEs), cont'd

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 3, cont'd (any grade AEs <5%)



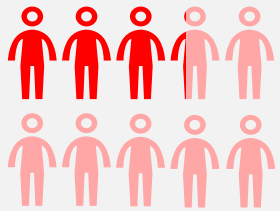
TRAEs of any grade occurred in 83.5% of Cohort 2 patients, and the most frequent were low-grade lower urinary tract events, including pollakiuria (43.5%), dysuria (40.0%), micturition urgency (24.7%), and urinary tract infection (21.2%)

*Safety data are shown for all patients who received at least one 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 is 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. ‡In addition to the Grade ≥3 TRAEs shown by preferred term in the graph, all other Grade ≥3 TRAEs were reported in only one patient each and included acute kidney injury, pseudomonal cystitis, and urosepsis. Patients may have had one or more Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥2% of patients in the TAR-200 monotherapy in CIS with or without papillary disease cohort.
AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 2: Safety (TAR-200 interruption and discontinuation rates)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table 3

TRAEs leading to TAR-200 interruption:*,†,‡,§



31.8%
(27 patients)

Most **interruptions** were limited to **one to two doses**, and most patients resumed treatment

Most frequent TRAEs leading to interruption:

- **5.9%** Urinary tract pain (n=5)
- **4.7%** Hematuria (n=4)
- **4.7%** Pollakiuria (n=4)

TRAEs leading to TAR-200 discontinuation:*,†,¶

3.5%
(3 patients)

- **2.4%** Noninfective Cystitis (n=2)
- **1.2%** Pollakiuria and urinary tract disorder (n=1)

TRAEs leading to TAR-200 interruption occurred in 27 patients (31.8%), with urinary tract pain (5.9%), hematuria (4.7%), and pollakiuria (4.7%) being the most frequent. TRAEs leading to TAR-200 discontinuation occurred in three patients (3.5%)

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ‡Number of patients who experienced AEs related to TAR-200, insertion procedure, removal procedure, or urinary placement catheter that led to interruption of TAR-200. §TAR-200 interruption is defined as when a TAR-200 dose is skipped or TAR-200 is removed early. ¶Number of patients who experienced AEs related to TAR-200, insertion procedure, removal procedure, or urinary placement catheter that led to discontinuation of TAR-200.

AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 2: Safety (additional safety information)

TAR-200 monotherapy in patients with CIS ± papillary disease: Table S3 (cont'd)

Patients with event, n (%)*	TAR-200 monotherapy (N=85)		
	Any grade	Grade ≥3	Serious
Related AEs†	**71 (83.5)**	**11 (12.9)**	**5 (5.9)‡**
TAR-200	63 (74.1)	9 (10.6)	3 (3.5)
Insertion procedure	30 (35.3)	1 (1.2)	1 (1.2)
Removal procedure	14 (16.5)	0	0
Urinary placement catheter	19 (22.4)	1 (1.2)	1 (1.2)

Rates of Grade ≥3 TRAEs and serious TRAEs were 12.9% and 5.9%, respectively, in patients with high-risk NMIBC with CIS with or without papillary disease receiving TAR-200 monotherapy

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ‡Serious TRAEs included acute kidney injury, bladder pain, cystitis, pseudomonal cystitis, urinary tract infection, urinary tract pain, and urosepsis in one patient each. Note, patients may have had ≥1 serious TRAE.

AE, adverse event; CIS, carcinoma *in situ*; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4

TAR-200 monotherapy in patients with papillary disease only NMIBC

Cohort 4: Baseline characteristics

TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S4

Characteristic	TAR-200 monotherapy (N=52)*
Age, years, median (range)	**71.0 (42–88)**
Sex, n (%)	
Male	37 (71.2)
Female	15 (28.8)
Race, n (%)	
White	45 (86.5)
Asian	6 (11.5)
Black or African American	1 (1.9)
Geographic region, n (%)†	
America	18 (34,6)
Asia Pacific	5 (9.6)
EMEA	29 (55.8)
Nicotine use, n (%)	
Current	7 (13.5)
Former	29 (55.8)
Never	16 (30.8)
ECOG PS, n (%)	
0	49 (94.2)
1	2 (3.8)
2	1 (1.9)

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of TAR-200 monotherapy in papillary-disease only cohort (N=52). †America includes Canada, USA; Asia Pacific includes Australia, Japan, South Korea; EMEA includes Belgium, France, Germany, Greece, Italy, Netherlands, Portugal, Russia, Spain.
ECOG PS, Eastern Cooperative Oncology Group performance status; EMEA, Europe, Middle East, and Africa; NMIBC; non–muscle-invasive bladder cancer.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Baseline characteristics (cont'd)

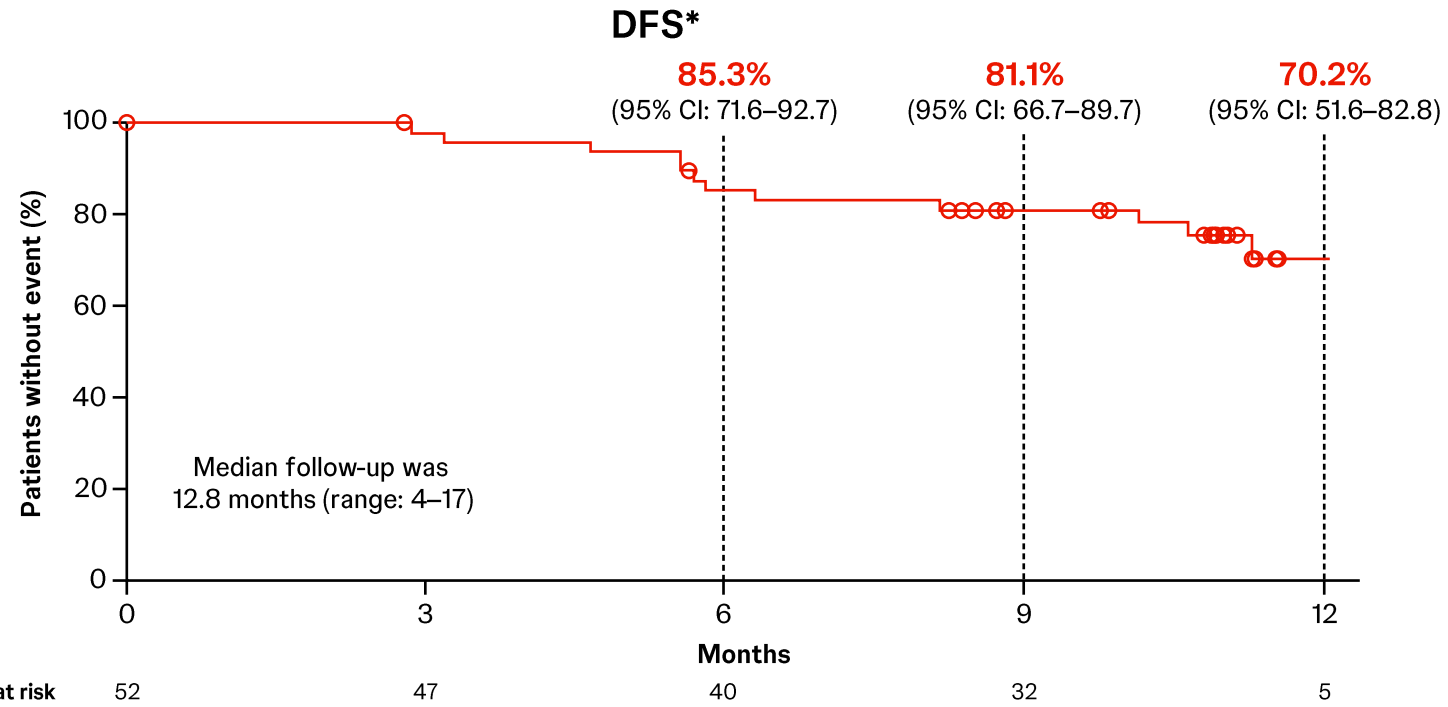
TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S4 (cont'd)

Characteristic	TAR-200 monotherapy (N=52)*
Tumor stage, n (%)	
Papillary disease	**52 (100.0)**
Higher-grade Ta	31 (59.6)
T1	21 (40.4)
Number of total doses of prior BCG, median (range)	**12 (8–45)**
Time from last BCG to diagnosis of high-grade papillary NMIBC, months, median (range)	**2.8 (0.3–9.9)**
Reason for not undergoing radical cystectomy, n (%)†	
Declined	**42 (82.4)**
Preservation of bladder	24 (47.1)
Preservation of sexual function	0
Concern about quality of life after procedure	17 (33.3)
Concern about mortality and morbidity risk of procedure	1 (2.0)
Ineligible	**3 (17.6)**
Age	3 (5.9)
High American Society of Anesthesiologists class score	1 (2.0)
Medical and surgical comorbidities	5 (9.8)

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of TAR-200 monotherapy in papillary-disease only cohort (N=52). †Percentages are based on number of patients with available data (n=51).
BCG, Bacillus Calmette-Guérin; NMIBC, non–muscle-invasive bladder cancer.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Efficacy outcomes (DFS and disease recurrence/progression)

TAR-200 monotherapy in patients with papillary disease only NMIBC: Figure 3



- The median DFS was not estimable

Twelve-month DFS rates were consistent in patients with high-grade Ta and T1 disease

High-grade Ta
(95% CI: 44.8–85.4)

70.0%

T1
(95% CI: 44.8–87.6)

72.2%

Of 52 patients

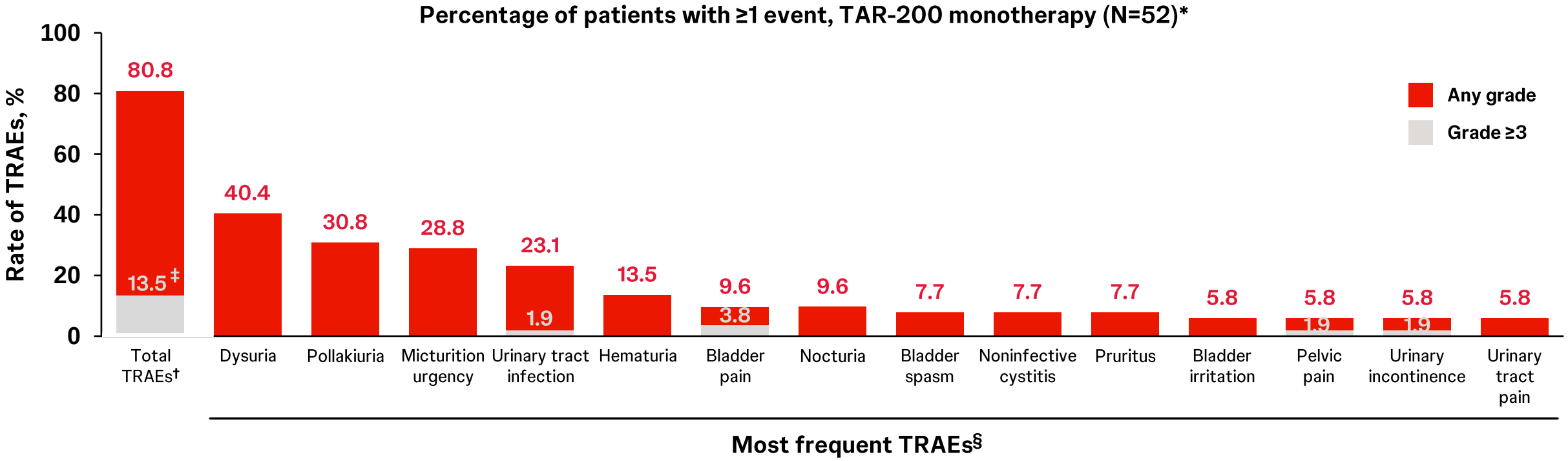
- **11 (21.2%)** had NMIBC recurrence or progression
- **Two (3.8%)** died (unrelated to treatment)

TAR-200 provided a high DFS rate in high-risk papillary disease-only NMIBC (12-month DFS rate 70.2%)
DFS rates were consistent in patients with high-grade Ta and T1 disease

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.
*Timepoints with fewer than five patients at risk are excluded from the plot.
CI, confidence interval; DFS, disease-free survival; NMIBC, non–muscle-invasive bladder cancer.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Safety (TRAEs)

TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S5 (any grade AEs ≥5%)



TRAEs of any grade occurred in 80.8% of Cohort 4 patients and were mostly low-grade lower urinary tract events including dysuria (40.4%), pollakiuria (30.8%), micturition urgency (28.8%), and urinary tract infection (23.1%)

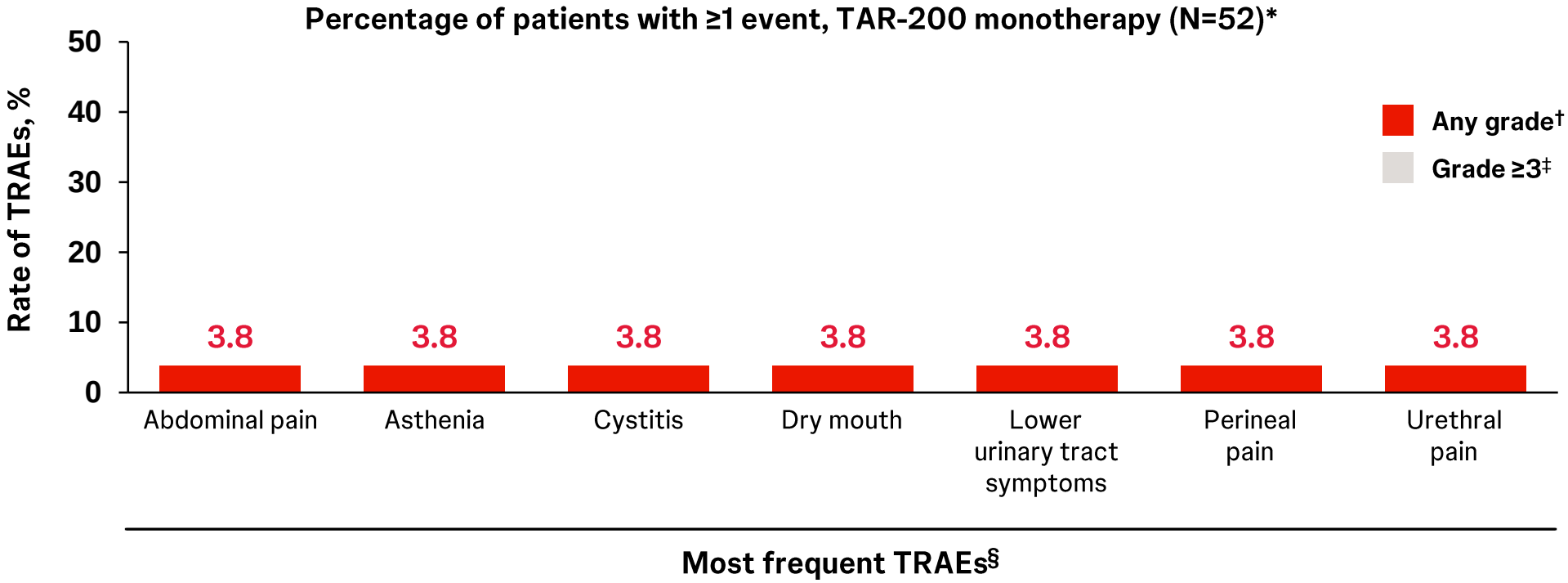
*Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort (N 52). †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal 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. ‡TRAEs of Grade ≥3 by preferred term are listed if they were reported in ≥2 patients in the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort. All other TRAEs of Grade ≥3 by preferred term for TAR-200 monotherapy were reported in only one patient each and included sepsis and spinal fracture (procedure related). Note, patients may have had ≥1 Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥2% of patients in the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort.

AE, adverse event; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Safety (TRAEs), cont'd

TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S5, cont'd (any grade AEs <5%)



- **Serious TRAEs** occurred in three patients **(5.8%)**, including sepsis, spinal fracture (procedure related), and urinary tract infection in one patient each

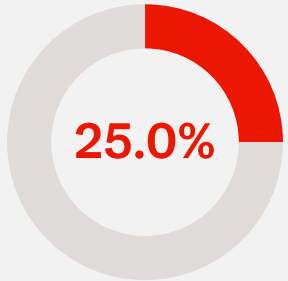
TRAEs of any grade occurred in 80.8% of Cohort 4 patients and were mostly low-grade lower urinary tract events including dysuria (40.4%), pollakiuria (30.8%), micturition urgency (28.8%), and urinary tract infection (23.1%)

*Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort (N 52). †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal 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. ‡TRAEs of Grade ≥3 by preferred term are listed if they were reported in ≥2 patients in the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort. All other TRAEs of Grade ≥3 by preferred term for TAR-200 monotherapy were reported in only one patient each and included sepsis and spinal fracture (procedure related). Note, patients may have had ≥1 Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥2% of patients in the TAR-200 monotherapy in high-risk papillary disease-only NMIBC cohort.
AE, adverse event; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Safety (TAR-200 interruption and discontinuation rates)

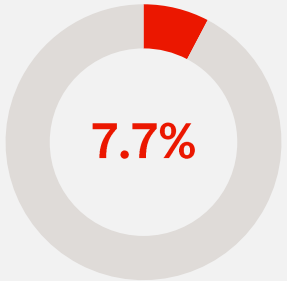
TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S5

TRAEs leading to TAR-200 interruption*,†,‡



13 patients

TRAEs leading to TAR-200 discontinuation*,†,§



4 patients

Most frequent TRAEs leading to TAR-200 discontinuation were:

Micturition urgency:
4 patients (7.7%)

Dysuria:
2 patients (3.8%)

Pollakiuria:
2 patients (3.8%)

In patients with high-risk papillary disease-only NMIBC treated with TAR-200 monotherapy, TRAEs leading to TAR-200 interruption occurred in 13 patients (25.0%) and TRAEs leading to TAR-200 discontinuation occurred in four patients (7.7%)

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ‡Number of patients who experienced AEs related to TAR-200, insertion procedure, removal procedure, or urinary placement catheter that led to interruption of TAR-200. §Number of patients who experienced AEs related to TAR-200, insertion procedure, removal procedure, or urinary placement catheter that led to discontinuation of TAR-200.
AE, adverse event; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 4: Safety (additional safety information)

TAR-200 monotherapy in patients with papillary disease only NMIBC: Table S5

Patients with ≥1 event, n (%)*	TAR-200 monotherapy (N=52)		
	Any grade	Grade ≥3	Serious
Related AEs†	**42 (80.8)**	**7 (13.5)**	**3 (5.8)‡**
TAR-200	38 (73.1)	5 (9.6)	1 (1.9)
Insertion procedure	19 (36.5)	4 (7.7)	3 (5.8)
Removal procedure	14 (26.9)	1 (1.9)	1 (1.9)
Urinary placement catheter	22 (42.3)	1 (1.9)	1 (1.9)

Rates of Grade ≥3 TRAEs and serious TRAEs were 13.5% and 5.8%, respectively, in patients with high-risk papillary disease-only NMIBC treated with TAR-200 monotherapy

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ‡Serious TRAEs included sepsis, spinal fracture, and urinary tract infection in one patient each.
AE, adverse event; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 1

TAR-200 + cetrelimab in patients with CIS ± papillary disease

Cohort 1: Baseline characteristics

TAR-200 + cetrelimab in patients with CIS ± papillary disease: Table S6

Characteristic	TAR-200 + cetrelimab (N=53)*
Age, years, median (range)†	**74.0 (45–85)**
Sex, n (%)†	
Male	46 (83.6)
Female	9 (16.4)
Race, n (%)†	
White	45 (81.8)
Asian	7 (12.7)
Black or African American	1 (1.8)
Not reported/unknown	2 (3.6)
Geographic region, n (%)†,‡	
America	12 (21.8)
Asia Pacific	7 (12.7)
EMEA	36 (65.5)
Nicotine use, n (%)†	
Current	7 (12.7)
Former	24 (43.6)
Never	24 (43.6)
ECOG PS, n (%)	
0	46 (86.8)
1	6 (11.3)
2	1 (1.9)

Characteristic	TAR-200 + cetrelimab (N=53)*
Tumor stage, n (%)	
CIS only	**39 (73.6)**
CIS + papillary disease	**14 (26.4)**
CIS + Ta	10 (18.9)
CIS + T1	4 (7.5)
PD-L1 status 1, n (%)§	
CPS ≥10	2 (6.5)
CPS ≤10	29 (93.5)
PD-L1 status 2, n (%)§	
CPS ≥1	10 (32.3)
CPS ≤1	21 (67.7)
No. of total doses of prior BCG, median (range)	**12 (7–35)**
Time from last BCG to CIS diagnosis, months, median (range)	**3.5 (0.3–11.5)**
Reason for not undergoing radical cystectomy, n (%)	
Declined	**51 (96.2)**
Preservation of bladder	30 (56.6)
Preservation of sexual function	0
Concern about quality of life after procedure	20 (37.7)
Concern about mortality and morbidity risk of procedure	1 (1.9)
Ineligible	**2 (3.8)**
Age	1 (1.9)
Medical and surgical comorbidities	1 (1.9)

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of the TAR-200 + cetrelimab cohort (N=53), except where noted. †Patient characteristics of age, sex, race, geographic region, and nicotine use are shown for the enrolled analysis set in the TAR-200 + cetrelimab cohort (N=55). ‡America includes Canada, USA; Asia Pacific includes Australia, Japan, South Korea; EMEA includes Belgium, France, Germany, Greece, Italy, Netherlands, Portugal, Russia, Spain. §Percentages are based on number of patients with available data (n=31).
BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CPS, combined positive score; ECOG, Eastern Cooperative Oncology Group performance status; EMEA, Europe, Middle East, and Africa; PD-L1, programmed death-ligand 1.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

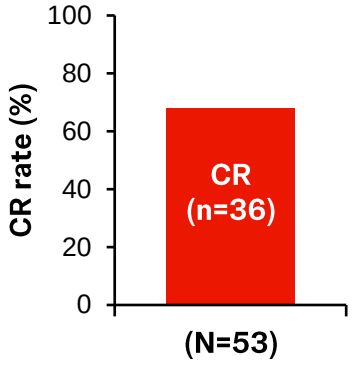
Cohort 1: Efficacy outcomes (CR rate, DOR and OS rate)

TAR-200 + cetrelimab in patients with CIS ± papillary disease

Overall CR rate, %

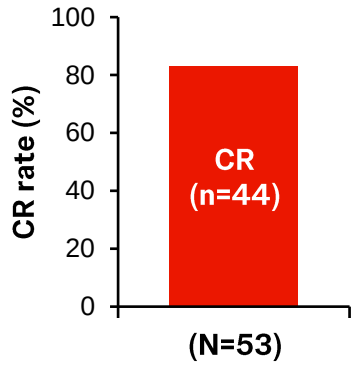
Centrally-assessed*

67.9%
(95% CI: 53.7–80.1)



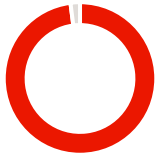
Investigator-assessed

83.0%
(95% CI: 70.2–91.9)



Overall OS rate

98.0%



12-month OS rate†
(95% CI: 86.6–99.7)

TAR-200 + cetrelimab responders (n=36)

After a median follow-up in responders of **33.4 months** (range: 10–47):

76.3%
12-month DOR rate
(95% CI: 58.1–87.4)

55.6%
Patients remained in CR
(n=20)

- Median DOR was not estimable

TAR-200 + cetrelimab demonstrated a CR rate of 67.9% in patients with high-risk NMIBC with CIS with or without papillary disease

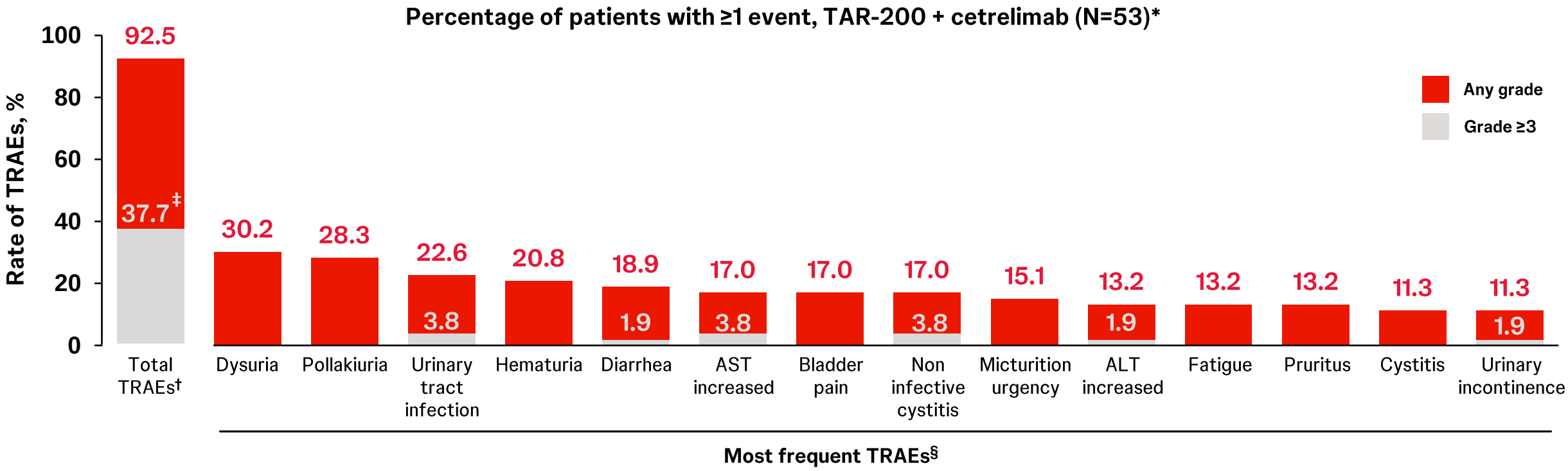
*Response is based on centrally reviewed urine cytology, local cystoscopy, and central biopsy (if available). A CR is defined as having a negative cystoscopy and negative (including atypical) centrally read urine cytology, or positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative (including atypical) centrally read cytology at any timepoint. †Two deaths occurred in follow-up (both due to progressive disease unrelated to treatment.

CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; DOR, duration of response; OS, overall survival.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 1: Safety (TRAEs)

TAR-200 + cetrelimab in patients with CIS ± papillary disease: Table S7 (any grade AEs ≥10%)



In patients with high-risk NMIBC with CIS with or without papillary disease treated with TAR-200 + cetrelimab, rates of any grade TRAEs and Grade ≥3 TRAEs were 92.5% and 37.7%, respectively

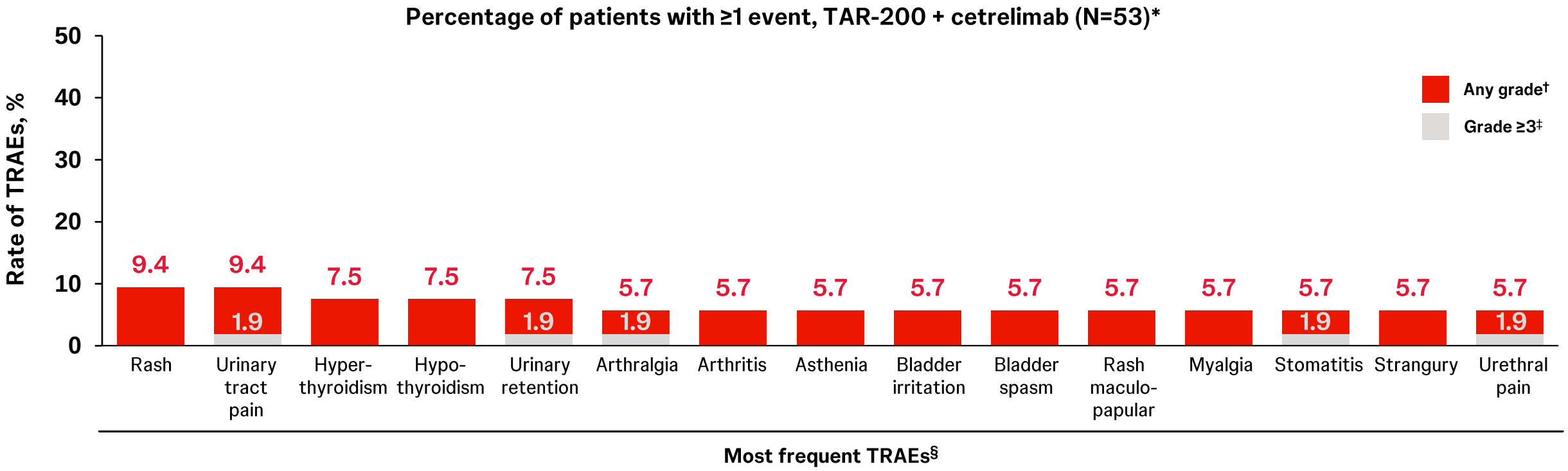
*Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 + cetrelimab cohort (N=53). †Two patients were assigned to receive TAR-200 and cetrelimab but only received cetrelimab. ‡TRAEs of Grade ≥3 by preferred term are listed if they were reported in ≥2 patients in the TAR-200 + cetrelimab cohort. All other TRAEs of Grade ≥3 by preferred term for TAR-200 + cetrelimab were reported in only one patient each and included dermatitis, device difficult to use, device occlusion, gamma-glutamyl transferase increased, hepatitis, hypoglycemia, hyponatremia, hypophysitis, immune-mediated hepatitis, lipase increased, pelvic pain, procedural pain, sepsis, suprapubic pain, urosepsis and vomiting. Note, patients may have had ≥1 Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥5% of patients in the TAR-200 + cetrelimab cohort.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 1: Safety (TRAEs)

TAR-200 + cetrelimab in patients with CIS ± papillary disease: Table S7, cont'd (any grade AEs <10%)



In patients with high-risk NMIBC with CIS with or without papillary disease treated with TAR-200 + cetrelimab, rates of any grade TRAEs and Grade ≥3 TRAEs were 92.5% and 37.7%, respectively

*Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 + cetrelimab cohort (N=53). †Two patients were assigned to receive TAR-200 and cetrelimab but only received cetrelimab. ‡TRAEs of Grade ≥3 by preferred term are listed if they were reported in ≥2 patients in the TAR-200 + cetrelimab cohort. All other TRAEs of Grade ≥3 by preferred term for TAR-200 + cetrelimab were reported in only one patient each and included dermatitis, device difficult to use, device occlusion, gamma-glutamyl transferase increased, hepatitis, hypoglycemia, hyponatremia, hypophysitis, immune-mediated hepatitis, lipase increased, pelvic pain, procedural pain, sepsis, suprapubic pain, urosepsis and vomiting. Note, patients may have had ≥1 Grade ≥3 TRAE. §TRAEs of any grade by preferred term are listed if they were reported in ≥5% of patients in the TAR-200 + cetrelimab cohort.

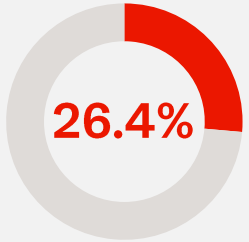
CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.

Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 1: Safety (treatment discontinuation rates)

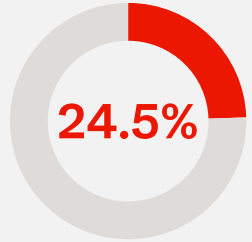
TAR-200 + cetrelimab in patients with CIS ± papillary disease: Table S7

TRAEs leading to TAR-200 discontinuation[*,†,‡,§,¶]



14 patients

TRAEs leading to cetrelimab discontinuation[*,†,‡,§,**]



13 patients

Most common TRAEs leading to discontinuation were:

Bladder pain	Pollakiuria
6 patients (11.3%)	3 patients (5.7%)

Rates of TRAEs leading to TAR-200 interruption and cetrelimab interruption were 37.7% and 20.8%, respectively.
Rates of TRAEs leading to TAR-200 discontinuation and cetrelimab discontinuation were 26.4% and 24.5%, respectively

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †Two patients were assigned to receive TAR-200 and cetrelimab but only received cetrelimab. ‡Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 + cetrelimab cohort (N=53). §An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ¶Number of patients who experienced AEs related to TAR-200, insertion procedure, removal procedure, or urinary placement catheter that led to discontinuation of TAR-200. ** Number of patients who experienced AEs related to cetrelimab that led to discontinuation of cetrelimab.

AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.

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Cohort 1: Safety (additional safety information)

TAR-200 + cetrelimab in patients with CIS ± papillary disease: Table S7 (cont'd)

Patients with ≥1 event, n (%)*	TAR-200 + cetrelimab (N=53)†,‡		
	Any grade	Grade ≥3	Serious
Related AEs§	**49 (92.5)**	**20 (37.7)**	**8 (15.1)¶**
TAR-200	42 (79.2)	9 (17.0)	4 (7.5)
Cetrelimab	34 (64.2)	11 (20.8)	5 (9.4)
Insertion procedure	15 (28.3)	5 (9.4)	2 (3.8)
Removal procedure	7 (13.2)	1 (1.9)	1 (1.9)
Urinary placement catheter	10 (18.9)	1 (1.9)	0

Rates of Grade ≥3 TRAEs and serious TRAEs were 37.7% and 15.1%, respectively, with UTI being the most common serious TRAE (3.8%)

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †Two patients were assigned to receive TAR-200 and cetrelimab but only received cetrelimab. ‡Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the TAR-200 + cetrelimab cohort (N=53). §An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. ¶Serious TRAEs included urinary tract infection in two patients, and diarrhea, device difficult to use, device occlusion, hyponatremia, hypophysitis, immune-mediated hepatitis, noninfective cystitis, sepsis, stomatitis, urosepsis, and vomiting in one patient each. Note, patients may have had ≥1 serious TRAE.

AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.

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Cohort 3

Cetrelimab monotherapy in patients with CIS ± papillary disease

Cohort 3: Baseline characteristics

Cetrelimab monotherapy in patients with CIS ± papillary disease: Table S8

Characteristic	Cetrelimab monotherapy (N=28)*
Age, years, median (range)	**69.5 (51–88)**
Sex, n (%)	
Male	21 (75.0)
Female	7 (25.0)
Race, n (%)	
White	27 (96.4)
Asian	1 (3.6)
Black or African American	0
Not reported/unknown	0
Geographic region, n (%)†	
America	10 (35.7)
Asia Pacific	1 (3.6)
EMEA	17 (60.7)
Nicotine use, n (%)	
Current	7 (25.0)
Former	13 (46.4)
Never	8 (28.6)
ECOG PS, n (%)	
0	26 (92.9)
1	2 (7.1)
2	0

Characteristic (cont'd)	Cetrelimab monotherapy (N=28)*
Tumor stage, n (%)	
CIS only	**18 (64.3)**
CIS + papillary disease	**9 (32.1)**
CIS + Ta	6 (21.4)
CIS + T1	3 (10.7)
T1	**1 (3.6)**
PD-L1 status 1, n (%)‡	
CPS ≥10	4 (23.5)
CPS ≤10	13 (76.5)
PD-L1 status 2, n (%)‡	
CPS ≥1	6 (35.3)
CPS ≤1	11 (64.7)
No. of total doses of prior BCG, median (range)	**12 (7–30)**
Time from last BCG to CIS diagnosis, months, median (range)	**3.1 (0.3–10.2)**
Reason for not undergoing radical cystectomy, n (%)	
Declined	**28 (100)**
Preservation of bladder	15 (53.6)
Preservation of sexual function	0
Concern about quality of life after procedure	10 (35.7)
Concern about mortality and morbidity risk of procedure	3 (10.7)
Ineligible	**0**

*Patient characteristics are shown for all patients who received at least one dose of study treatment in the full analysis set of the cetrelimab monotherapy cohort (N=28).†America includes Canada, USA; Asia Pacific includes Australia, Japan, South Korea; EMEA includes Belgium, France, Germany, Greece, Italy, Netherlands, Portugal, Russia, Spain. ‡Percentages are based on number of patients with available data (n=17).
BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CPS, combined positive score; ECOG, Eastern Cooperative Oncology Group performance status; EMEA, Europe, Middle East, and Africa; PD-L1, programmed death-ligand 1.
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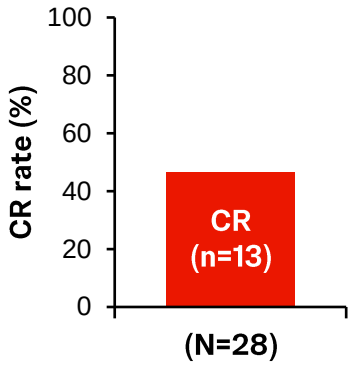
Cohort 3: Efficacy outcomes (CR rate, DOR and OS rate)

Cetrelimab monotherapy in patients with CIS ± papillary disease

Overall CR rate, % (95% CI)

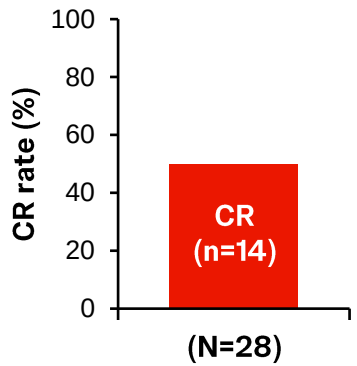
Centrally-assessed*

46.4%
(95% CI: 27.5–66.1)



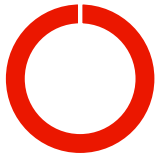
Investigator-assessed

50.0%
(95% CI: 30.6–69.4)



Overall OS rate

100.0%



12-month OS rate†
(95% CI: 100–100)

Cetrelimab monotherapy responders (n=13)

After a median follow-up in responders of **29.2 months** (range: 11–45):

Median DOR
(95% CI: 2.8–NE)

38.5%
12-month DOR rate
(95% CI: 14.1–62.8)

Cetrelimab monotherapy demonstrated a CR rate of 46.4% in patients with high-risk NMIBC with CIS with or without papillary disease

*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 timepoint †No deaths occurred.
CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; DOR, duration of response; NE, not estimable; OS, overall survival.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Cohort 3: Safety summary

Cetrelimab monotherapy in patients with CIS ± papillary disease: Table S9

Patients with ≥1 event, n (%)*	Cetrelimab monotherapy (N=28)†	
	Any grade	Grade ≥3
≥1 TRAEs‡	**15 (53.6)**	**2 (7.1)§**
Most frequent TRAEs¶		
Pruritus	3 (10.7)	0
Arthralgia	2 (7.1)	0
Diarrhea	2 (7.1)	0
Dry mouth	2 (7.1)	0
Fatigue	2 (7.1)	0
Hyperthyroidism	2 (7.1)	0
Hypothyroidism	2 (7.1)	0
Lipase increased	2 (7.1)	0
Psoriasis	2 (7.1)	0
Rash maculopapular	2 (7.1)	0

Patients with ≥1 event, n (%)*	Cetrelimab monotherapy (N=28)
Related AEs‡	**15 (53.6)**
Related Grade ≥3 AEs‡	**2 (7.1)**
Related serious AEs‡	**1 (3.6)****
Related AEs leading to cetrelimab interruption‡,††	**2 (7.1)**
Related AEs leading to cetrelimab discontinuation‡,‡‡	**2 (7.1)**
Related AEs with fatal outcome	**0**

In patients treated with cetrelimab monotherapy, rates of any grade TRAEs and Grade ≥3 TRAEs were 53.6% and 7.1%, respectively

*Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. †Safety data are shown for all patients who received at least one dose of study drug in the full analysis set of the cetrelimab monotherapy cohort (N=28). ‡An AE is categorized as related if the investigator determines that there is a possible, probable, or causal relationship between the AE and study drug/procedure. §TRAEs of Grade ≥3 for cetrelimab monotherapy were hyperglycemia (n=1), neutropenia (n= 1), and myopericarditis (n=1). Note, patients may have had ≥1 Grade ≥3 TRAE. ¶TRAEs of any grade by preferred term are listed if they were reported in ≥5% of patients in the cetrelimab monotherapy cohort. **Serious TRAEs included myopericarditis in one patient. †† Number of patients who experienced AEs related to cetrelimab that led to interruption of cetrelimab. ‡‡Number of patients who experienced AEs related to cetrelimab that led to discontinuation of cetrelimab.
AE, adverse event; CIS, carcinoma *in situ*; TRAE, treatment-related adverse event.
Daneshmand S, et al. *J Clin Oncol.* 2025 Jul 30:101200JCO2501651. doi: 10.1200/JCO-25-01651.

Summary

- In Cohort 2 of the SunRISe-1 study, TAR-200 monotherapy demonstrated a **high CR rate of 82.4%** and **durable response of 25.8 months** in patients with high-risk NMIBC with CIS with or without papillary disease
  - The rate of Grade ≥3 TRAEs was low (12.9%) and no treatment-related deaths occurred
- **DFS was 70.2% at 12 months** in patients with high-risk papillary disease-only NMIBC treated with TAR-200 monotherapy in Cohort 4 of the SunRIse-1 study
  - The rate of Grade ≥3 TRAEs was low (13.5%) and no treatment-related deaths occurred
- In Cohort 1 of the SunRISe-1 study, TAR-200 + cetrelimab demonstrated a CR rate of 67.9% in patients with high-risk NMIBC with CIS with or without papillary disease
  - The rate of Grade ≥3 TRAEs was (37.7%) and no treatment-related deaths occurred
- Cetrelimab monotherapy demonstrated a CR rate of 46.4% in patients with high-risk NMIBC with CIS with or without papillary disease in Cohort 3 of SunRISe-1
  - The rate of Grade ≥3 TRAEs was (7.1%) and no treatment-related deaths occurred
- Results of SunRISe-1 **establish TAR-200 monotherapy as the first intravesical releasing system** with proven efficacy and a favorable risk-benefit profile, supporting TAR-200 as a novel bladder-sparing treatment option for patients with BCG-unresponsive high-risk NMIBC
- TAR-200 is under investigation in the **SunRISe program** (NCT05714202, NCT04919512, and NCT06211764)

CIS, carcinoma *in situ*; CR, complete response; DFS, disease-free survival; NMIBC, non–muscle-invasive bladder cancer; TRAE, treatment-related adverse event.

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