Neoadjuvant Gemcitabine Intravesical System (Gem-iDRS) Plus Cetrelimab or Cetrelimab Alone in Patients With Muscle-Invasive Bladder Cancer Ineligible for/Refusing Neoadjuvant Cisplatin-Based Chemotherapy: Updated Perioperative Outcomes From SunRISe-4

Sarah P Psutka[1], Bernardo Herrera-Imbroda[2], Paul L Crispen[3], Andrea Necchi[4,5], Rohan Garje[6], Bernadett Szabados[7,8], Charles C Peyton[9], Benjamin Pradere[10], Neal Shore[11], Martin Bögemann[12,13], Mark A Preston[14], Evanguelos Xylinas[15], Cinty Gong[16], Mohamad Hasan[17], Hind Stitou[18], Sumeet Bhanvadia[17], Won Kim[17], Félix Guerrero-Ramos[19]

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KEY TAKEAWAY

Surgical outcomes data from SunRISe-4 support the safety and tolerability of gem-iDRS plus cetrelimab as neoadjuvant treatment to improve oncological outcomes for patients with MIBC who are ineligible for or refuse NAC

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CONCLUSIONS

- In patients with MIBC who were ineligible for or refused NAC, neoadjuvant gem-iDRS plus cetrelimab was not associated with declines in overall health, delays to RC, or significant increase in 30- and 90-day post-RC morbidity or mortality
- Addition of gem-iDRS to the checkpoint inhibitor cetrelimab did not worsen safety and post-RC morbidity compared with cetrelimab alone

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INTRODUCTION

- Standard of care for muscle-invasive bladder cancer (MIBC) involves radical cystectomy (RC) with neoadjuvant cisplatin-based chemotherapy (NAC), which has demonstrated increased survival benefit versus RC only[1-3]
  - Up to 50% of patients with MIBC are ineligible for NAC[4,5]
  - NAC is associated with decreased general health status and lean muscle mass, increased asthenia and gastrointestinal toxicities, and a delay in time to RC[5-9]
  - About 2-3% and 3-8% of patients experience mortality 30 and 90 days after RC, respectively[10]
- Available treatment options are limited for patients who are ineligible for or refuse NAC[11]
  - Therefore, there is a high unmet need for effective neoadjuvant treatments that maintain overall health and do not delay or complicate planned RC for comorbid patients with MIBC
- Gemcitabine intravesical system (gem-iDRS), previously TAR-200, is a novel intravesical drug-releasing system designed to provide prolonged delivery of gemcitabine in the bladder[12-14]
- In the randomized phase 2 SunRISe-4 study, neoadjuvant gem-iDRS + cetrelimab showed a high pathologic complete response, pathologic overall response, and 1-year recurrence-free survival in patients with MIBC who are ineligible for or refuse NAC[11]
  - We evaluated pre- and post-RC surgical, laboratory, and safety outcomes with neoadjuvant gem-iDRS plus cetrelimab versus cetrelimab alone, including clinical declines, delay to RC, and perioperative complications

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METHODS

- SunRISe-4 enrolled patients with histologically confirmed cT2-T4a N0M0 MIBC who were ineligible for or refused NAC and were scheduled for RC (Figure 1)
- Patients were randomized 5:3 to receive gem-iDRS plus cetrelimab (Cohort 1) or cetrelimab alone (Cohort 2) every 3 weeks (Q3W) for 12 weeks, followed by RC (protocol-specified RC window: 11-15 weeks)
- Perioperative outcomes included change during treatment in key indicators including ECOG PS (baseline, Weeks 6 and 36) and major laboratory values (baseline to Week 12), time to RC, and 30- and 90-day post-RC morbidity and mortality

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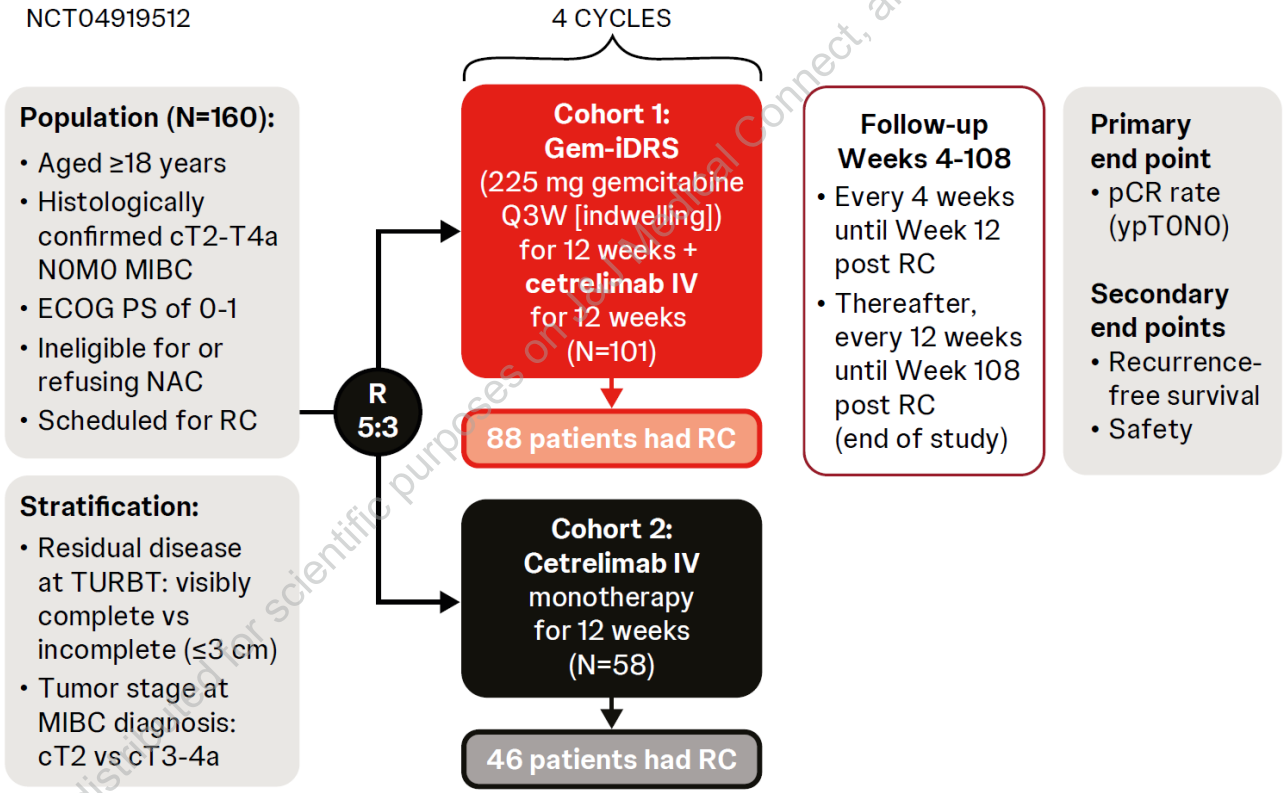
Figure 1: SunRISe-4 study design



ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; pCR, pathologic complete response; TURBT, transurethral resection of bladder tumor.

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RESULTS

Patients

- As of clinical cutoff (May 9, 2025), 101 patients were treated in Cohort 1 and 58 in Cohort 2; 88 and 46 patients, respectively, had undergone RC (Figure 1)
- Demographics and baseline disease characteristics for patients receiving RC were balanced across treatment cohorts (Table 1)

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RESULTS

TABLE 1: Baseline characteristics

Characteristics	Gem-iDRS + cetrelimab N=88	Cetrelimab monotherapy N=46
Age, years, median (IQR)	74 (54-85)	69 (43-82)
Sex, male, n (%)	73 (83.0)	37 (80.4)
Race, n (%)		
White	63 (71.6)	35 (76.1)
Asian	17 (19.3)	8 (17.4)
Other/Multiple/Not reported	8 (9.1)	3 (6.5)
Nicotine use, n (%)		
Current	23 (26.1)	11 (23.9)
Former	47 (53.4)	27 (58.7)
Never	1 (1.1)	0
Unknown	17 (19.3)	8 (17.4)
ECOG performance status 0, n (%)	74 (84.1)	36 (78.3)
Tumor stage, n (%)		
cT2	71 (80.7)	38 (82.6)
cT3-4a	17 (19.3)	8 (17.4)
Residual disease (visually incomplete) , n (%)	19 (21.6)	3 (6.5)
Urothelial carcinoma with variant histology, n (%)	20 (22.7)	13 (28.3)
Neoadjuvant chemotherapy, n (%)		
Ineligible	40 (45.5)	20 (43.5)
Refused	48 (54.5)	26 (56.5)
Prior intravesical therapy, n (%)	8 (9.1)	7 (15.2)

IQR, interquartile range.

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RESULTS

Surgical approach

- Surgical approach was per physician preference
- Ileal conduit was the most frequently used type of urinary diversion in either cohort (79.5% in Cohort 1 and 76.1% in Cohort 2; Table 2)

Change from baseline to RC in ECOG PS and major laboratory values

- ECOG PS was preserved in the majority of patients in both cohorts (Table 3)
- No clinically significant changes in body mass index, albumin, creatinine, or hemoglobin were reported during the neoadjuvant period (Table 3)

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TABLE 2: Surgical approach

Patients, n (%)	Gem-iDRS + cetrelimab N=88	Cetrelimab monotherapy N=46
Method of RC		
Robotic	55 (62.5)	18 (39.1)
Open	23 (26.1)	21 (45.7)
Laparoscopic	10 (11.4)	7 (15.2)
Type of urinary diversion[a]		
Incontinent diversions		
Ileal conduit (including Bricker, Bricker type, and urostomy)	70 (79.5)	35 (76.1)
Ureterocutaneostomy	1 (1.1)	0
Continent diversions		
Neobladder	11 (12.6)	10 (21.7)
Continent pouch	5 (5.7)	1 (2.2)
Margins assessed		
Yes	88 (100.0)	46 (100)

[a]For gem-iDRS + cetrelimab, type of urinary diversion was captured for 87 patients.

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TABLE 3: Change from baseline to RC in ECOG PS and major laboratory values

	Gem-iDRS + cetrelimab	Cetrelimab monotherapy
No ECOG PS worsening[a], n/N (%)	80/95 (84.2)	48/55 (87.3)
Change from baseline to last recorded value prior to RC, median (range)		
BMI[b], kg/m^2	-0.3 (-3.6 to 2.6)	0.1 (-3.7 to 2.0)
Albumin[c], g/L	-1.3 (-25.0 to 4.8)	-1.0 (-14.0 to 9.0)
Creatinine[c], mg/dL	0.0 (-0.3 to 1.8)	0.1 (-0.8 to 1.1)
Hemoglobin[b], g/dL	-0.2 (-4.9 to 6.8)	-0.3 (-4.1 to 2.7)

BMI, body mass index.
[a]ECOG PS at baseline and Week 6.
[b]n=87 and n=46 for gem-iDRS + cetrelimab and cetrelimab monotherapy cohorts, respectively.
[c]n=86 and n=46 for gem-iDRS + cetrelimab and cetrelimab monotherapy cohorts, respectively.

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RESULTS

Time to RC

- Most patients had RC within the protocol-specified window (85.2% in Cohort 1 and 84.8% in Cohort 2; Table 4)
- Median time from neoadjuvant therapy initiation to RC within protocol-specified window was 13.6 weeks (range, 11.3-17.1) in Cohort 1 and 13.0 weeks (range, 9.6-15.7) in Cohort 2
- Among 11 patients who had RC after the protocol-specified window, only 1 RC was delayed because of an adverse event during neoadjuvant treatment (grade 2 hematuria in the cetrelimab monotherapy cohort) (Table 4)

Post-RC morbidity and mortality (RC evaluable set)

- Post-RC mortality rates at 30 and 90 days were 1.3% and 2.9% (Cohort 1), and 4.8% and 6.3% (Cohort 2), respectively (all unrelated to treatment), consistent with historical data[15-17] (Table 5)

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TABLE 4: Time to cystectomy

	Gem-iDRS + cetrelimab N=88	Cetrelimab monotherapy N=46
Within protocol-specified window, n (%)	75 (85.2)	39 (84.8)
Median time to RC, weeks (range)	13.6 (11.3-17.1)	13.0 (9.6-15.7)
Before protocol-specified window, n (%)	8 (9.1)	1 (2.2)
Median time to RC, weeks (range)	9.4 (2.6-11.0)	12.7 (12.7-12.7)
Investigator decision, n (%)	2 (2.3)	1 (2.2)
Other, n (%)	2 (2.3)	0
Symptomatic progression, n (%)	2 (2.3)	0
Local progression, n (%)	1 (1.1)	0
Patient decision, n (%)	1 (1.1)	0
After protocol-specified window, n (%)	5 (5.7)	6 (13.0)
Median time to RC, weeks (range)	18.4 (16.0-19.4)	16.5 (12.4-19.0)
Other, n (%)	2 (2.3)	3 (6.5)
Investigator decision, n (%)	1 (1.1)	2 (4.3)
Patient decision, n (%)	2 (2.3)	0
Hematuria, n (%)	0	1 (2.2)

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TABLE 5: Safety outcomes within 30 and 90 days post RC (RC evaluable set)

Patients with ≥1 event	Within 30 days post RC			Within 90 days post RC		
n (%)	Overall (N=118)[a]	Gem-iDRS + cetrelimab (n=76)	Cetrelimab monotherapy (n=42)	Overall (N=100)[a]	Gem-iDRS + cetrelimab (n=68)	Cetrelimab monotherapy (n=32)
Post-RC morbidity						
≥1 TEAE any grade	93 (78.8)	62 (81.6)	31 (73.8)	86 (86.0)	58 (85.3)	28 (87.5)
Serious TEAE	46 (39.0)	32 (42.1)	14 (33.3)	49 (49.0)	37 (54.4)	12 (37.5)
Grade ≥3 TEAE	54 (45.8)	38 (50.0)	16 (38.1)	55 (55.0)	40 (58.8)	15 (46.9)
Post-RC mortality[b]						
Any cause	3 (2.5)	1 (1.3)[c]	2 (4.8)[d]	4 (4.0)	2 (2.9)[e]	2 (6.3)

[a]Number of patients who reached 30 or 90 days post RC and with at least 1 TEAE occurring within 30 or 90 days post RC. [b]No deaths that occurred within 30 and 90 days post RC were related to neoadjuvant treatment with gem-iDRS or cetrelimab. [c]Due to hypoxia. [d]Due to peritonitis and cardiac arrest in 1 patient each. [e]Due to hypoxia and cardio-respiratory arrest in 1 patient each.
TEAE, treatment-emergent adverse event.

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NAVIGATION

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