MasterClass in Bladder Cancer 2026

High-risk NMIBC: Other intravesical therapies will be the winners?

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Conflicts of interest

- Advisory board : Ipsen Pharma, Janssen, Ferring, Astellas, MSD, BMS.
- Speaker : Ipsen Pharma, Janssen-Oncology, Ferring, BMS, MSD.
- Investigator and steering committee member : Astrazeneca, Bayer, Ferring, Ipsen, Janssen-Oncology, MSD, Pfizer, QED.

- Panel member French Guidelines in Bladder Cancer (CC-AFU).
- Panel member European Guidelines NMIBC (EAU).
- Board member European School of Urology (ESU-EAU).

1. Available intensification trials in HR NMIBC

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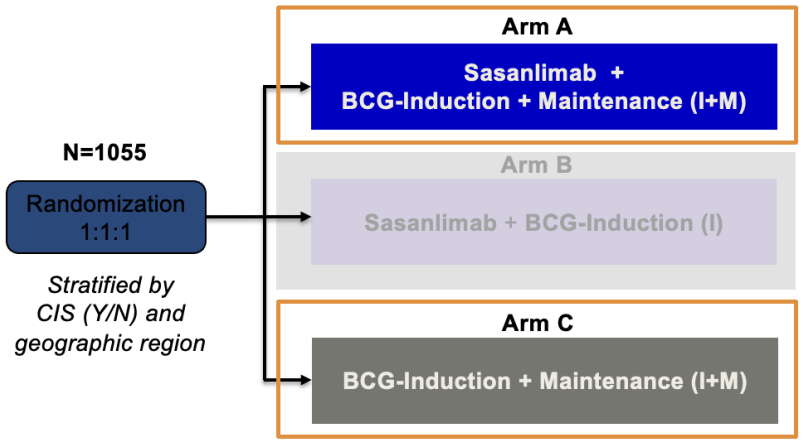
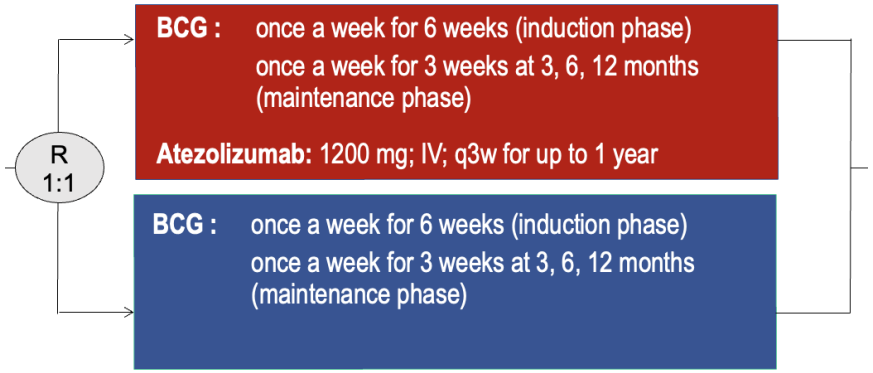
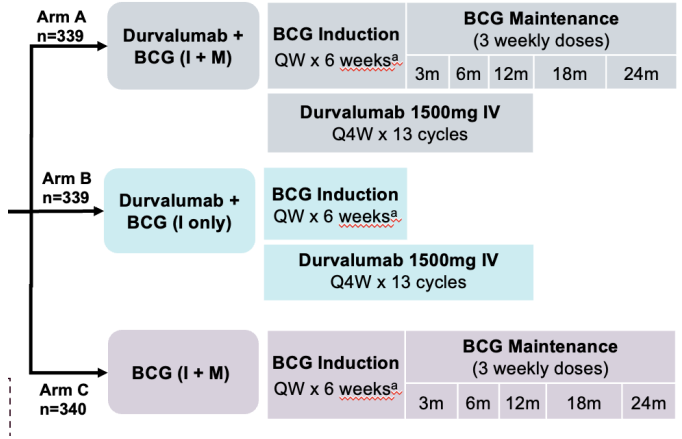
CREST



ALBAN



POTOMAC



	CREST	ALBAN	POTOMAC
BCG	2y	1y	2y
Drug	Sasanlimab SC 2y	Atezolizumab q4w IV 1y	Durvalumab q4w IV 1y
Endpoint	EFS (HG DzRec, DP,Cis, Death)	EFS (Any Dz Rec, Death)	DFS (HG DzRec, DP, Death)

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Shore et al. Nat Med 2025; Roupret et al. Ann Oncol 2025; De Santis Lancet 2025

2. Marginal benefit in published intensification trials

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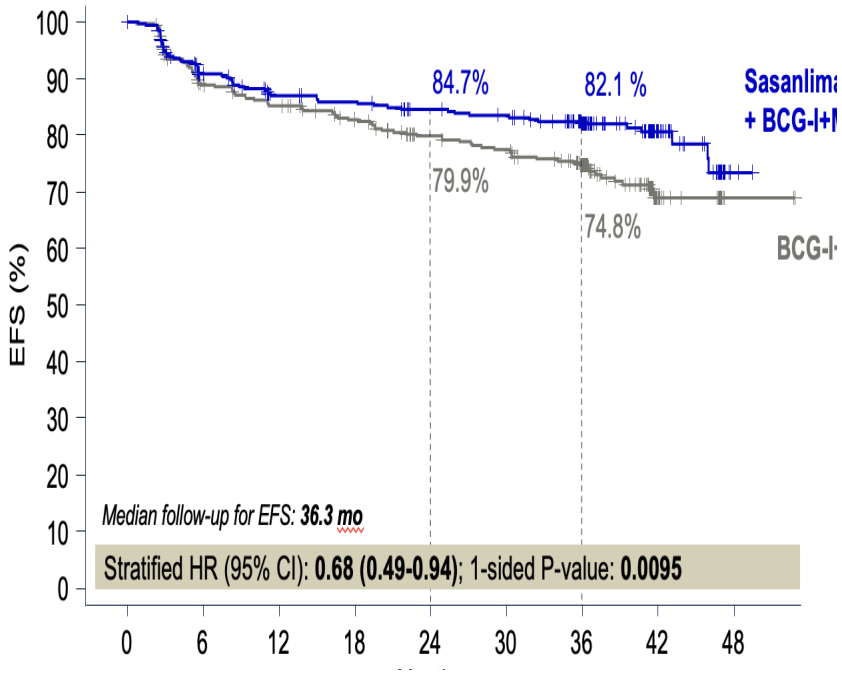
CREST



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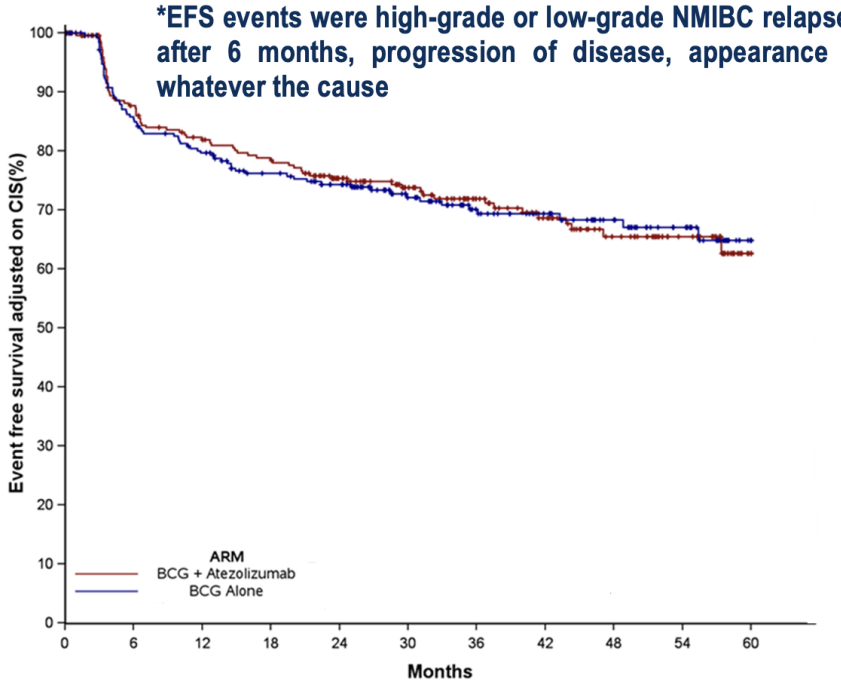
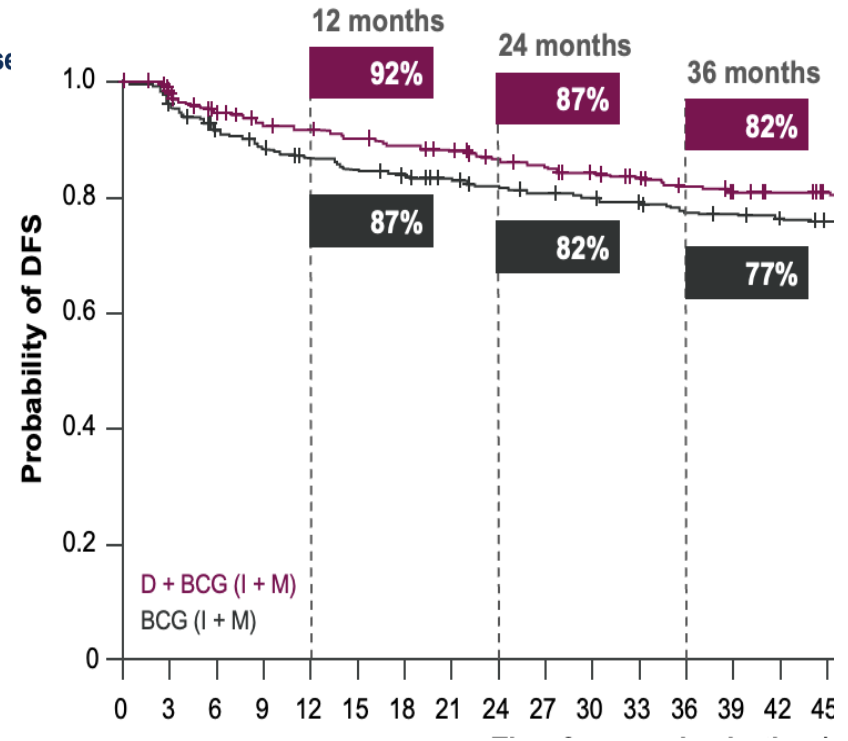


POTOMAC



HR **0.68 (0.49-0.94); p=0.0095** | **0.98 (0.71-1.36); p=0.9106** | **0.68 (0.50–0.93); p=0.0154**

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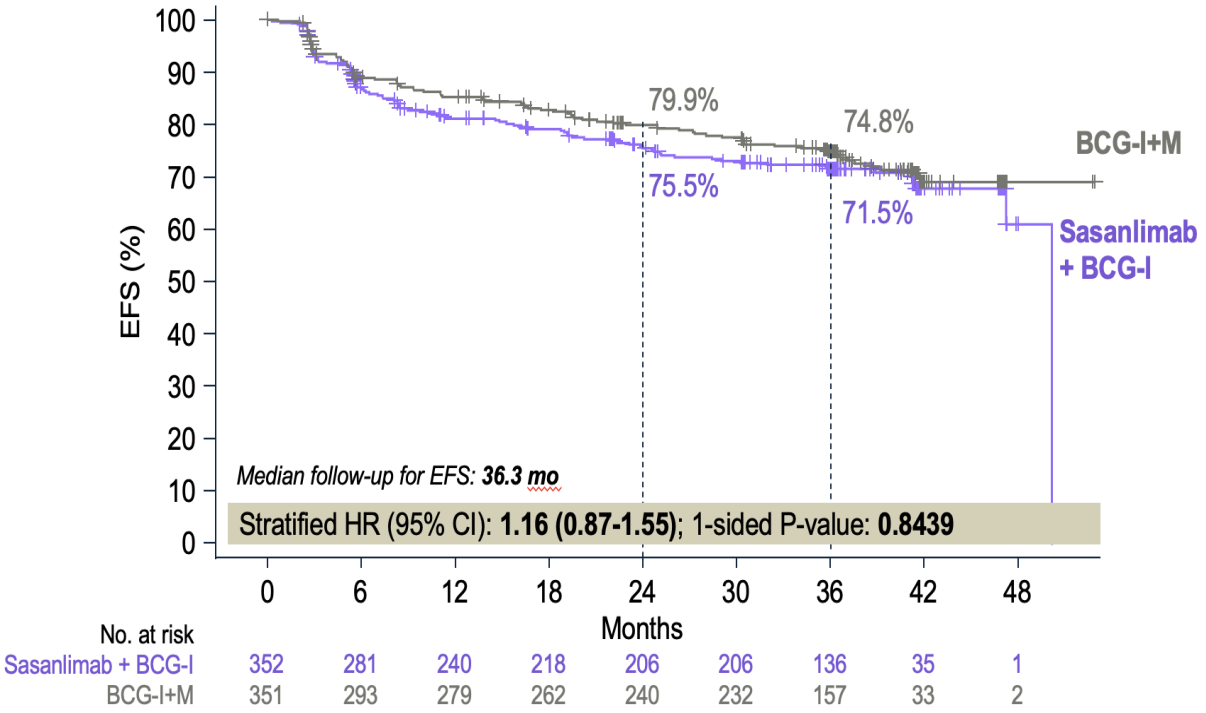
Shore et al. Nat Med 2025; Roupret et al. Ann Oncol 2025; De Santis Lancet 2025

3. BCG maintenance is still needed despite intensification

CREST



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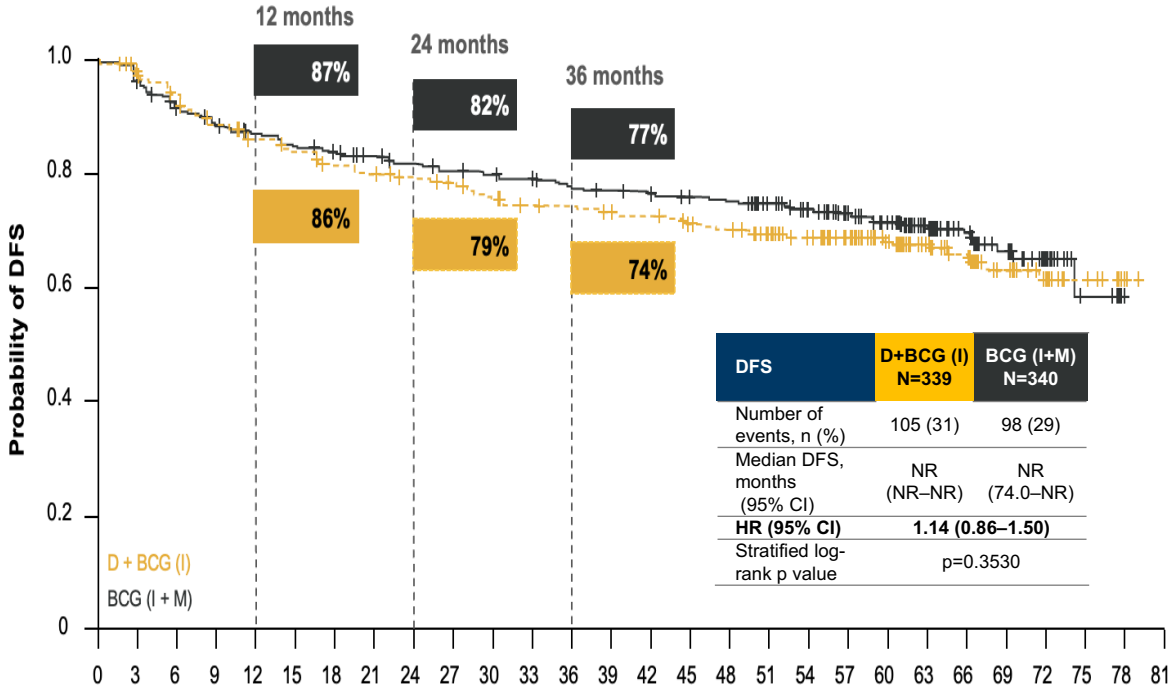

DFS	D+BCG (I) N=339	BCG (I+M) N=340
Number of events, n (%)	105 (31)	98 (29)
Median DFS, months (95% CI)	NR (NR–NR)	NR (74.0–NR)
HR (95% CI)	**1.14 (0.86–1.50)**	
Stratified log-rank p value	p=0.3530	

Shore et al. Nat Med 2025; De Santis Lancet 2025

4. Clinical relevance
Events Contributing to the EFS/DFS benefit

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CREST

	Sasanlimab + BCG-I+M (N=352)	BCG-I+M (N=351)
Patients with EFS event, n (%)	61 (17.3)	89 (25.4)
Recurrence of high-grade disease	**26 (7.4)**	**53 (15.1)**
Persistence of CIS	1 (0.3)	1 (0.3)
Progressive disease	18 (5.1)	22 (6.3)
Progression to N+/M+, n	3	7
Progression to MIBC (≥T2), n	7	7
Stage Progression (high-grade Ta, T1), n	7	7
Unknown, n	1	1
Death	16 (4.5)	13 (3.7)

POTOMAC

	Durvalumab + BCG-I+M	BCG-I+M
DFS event		
HG recurrence	**36 (10.6%)**	**71 (20.9%)**
Persistence of Cis	1 (0.3%)	3 (0.9%)
MIBC/M+	16 (4.7%)	13 (3.8%)
Death	14 (4.1%)	18 (5.3%)

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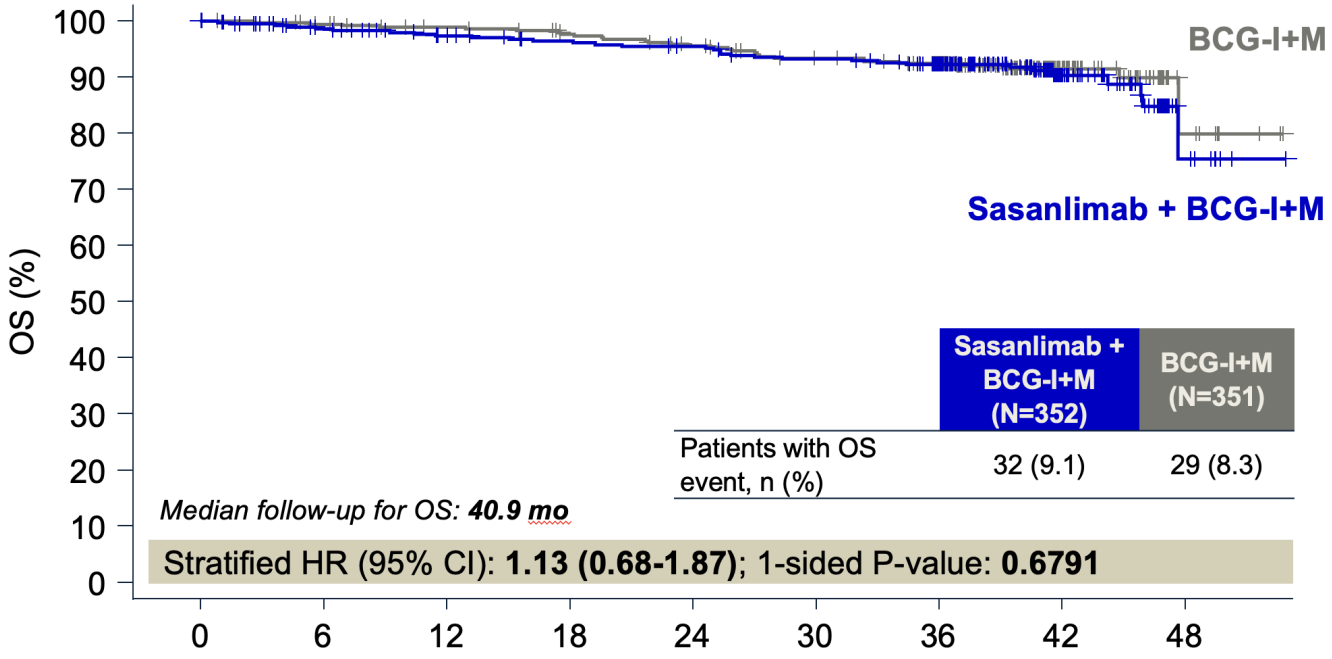
Shore et al. Nat Med 2025; De Santis Lancet 2025

5. OS not impacted by intensification

CREST



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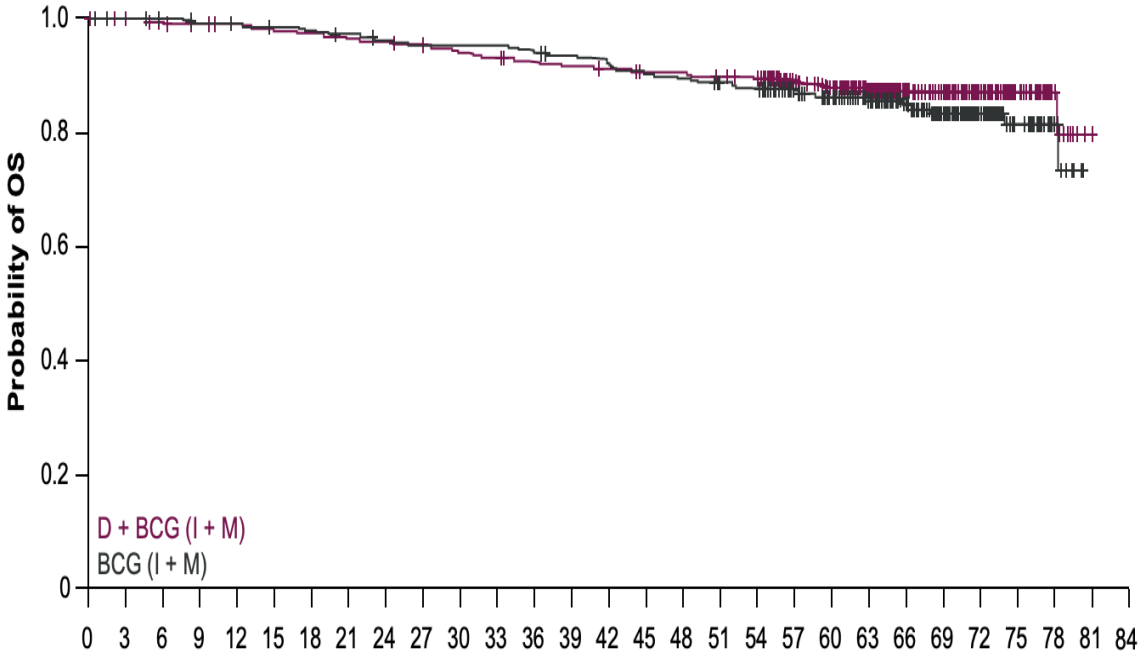
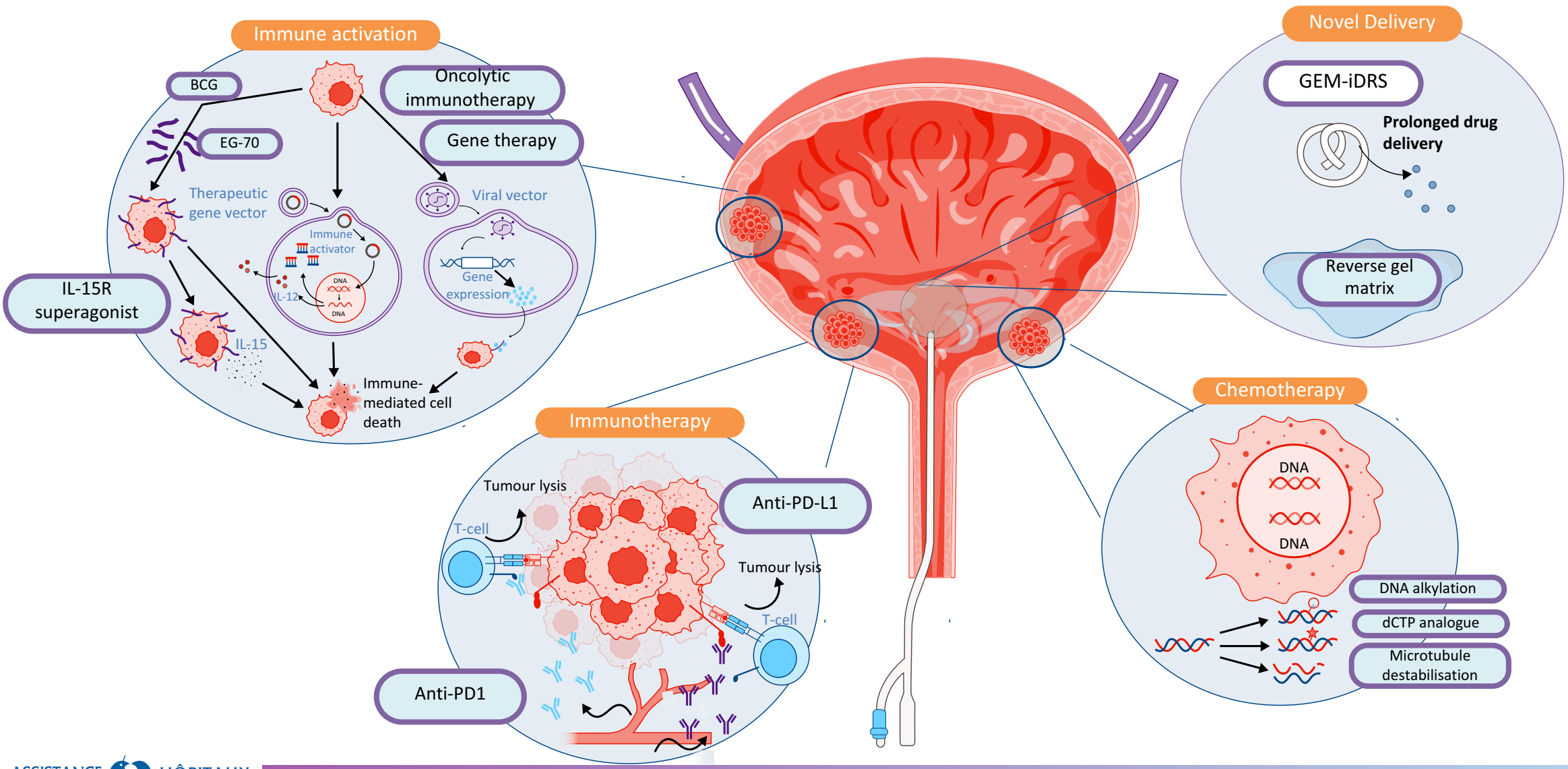


Shore et al. Nat Med 2025; De Santis Lancet 2025

6. Need to improve our local therapies with new targets/devices



GemIDRS - Sunrise 3 study

Key eligibility criteria

- Patients with histologically confirmed HR NMIBC (high-grade Ta, any T1, or CIS)
- BCG-naive (no prior BCG or last exposure >3 years prior to randomization)

Age ≥18 years

Eastern Cooperative Oncology Group performance status 0, 1, or 2

All visible papillary disease must be fully resected (absent) prior to randomization and documented at baseline cystoscopy. Local urine cytology at screening must be negative or atypical for high-grade urothelial carcinoma in patients with papillary-only disease

All adverse events associated with any prior surgery and/or intravesical therapy must have resolved to CTCAE v5.0 grade <2 prior to date of randomization

1:1:1
(N≈1050)

R

Group A (n≈350)
TAR-200 (225 mg gemcitabine Q3W [induction phase] and Q12W [maintenance phase]) + cetrelimab[a]

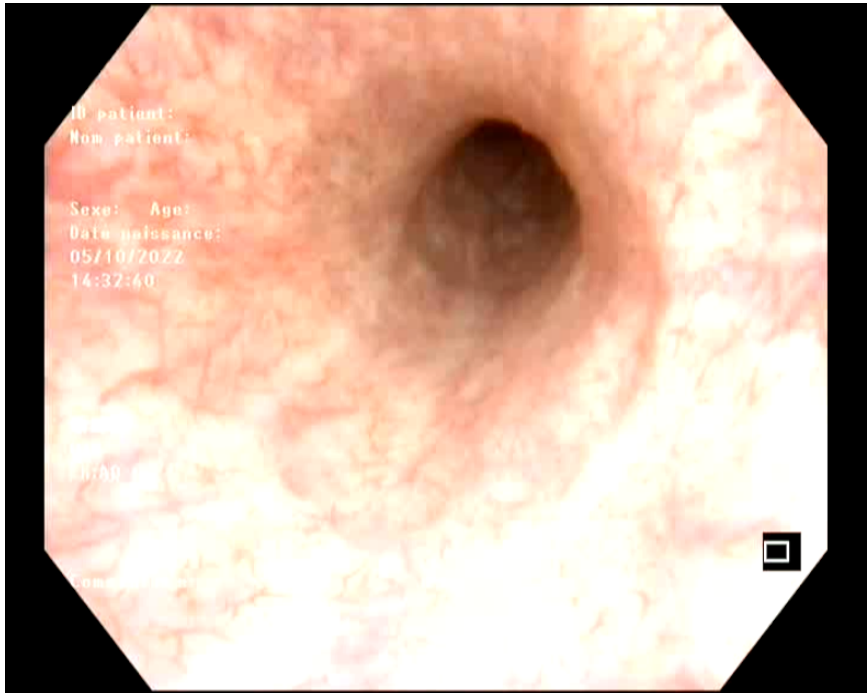
Group C (n≈350)
TAR-200 (225 mg gemcitabine Q3W [induction phase] and Q12W [maintenance phase])

Group B (n≈350)
BCG (QW for 6 weeks [induction] and QW for 3 weeks at Weeks 12, 24, 48, 72, and 96 [maintenance])

Primary end point — EFS
Time from randomization to first occurrence of HR disease, progression,[b] or any-cause death, whichever occurs first[c]

Secondary end points

- Overall CR rate (CIS only)[d]/duration of CR[e]
- Recurrence-free survival
- Time to progression
- Overall survival
- Cancer-specific survival
- Safety and tolerability
- Patient-reported outcomes



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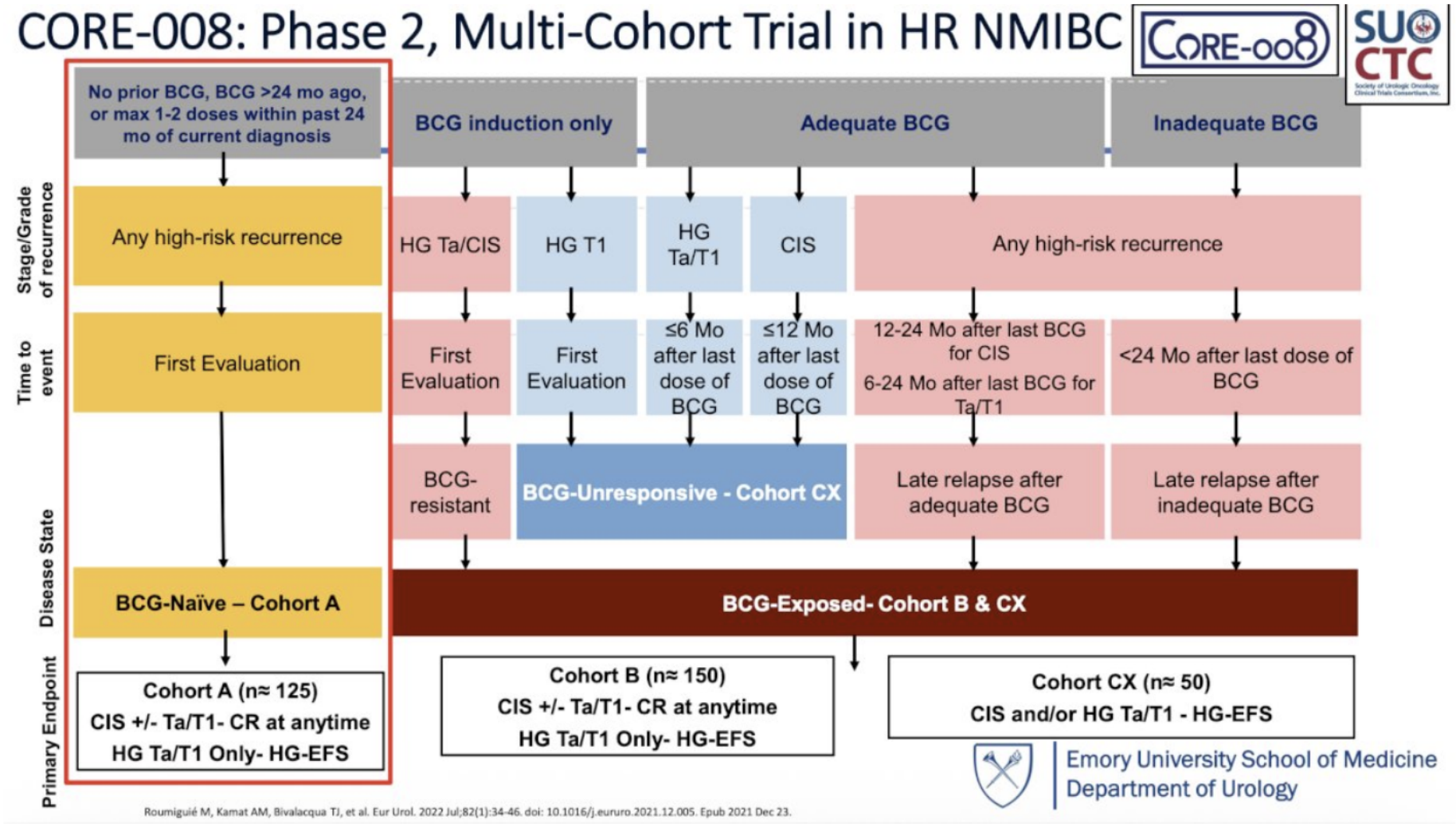
Catto et al. EAU 2024

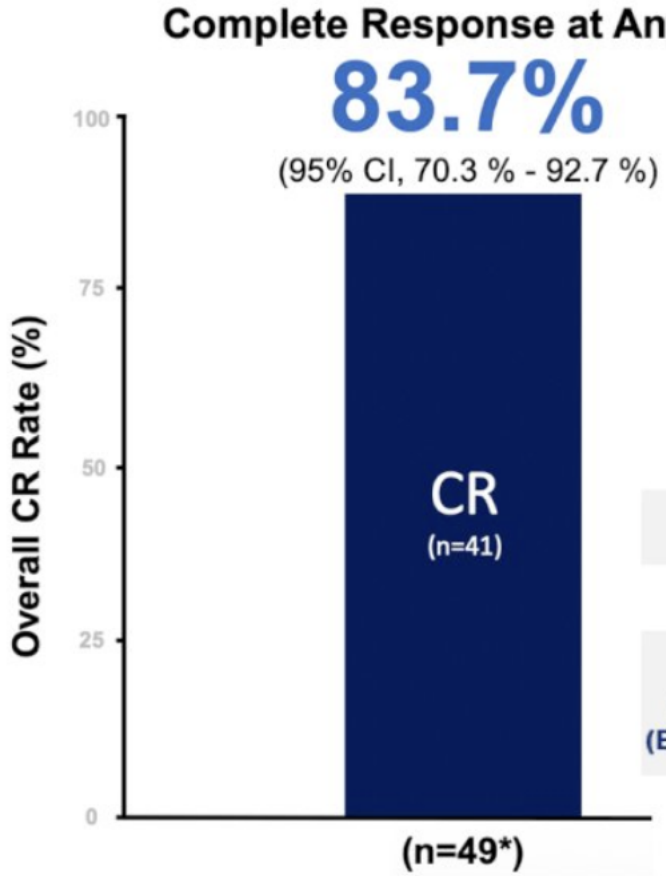
Cretostimogene Grenadenopvnec CORE-008 study



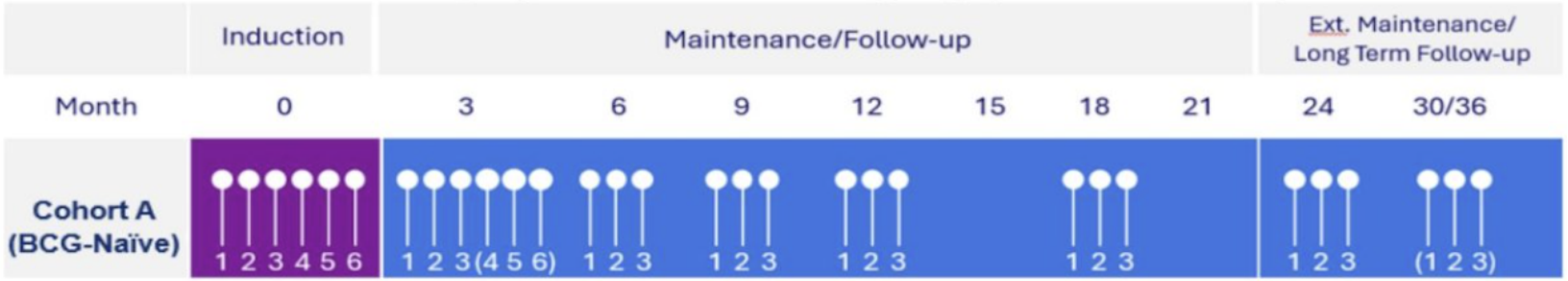
Roumiguié M, Kamat AM, Bivalacqua TJ, et al. Eur Urol. 2022 Jul;82(1):34-46. doi: 10.1016/j.eururo.2021.12.005. Epub 2021 Dec 23.

Steinberg et al. GU ASCO 2026

Cretostimogene Grenadenpvnec CORE-008 study



CR Rate	% (n/N)	Confidence Interval (95% CI)
Original Admin**	**79.2%** *19 out of 24 patients*	(57.8, 92.9)
Optimized Admin***	**88.0%** *22 out of 25 patients*	(68.8, 97.5)



Conclusion

- 3 RCT well designed, fully accrued, follow-up
- Marginal benefit of intensification in HR NMIBC with expected toxicity (immune related)
- BCG still needed
- Prevention of disease recurrence
- Other intravesical options are needed
- **Winner either device assisted or gene therapies ?**

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Other intravesical therapies will be the winners?



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