7th ANNUAL UC COURSE

Emerging personalized therapies for the management of urothelial carcinomas

7th MAY 2026
MADRID

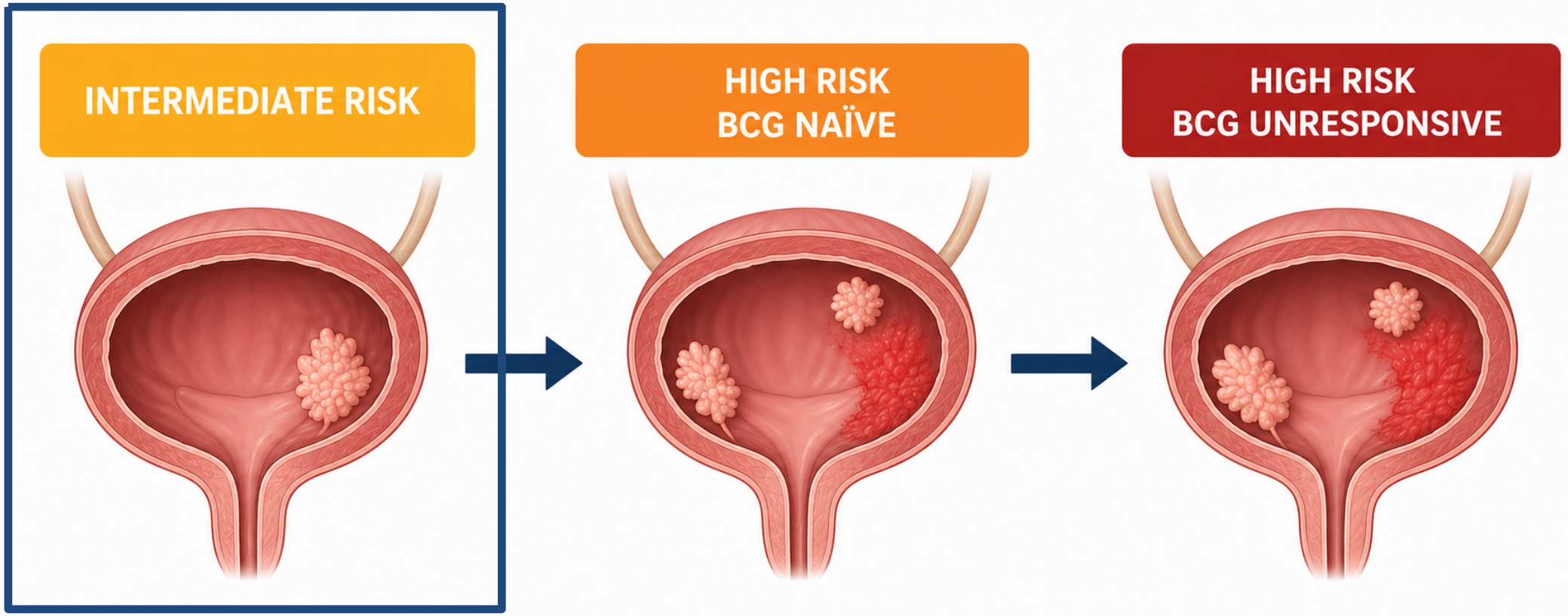
NMIBC clinical trials: landmark report from 2025

Félix Guerrero Ramos

Hospital Universitario 12 de Octubre

Madrid

Research support/PI	Johnson & Johnson, Pfizer, Taris, BMS, Roche, Seagen, AstraZeneca, Combat Medical, Cepheid, Fidia, Astellas, UroGen, MSD, enGene, Tyra Bio
Employee	SERMAS (Servicio Madrileño de Salud)
Consultant	Johnson & Johnson, Pfizer, Merck, Roche, Taris, Combat Medical, AstraZeneca, MSD, BMS, enGene, Nanobots Therapeutics, Gebro, Photocure
Stockholder	CG Oncology, Johnson & Johnson, Pfizer, Danae Urogenomics
Speaker bureau	Nucleix, MSD, Pfizer, Merck, BMS, AstraZeneca, Palex, Combat Medical, Johnson & Johnson, Recordati, Gebro
Travel	Pfizer, Recordati, Ipsen, Combat Medical, Alter, Salvat, Nucleix, AstraZeneca, Fidia, Johnson & Johnson
Scientific advisory board	AstraZeneca, BMS, Combat Medical, Johnson & Johnson, Nucleix, Pfizer, Taris, Roche, MSD, enGene
Manuscript support	Pfizer, Janssen, Combat Medical, AstraZeneca, Johnson & Johnson, BMS, Gebro
Others	Co-founder of Danae Urogenomics


INTERMEDIATE RISK
HIGH RISK
BCG NAÏVE
HIGH RISK
BCG UNRESPONSIVE

Intermediate risk

Table 3. Sur
Assessment

Response
CR[a]
NCR
Residual disease
Progression to H
Indeterminate
Missing

Yes	4	5/21/2025
No	5	11:22:32 AM
Abstain	0	
Non-Vote Member	0	

Yes	Vote: 4		
[redacted]			
No	Vote: 5		
[redacted]			
Abstain	Vote: 0		
No-Voting	Total: 0		

18

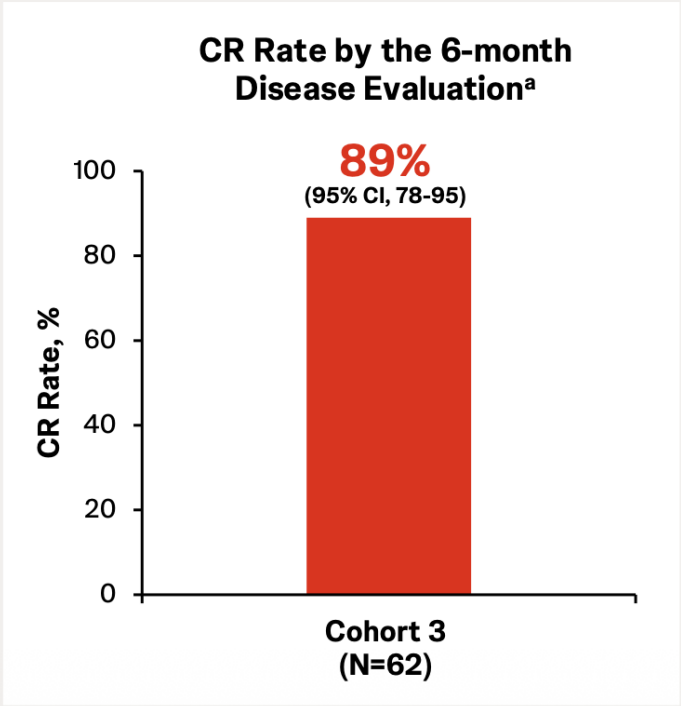
9

Events include recurrence,

Prasad SM, J Urol 2025

Intermediate risk

Erda-iDRS Showed a High CR Rate as Ablative Therapy in Patients With IR NMIBC



	Cohort 3 (n=55)
Median CR duration (95% CI)[a]	**18 months** (14-25)
Median follow-up in responders (range)[a]	18 months (15-21)

- 81% of patients had achieved CR at the 3-month disease evaluation
- 49% of responders were in ongoing follow-up and remained in CR at the clinical data cutoff

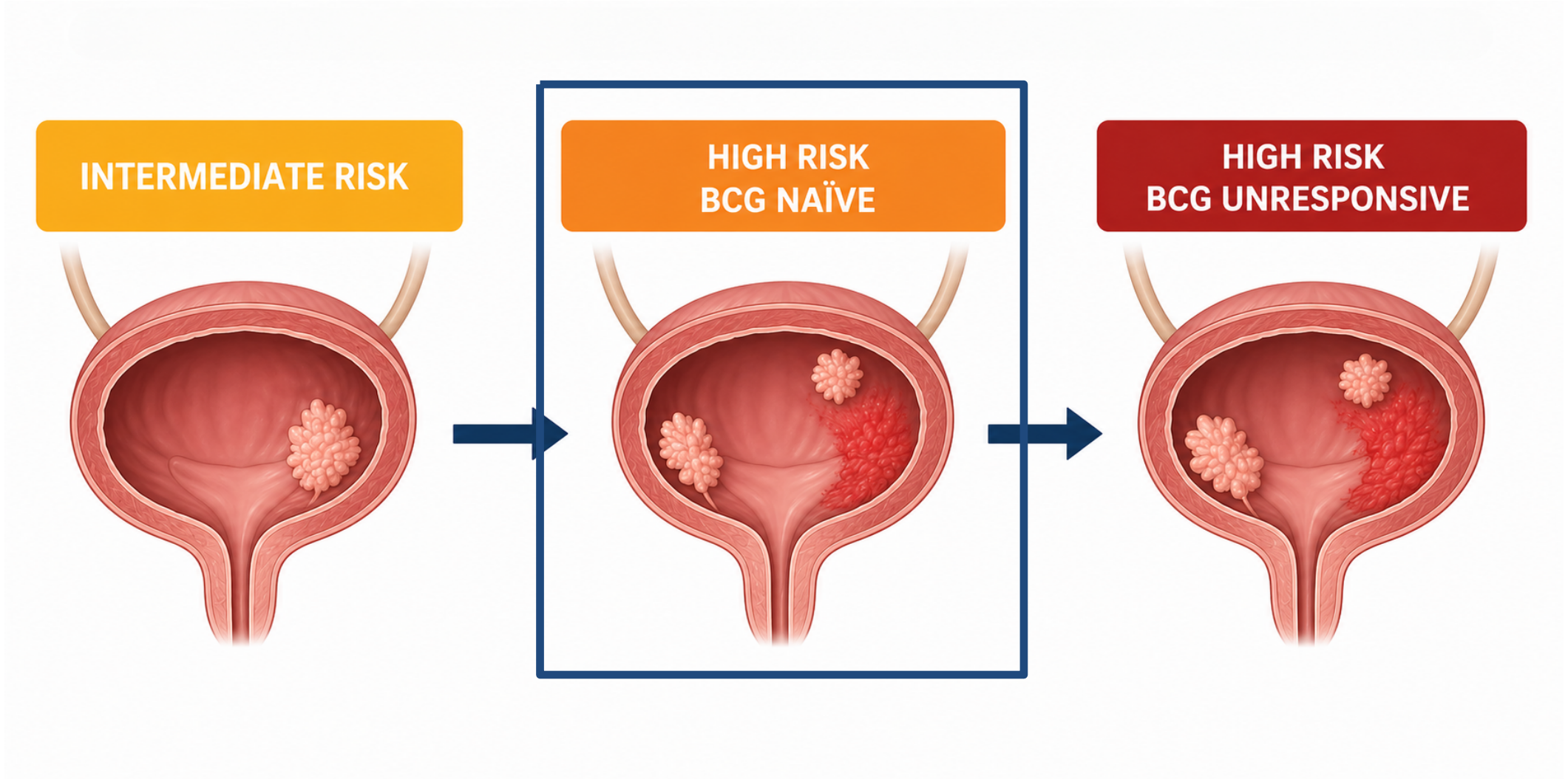
[a]Kaplan-Meier estimate.

Presented by A Vilaseca at the 41st Annual European Association of Urology (EAU26); 13-16 March 2026; London, UK

9

Vilaseca A, Guerrero-Ramos F, EAU 2026

@DrFelixGuerrero


INTERMEDIATE RISK
HIGH RISK
BCG NAÏVE
HIGH RISK
BCG UNRESPONSIVE

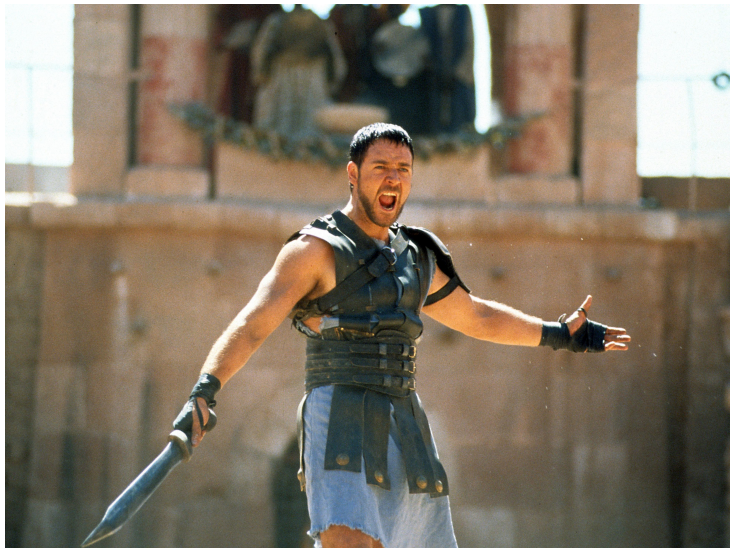
High risk BCG naïve

Table 1 – Comparative designs of the largest trials assessing novel agents in BCG-naïve high-risk non–muscle invasive bladder cancer

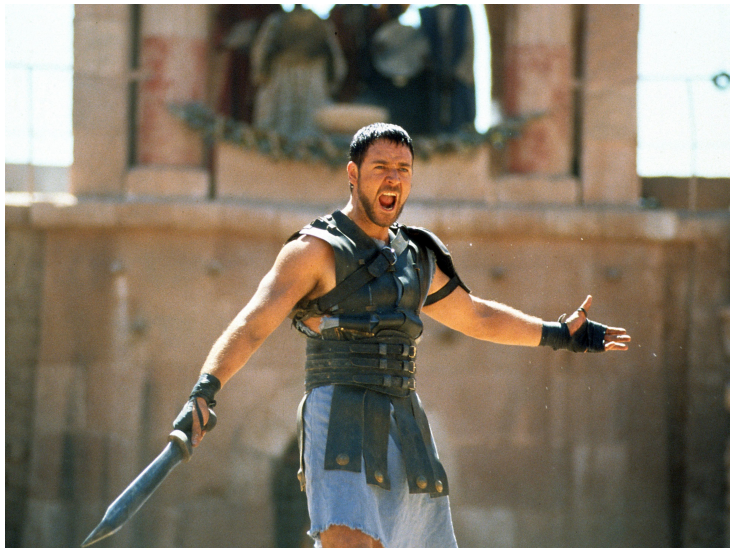
Study title	POTOMAC	ALBAN	KEYNOTE-676 (cohort B)	CREST	SunRISe-3	BRIDGE
Study ID	NCT03528694	NCT03799835	NCT03711032	NCT04165317	NCT05714202	NCT05538663
Intervention	Durv + BCG (I + M) vs Durv + BCG (I) vs BCG (I + M)	Atezolizumab + BCG (I + M) vs BCG (I + M)	Pembro + BCG (M) vs Pembro + BCG (reduced M) vs BCG (I + M)	Sasanlimab + BCG (I + M) vs Sasanlimab + BCG (I) vs BCG (I + M)	TAR-200 vs Cetrelimab + TAR-200 vs BCG (I + M)	Sequential Gem/Doc vs BCG (I + M)
Administration route	Durvalumab: i.v. BCG: IVS	Atezolizumab: i.v. BCG: IVS	Pembro: i.v. BCG: IVS	Sasanlimab: SC BCG: IVS	Cetrelimab: i.v. TAR-200: IVS BCG: IVS	Gem/Doc: IVS BCG: IVS
BCG M	24 mo	12 mo	18 mo	24 mo	24 mo (optional 36 mo)	36 mo
Participants (*n*)	1018	516	975	1070	1050	870
Primary EP	DFS	RFS	EFS	EFS	EFS	EFS
Key secondary EPs	OS, QoL, DSS, QoL	PFS, OS, CR, QoL	OS, CRR, RFS, DSS, TTC, DOR, safety/tolerability	OS, CR, duration of CR, TTC, QoL	RFS, OS, MFS, TTC, TTP, safety, QoL	QoL, safety, toxicity, PFS, CFR
BCG strain	OncoTICE	Medac, OncoTICE	OncoTICE	Various, including OncoTICE	BCG Culture	OncoTICE
Current status	Active, NRC	Active, NRC	Recruiting	Active, NRC	Recruiting	Recruiting
eSCD	September 2025	February 2028	October 2028	December 2027	May 2030	October 2030

BCG = bacillus Calmette-Guérin; CFR = cystectomy-free rate; CR = complete response; CRR = complete response rate; DFS: disease-free survival; DOR: duration of response; DSS: disease-specific survival; Durv = durvalumab; EFS = event-free survival; EP = endpoint; eSCD = estimated study completion date; Gem/Doc = gemcitabine + docetaxel; I = induction; i.v. = intravenous; IVS = intravesical; M = maintenance; MFS = metastasis-free survival; NRC = not recruiting; OS = overall survival; Pembro = pembrolizumab; PFS = progression-free survival; QoL = quality of life; RFS = recurrence-free survival; SC = subcutaneous; TTC = time to cystectomy; TTP = time to progression.

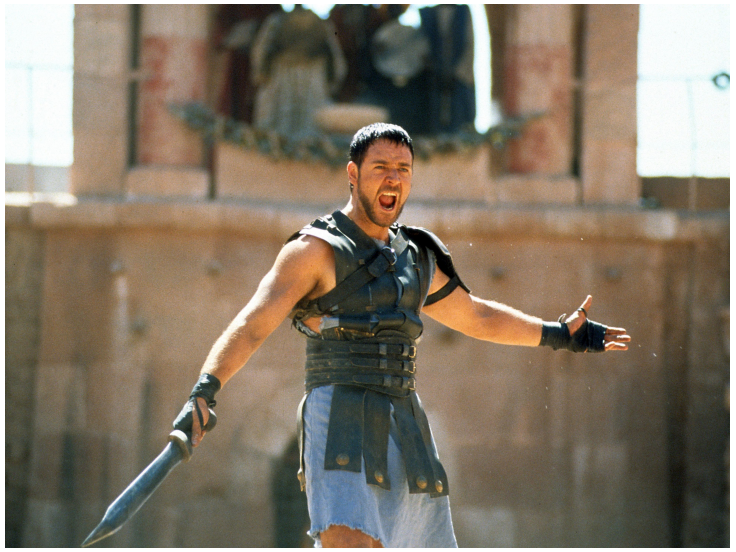
Guerrero-Ramos F, Eur Urol Oncol 2024



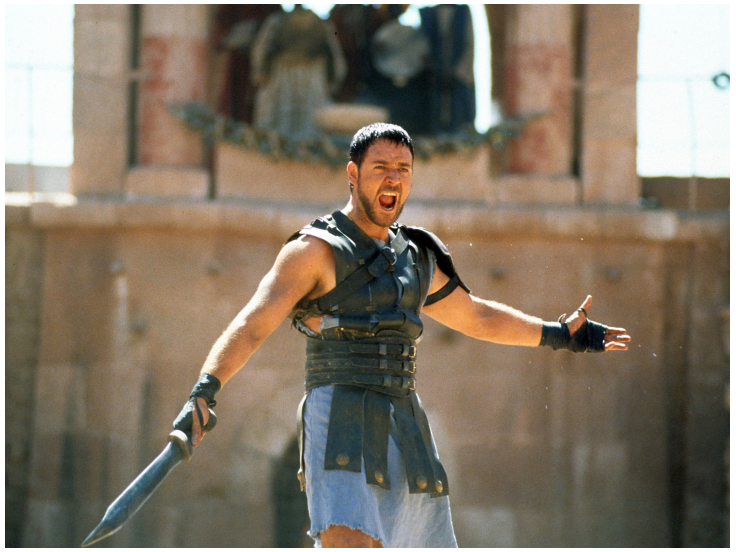
POTOMAC



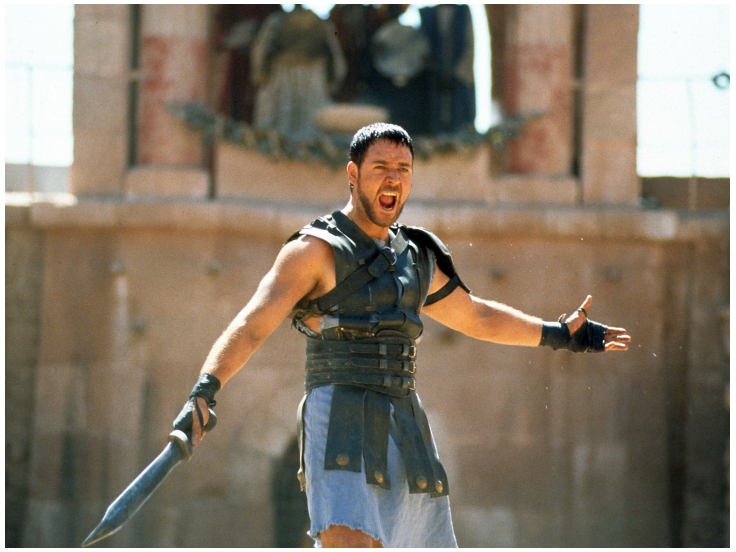
CREST



ALBAN



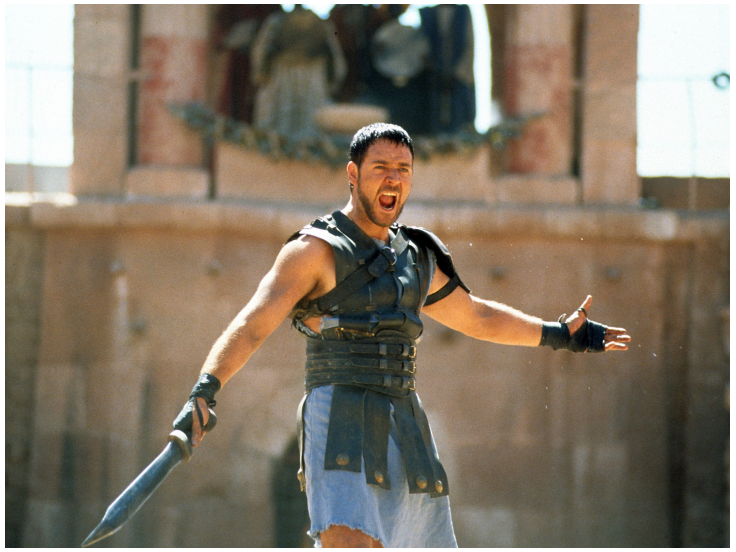
POTOMAC



CREST

ALBAN

Negative trial



POTOMAC

CREST

Positive trial

Withdrawn

ALBAN

Negative trial

POTOMAC	CREST	ALBAN
Positive trial	Positive trial	Negative trial
Ongoing	Withdrawn	

ALBAN – Study design

BCG-naive patients, with high-risk NMIBC after first and second look TURBT:

- High-risk defined as the presence of any high-grade/grade 3 Ta, T1 tumors and/or CIS
- No prior BCG therapy
- Absence of metastatic disease in the pelvis, abdomen, or chest
- ECOG PS of 0-2

R 1:1

BCG : once a week for 6 weeks (induction phase)
once a week for 3 weeks at 3, 6, 12 months (maintenance phase)

Atezolizumab: 1200 mg; IV; q3w for up to 1 year

BCG : once a week for 6 weeks (induction phase)
once a week for 3 weeks at 3, 6, 12 months (maintenance phase)

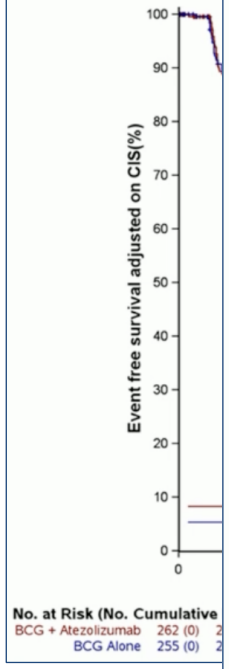
Primary endpoint
EFS

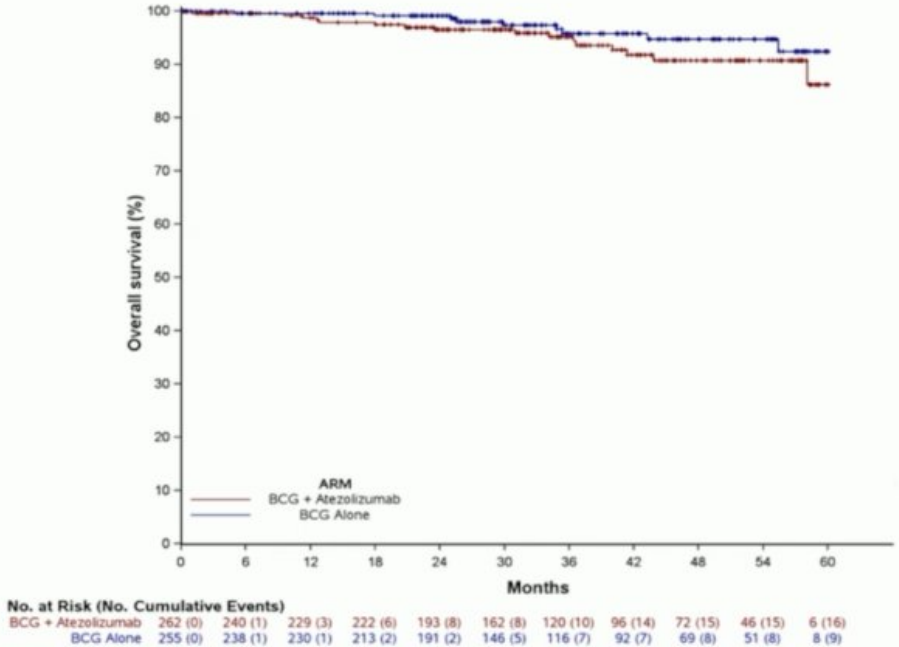
Key secondary endpoints
High-grade RFS
PFS
OS
DOR
Safety
QoL

CIS: carcinoma in situ; DOR, duration of response; EFS: Event-Free Survival; OS, Overall Survival; PFS: Progression-Free survival; QoL, Quality of Life; RFS: Recurrence-Free Survival

Rouprêt M, Ann Oncol 2025

ALBAN – Analysis of EFS* (primary endpoint, ITT population)

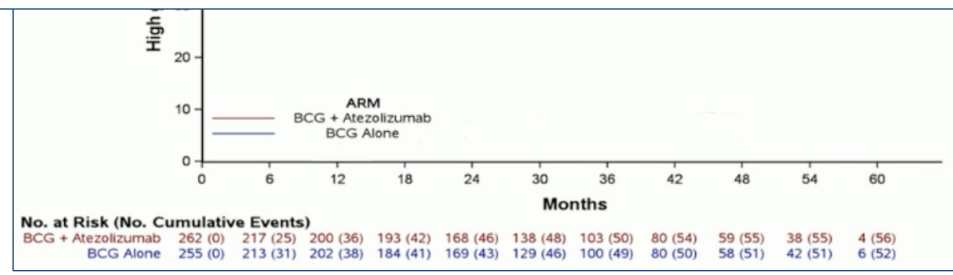




	BCG + atezolizumab	BCG
OS events, n / N	16 / 262	9 / 255
Median OS (95% CI), mo	NE	NE
Adjusted HR (95% CI), mo	**1.73** (0.76-3.92), *P*=0.1799	

HR was adjusted on the presence of CIS at inclusion

CI, confidence interval; HR, hazard ratio; NE, not evaluable; RFS: Recurrence-Free Survival



oint, ITT pop)

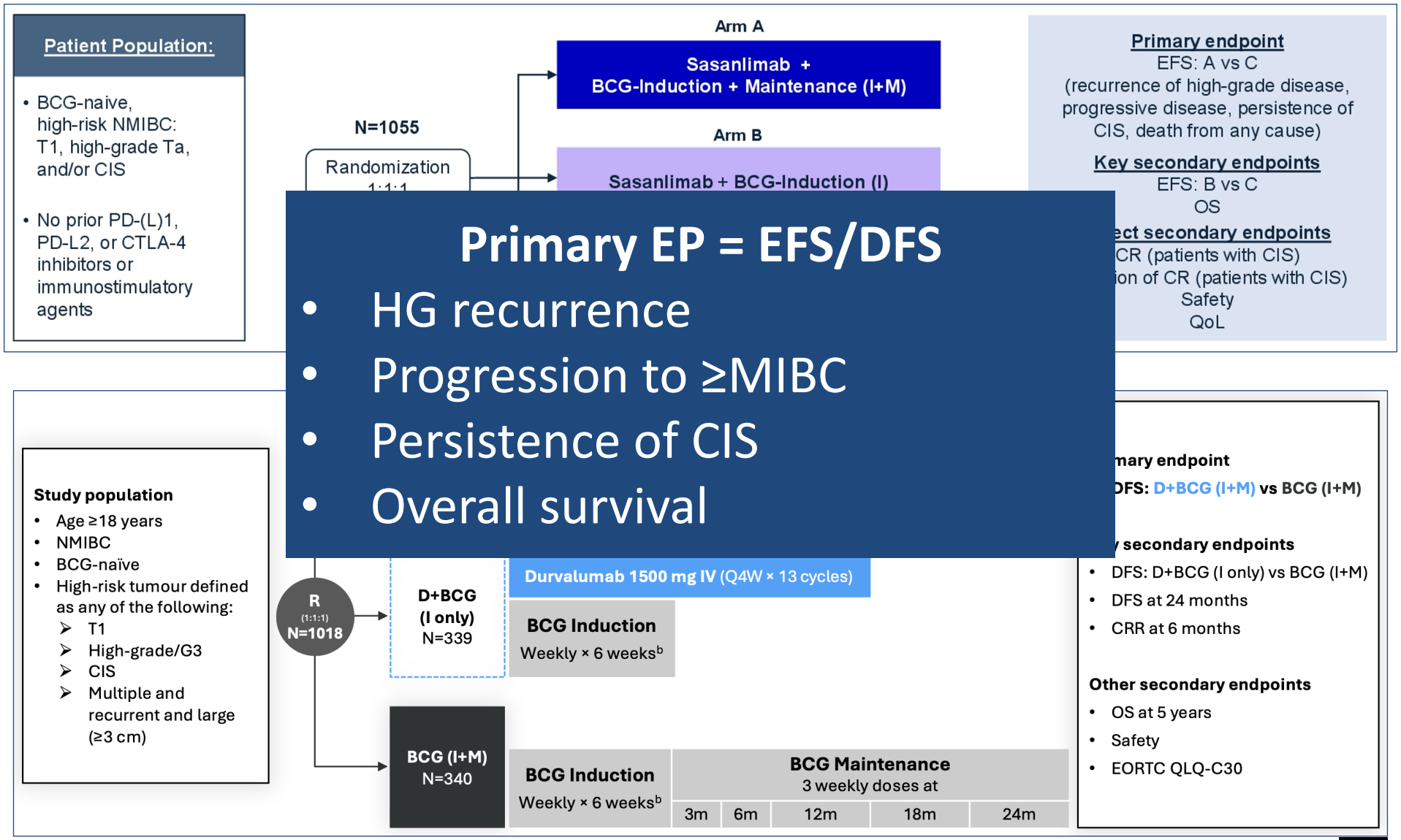
umab	BCG
	52 / 255
	NE

3-1.55), *P*=0.7658

usion

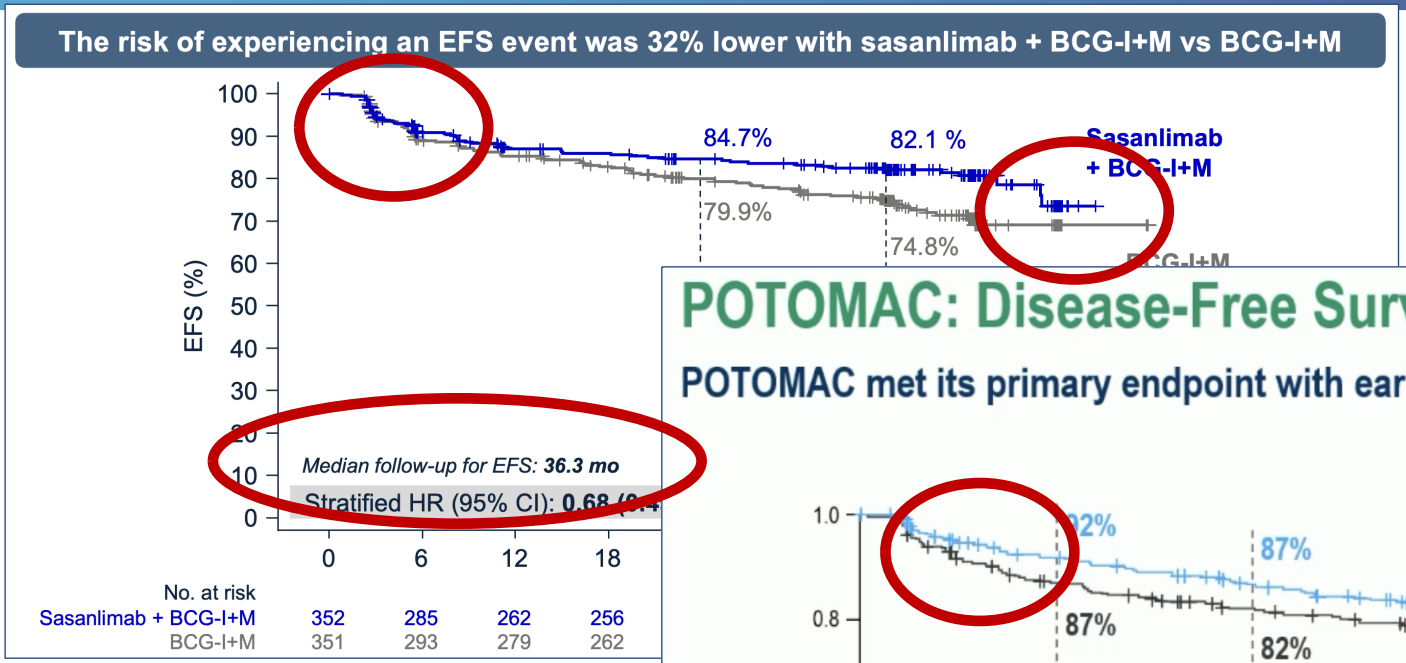
aluable; RFS: Recurrence-Free

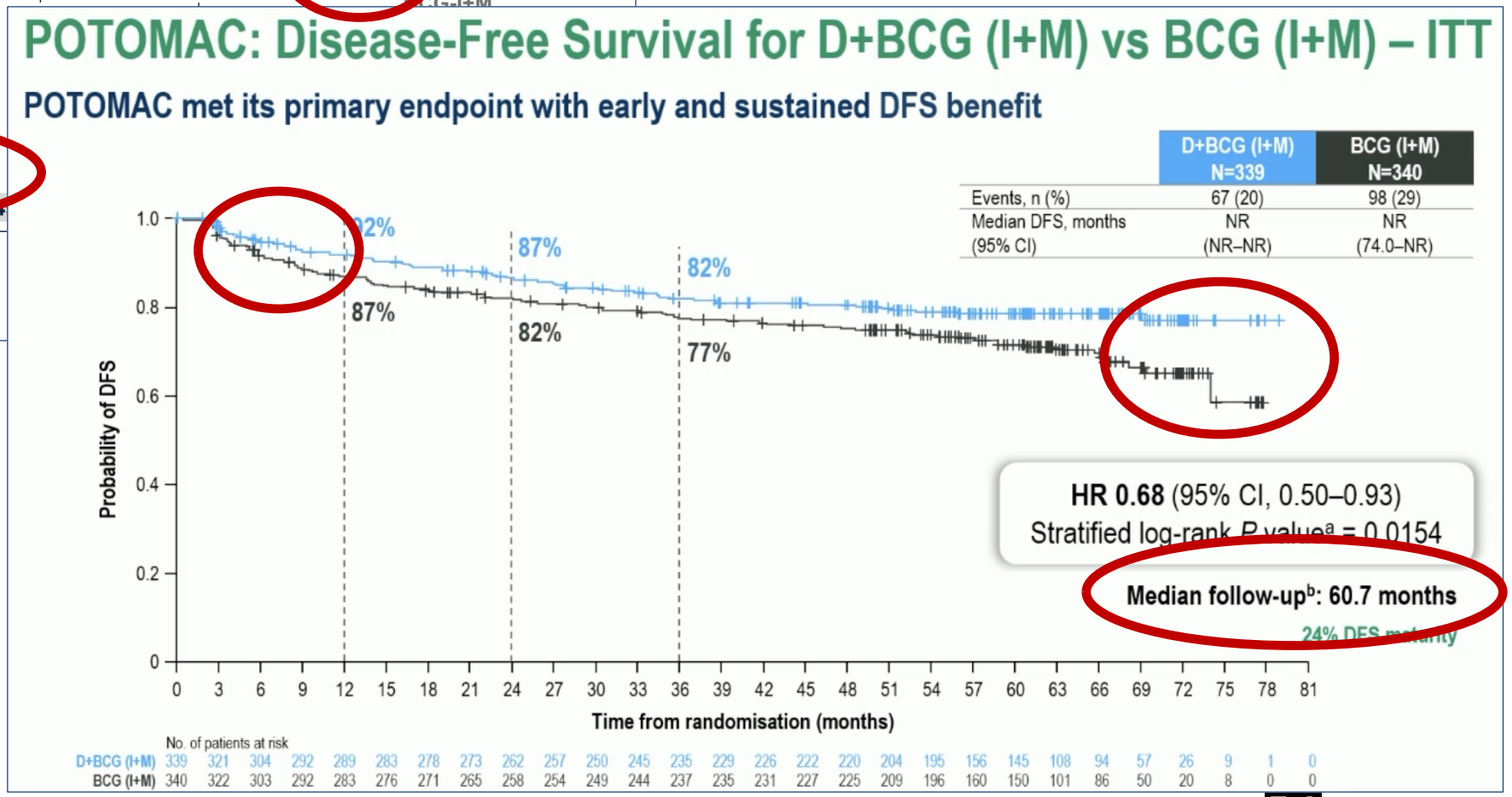
Rouprêt M, Ann Oncol 2025


Patient Population:
• BCG-naive, high-risk NMIBC: T1, high-grade Ta, and/or CIS
• No prior PD-(L)1, PD-L2, or CTLA-4 inhibitors or immunostimulatory agents
N=1055
Randomization
Arm A
Sasanlimab + BCG-Induction + Maintenance (I+M)
Arm B
Sasanlimab + BCG-Induction (I)
Primary endpoint
EFS: A vs C
(recurrence of high-grade disease, progressive disease, persistence of CIS, death from any cause)
Key secondary endpoints
EFS: B vs C
OS
CR (patients with CIS)
Safety
QoL
Primary EP = EFS/DFS
• HG recurrence
• Progression to ≥MIBC
• Persistence of CIS
• Overall survival
Study population
• Age ≥18 years
• NMIBC
• BCG-naïve
• High-risk tumour defined as any of the following:
➢ T1
➢ High-grade/G3
➢ CIS
➢ Multiple and recurrent and large (≥3 cm)
R (1:1:1) N=1018
D+BCG (I only) N=339
Durvalumab 1500 mg IV (Q4W × 13 cycles)
BCG Induction
Weekly × 6 weeks[b]
BCG (I+M) N=340
BCG Induction
Weekly × 6 weeks[b]
BCG Maintenance
3 weekly doses at
3m
6m
12m
18m
24m
mary endpoint
DFS: D+BCG (I+M) vs BCG (I+M)
y secondary endpoints
• DFS: D+BCG (I only) vs BCG (I+M)
• DFS at 24 months
• CRR at 6 months
Other secondary endpoints
• OS at 5 years
• Safety
• EORTC QLQ-C30

HR = 0.68

32% risk reduction in the primary outcome

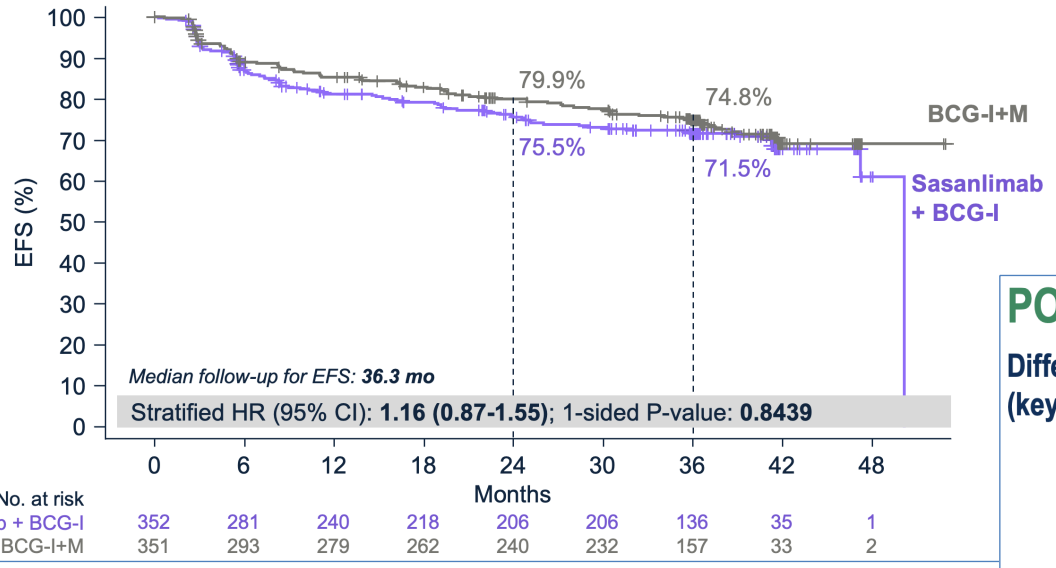




Shore ND, Guerrero-Ramos F, Nat Med 2025; De Santis M, Guerrero-Ramos F, Lancet 2025

Key Secondary Endpoint EFS by Investigator: Arm B vs Arm C

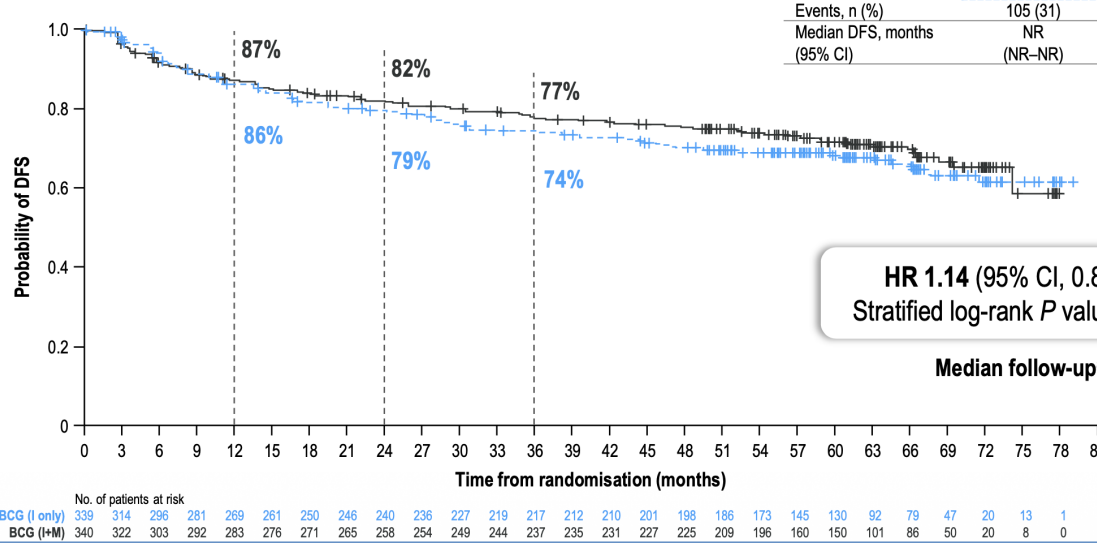
EFS was not different for sasanlimab + BCG-I vs BCG-I+M



POTOMAC: Disease-Free Survival for D+BCG (I Only) vs BCG (I+M) – ITT

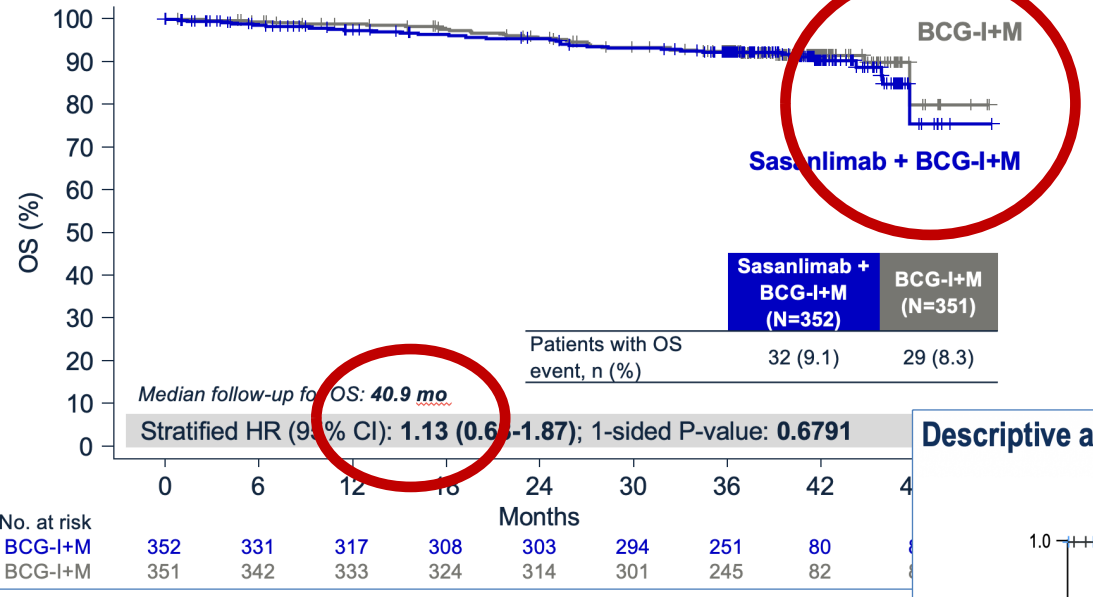
Difference in DFS between D+BCG (I only) vs BCG (I+M) arms was not statistically significant (key secondary endpoint)

	D+BCG (I only) N=339	BCG (I+M) N=340
Events, n (%)	105 (31)	98 (29)
Median DFS, months (95% CI)	NR (NR–NR)	NR (74.0–NR)



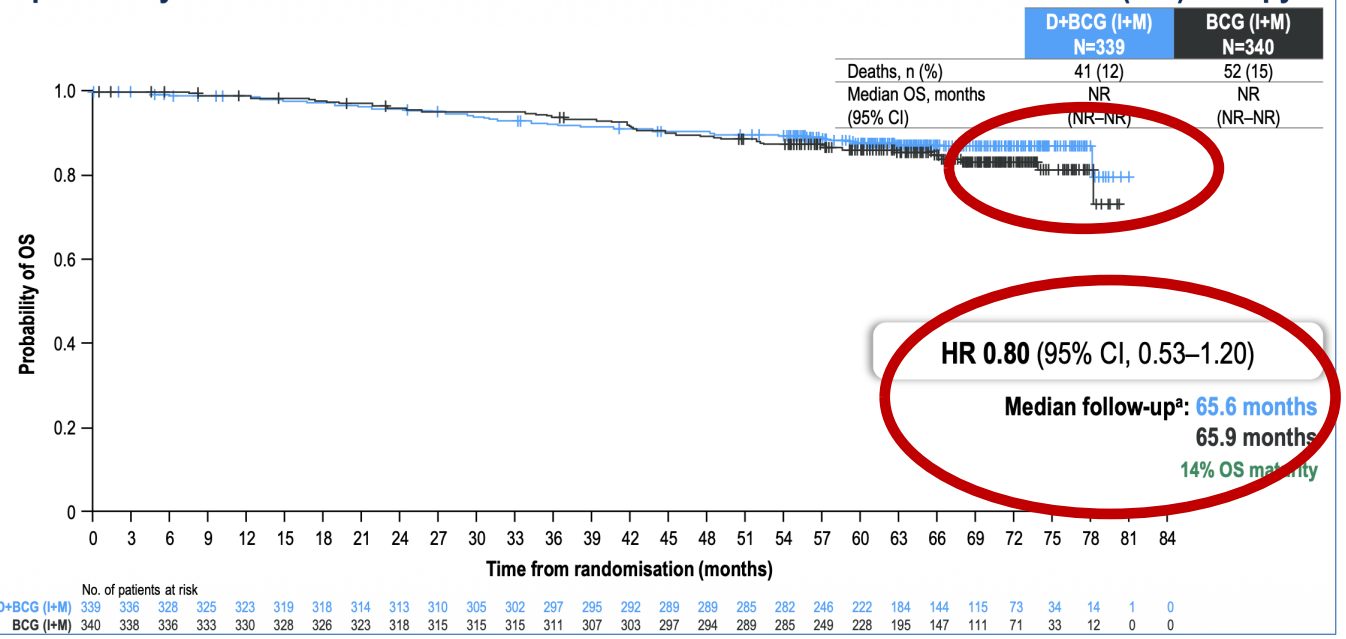
Shore ND, Guerrero-Ramos F, Nat Med 2025; De Santis M, Guerrero-Ramos F, Lancet 2025

Interim OS results suggest no meaningful difference between treatment arms



	Sasanlimab + BCG-I+M (N=352)	BCG-I+M (N=351)
Patients with OS event, n (%)	32 (9.1)	29 (8.3)

Descriptive analysis showed no detriment to OS with the addition of durvalumab to BCG (I+M) therapy



	D+BCG (I+M) N=339	BCG (I+M) N=340
Deaths, n (%)	41 (12)	52 (15)
Median OS, months (95% CI)	NR (NR–NR)	NR (NR–NR)

	CREST		POTOMAC		ALBAN	
	S+BCG	***BCG***	***D+BCG***	***BCG***	***A+BCG***	***BCG***
≥ Grade 3 TRAE (%)	30	2	21	4	23	9
irAE						
Any grade (%)	43	0	27	1	55	9
≥ Grade 3 (%)	16	0	8	0.3	6	1

Shore ND, Guerrero-Ramos F, Nat Med 2025; De Santis M, Guerrero-Ramos F, Lancet 2025; Rouprêt M, Ann Oncol 2026

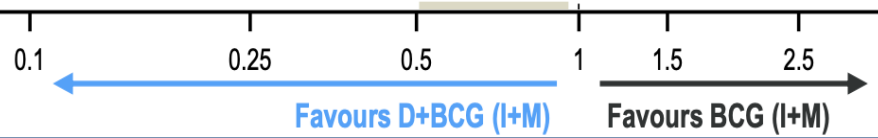
Treatment-related adverse events†			
Any grade	298 (89%)	269 (80%)	245 (72%)
Maximum grade 3 or 4*	71 (21%)	52 (15%)	13 (4%)
Serious adverse event	45 (13%)	38 (11%)	13 (4%)
Leading to death	0	0	0
Discontinuation of study treatment	92 (27%)	54 (16%)	56 (17%)
Serious TEAEs	120 (34.3)	99 (28.4)	49 (14.0)
Treatment-related	62 (17.7)	43 (12.4)	5 (1.4)
TEAEs leading to death	6 (1.7)	4 (1.1)	2 (0.6)
Treatment-related	0	2 (0.6)[a]	0
Treatment-related TEAEs leading to discontinuation of all trial drugs	14 (4.0)	3 (0.9)	30 (8.6)
Sasanlimab	92 (26.3)	58 (16.7)	–
BCG	59 (16.9)	8 (2.3)	30 (8.6)
Any-grade irAE	149 (42.6)	163 (46.8)	5 (1.4)
Grade ≥3 irAE	55 (15.7)	49 (14.1)	0
Corticosteroid administered for systemic use	69 (19.7)	70 (20.1)	1 (<1%)
Injection site reactions related to sasanlimab[b]	8 (2.3)	13 (3.7)	0

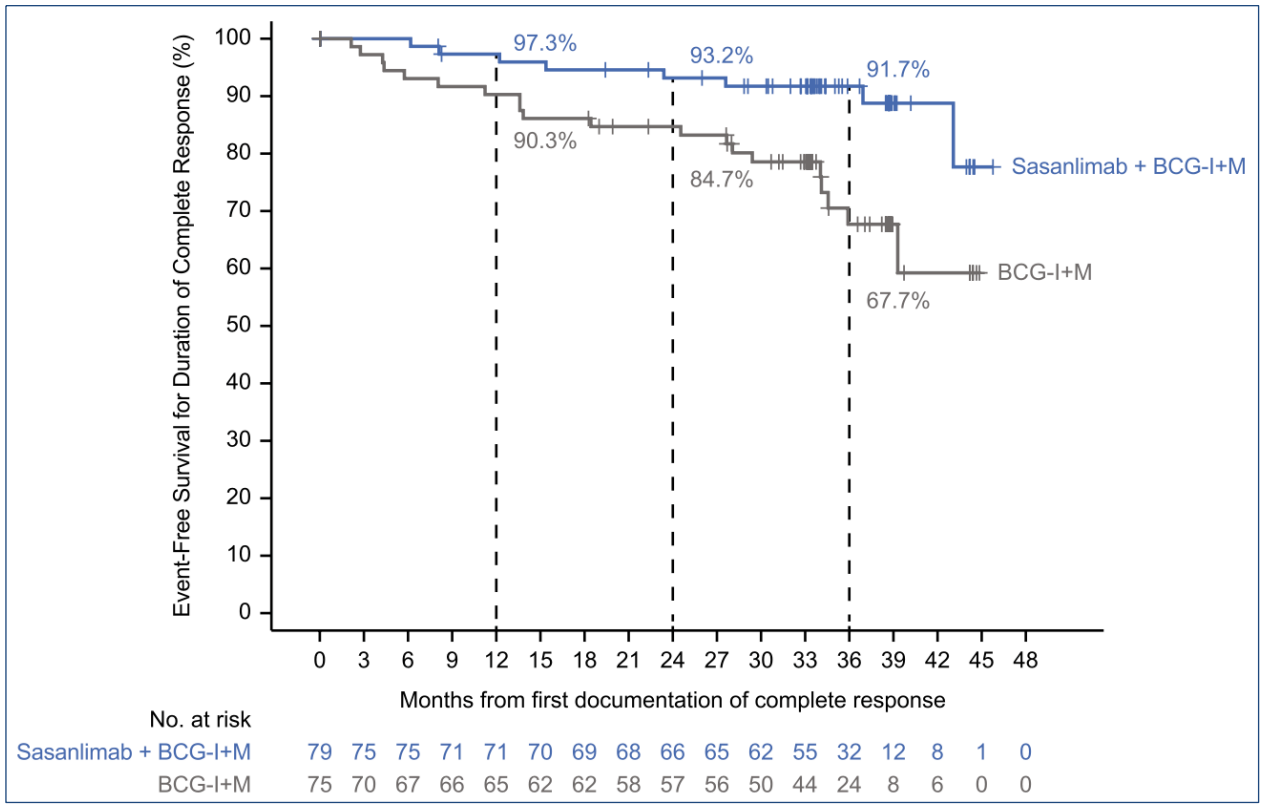
Shore ND, Guerrero-Ramos F, Nat Med 2025; De Santis M, Guerrero-Ramos F, Lancet 2025

	Events/N		
	Sasanlimab + BCG-I+M	BCG-I+M	Hazard ratio (95% CI)
Overall (stratified)	61/352	89/351	0.68 (0.49-0.94)
Age			
≥65 years			
<65 years			
Gender			
Female			
Male			
Race			
Asian			
White			
Geographic Region			
Western Europe/Ca			
Rest of world			
US			
TICE strain			
TICE			
No TICE[a]			
Presence of CIS			
Yes			
No			
T1 disease			
Yes			
No			

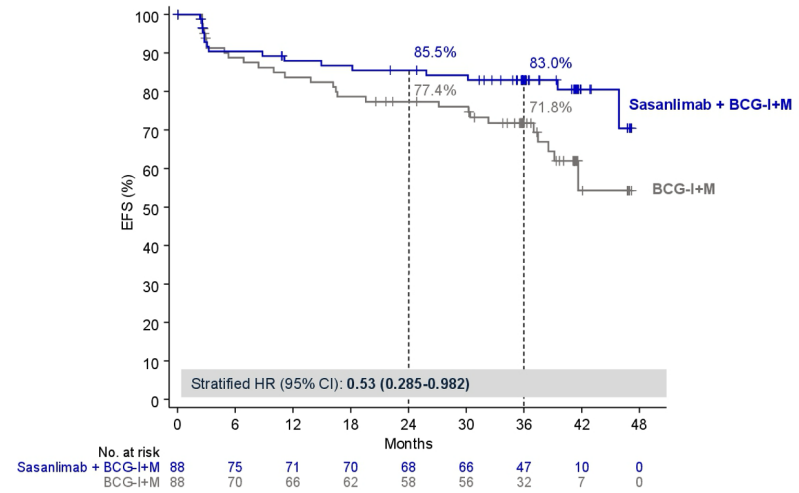
Subgroup	Category	N	Hazard Ratio (95% CI)
All patients		679	0.68 (0.50–0.93)
Age			0.74 (0.42–1.27)
			0.64 (0.44–0.93)
Sex			0.59 (0.41–0.83)
			1.21 (0.61–2.42)
Region			0.59 (0.36–0.95)
			0.75 (0.50–1.12)
ECOG PS			0.64 (0.45–0.90)
			0.77 (0.38–1.56)
Smoking status			0.38 (0.17–0.80)
			0.80 (0.52–1.22)
			0.74 (0.41–1.31)
BCG strain			0.68 (0.37–1.23)
			0.66 (0.46–0.95)
CIS[a]			1.01 (0.62–1.64)
			0.53 (0.34–0.79)
Higher risk pap			0.54 (0.35–0.83)
			0.88 (0.56–1.38)
PD-L1 expressi			0.50 (0.26–0.91)
			0.72 (0.48–1.05)
			NC (NC–NC)

	CREST		POTOMAC	
	S+BCG	*BCG*	*D+BCG*	*BCG*
CIS, N	88	88	125	125
Pure CIS, N (%) of those with CIS	52 (60%)	50 (52%)	31 (25%)	30 (24%)
Persistent CIS as EFS event, N (%)	2 (0.6%)	3 (0.9%)	1 (0.3%)	2 (0.6%)



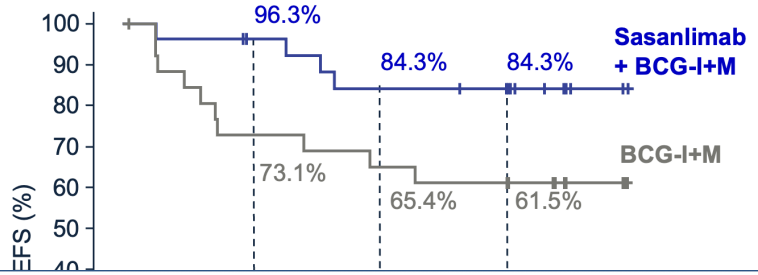


EFS prolongation was observed with sasanlimab + BCG-I+M in patients with CIS



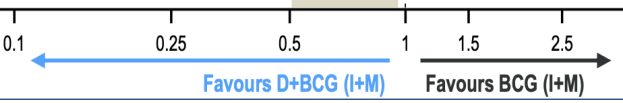
Shore ND, Guerrero-Ramos F, Nat Med 2025; Powles T, Guerrero-Ramos F, ASCO 2025

The risk of experiencing an EFS event was 66% lower with sasanlimab + BCG-I+M vs BCG-I+M



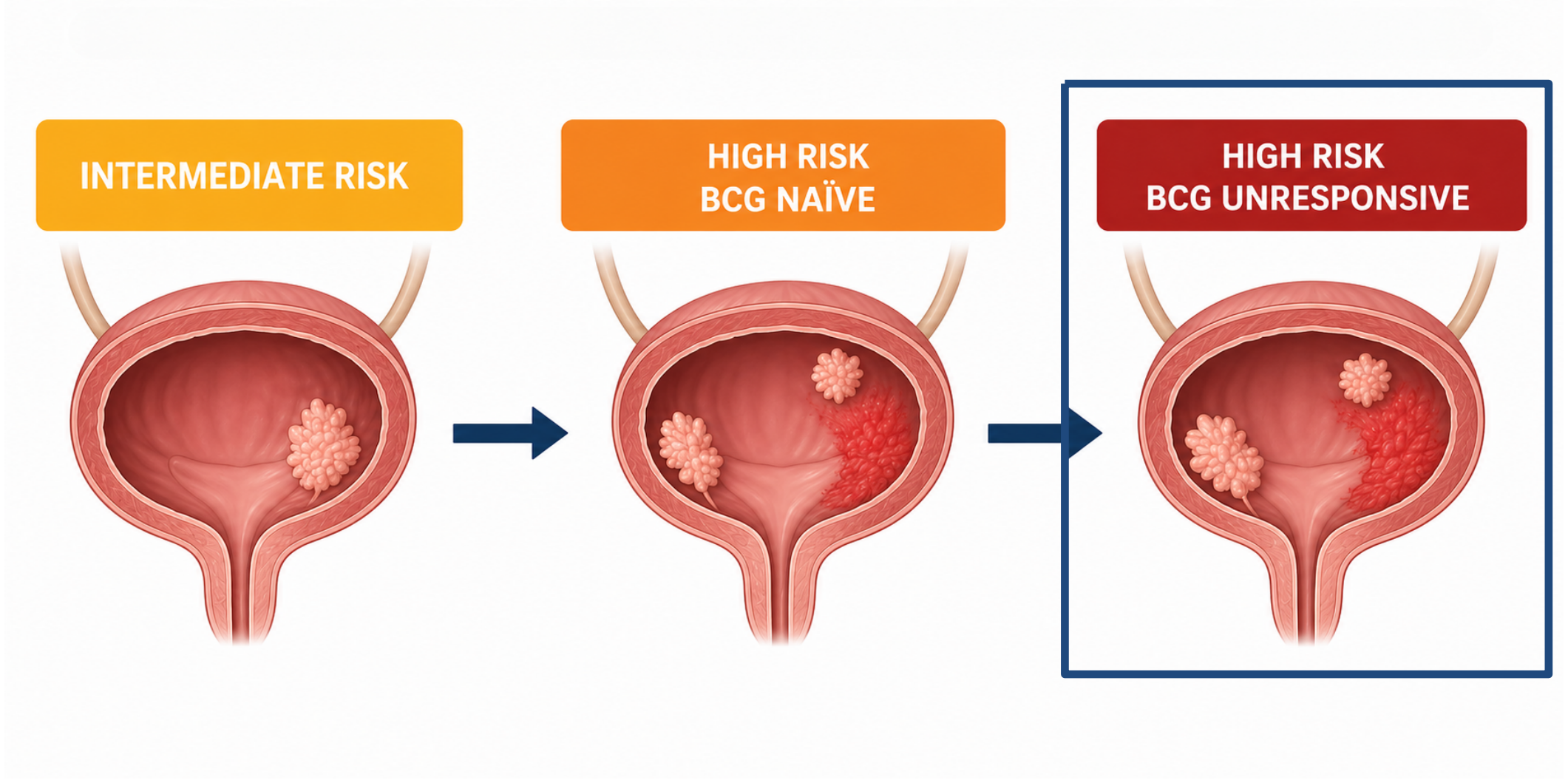
	Sasanlimab + BCG-I+M (n=28)	BCG-I+M (n=29)
Patients with EFS event, n (%)	4 (14.3)	10 (34.5)

Subgroup	Category	N	Hazard Ratio (95% CI)
All patients		679	0.68 (0.50–0.93)
Age	<65 years	258	0.74 (0.42–1.27)
	≥65 years	421	0.64 (0.44–0.93)
Sex	Male	547	0.59 (0.41–0.83)
	Female	132	1.21 (0.61–2.42)
Region	Western Europe	278	0.59 (0.36–0.95)
	Rest of world	401	0.75 (0.50–1.12)
ECOG PS	0	598	0.64 (0.45–0.90)
	1	81	0.77 (0.38–1.56)
Smoking status	Current	125	0.38 (0.17–0.80)
	Former	348	0.80 (0.52–1.22)
	Never	206	0.74 (0.41–1.31)
BCG strain	TICE®	162	0.68 (0.37–1.23)
	Other	513	0.66 (0.46–0.95)
CIS[a]	Yes	250	1.01 (0.62–1.64)
	No	429	0.53 (0.34–0.79)
Higher risk papillary disease[b]	Yes	346	0.54 (0.35–0.83)
	No	333	0.88 (0.56–1.38)
PD-L1 expression[c]	High (≥TC/IC25%)	166	0.50 (0.26–0.91)
	Low/negative	467	0.72 (0.48–1.05)
	Missing/not evaluable	46	NC (NC–NC)



Higher risk papillary disease was defined as T1G3/T1HG, or multiple AND recurrent AND tumor diameter ≥3 cm.

Xylinas E, Guerrero-Ramos F, EMUC 2025; De Santis M, Guerrero-Ramos F, Lancet 2025


INTERMEDIATE RISK
HIGH RISK
BCG NAÏVE
HIGH RISK
BCG UNRESPONSIVE

High

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Search

Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

Home > Medicines > Anktiva

Anktiva

nogapendekin alfa inbakicept

Medicine | Human

Share | RSS

Authorised

This medicine is authorised for use in the European Union

Agent,				≥MIBC
Pembr				
Nadofa				
BCG +				
TAR-20				

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Search

Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

Home > Medicines > Adstiladrin

Adstiladrin

nadofaragene firadenovec

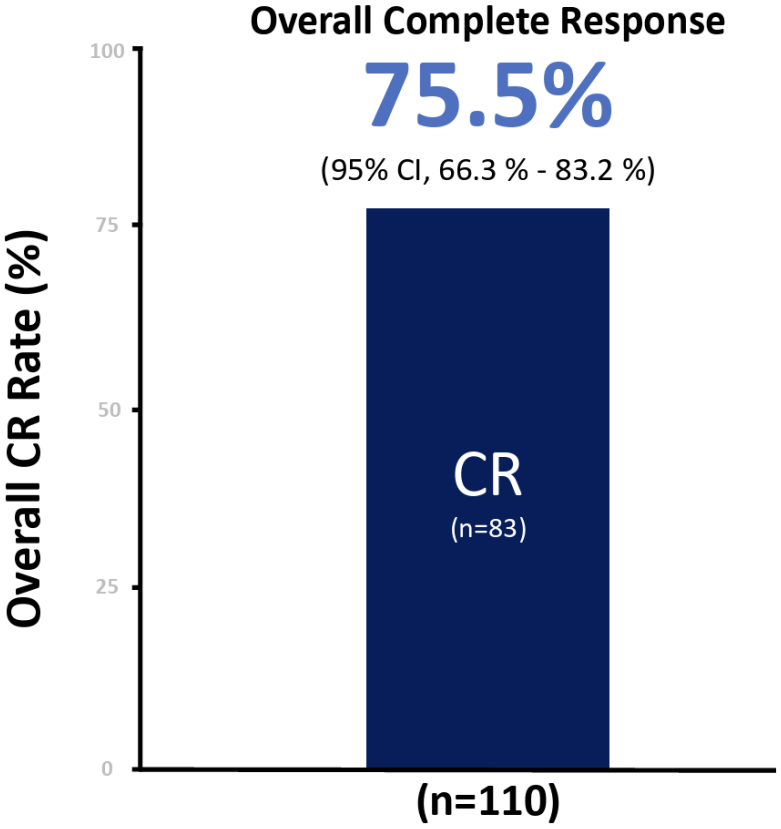
Medicine | Human

Share | RSS

Opinion

EMA has issued an opinion on this medicine

High risk BCG unresponsive – CIS



CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46.4%** (36.8, 56.1) *51 out of 110 patients*	**50.7%** (40.9, 59.8)
24-month	**41.8%** (32.5, 51.6) *46 out of 110 patients*	**42.4%** (32.7, 51.7)

- 96.4% (106/110) were free from progression to ≥ T2 disease
- 83.6% (92/110) did not undergo RC post recurrence or progression
  - Among RCs, 83.3% (15/18) were T0 or NMIBC
- All Complete Responses are centrally confirmed*
  - Local:Central concordance: 97.1% of assessments

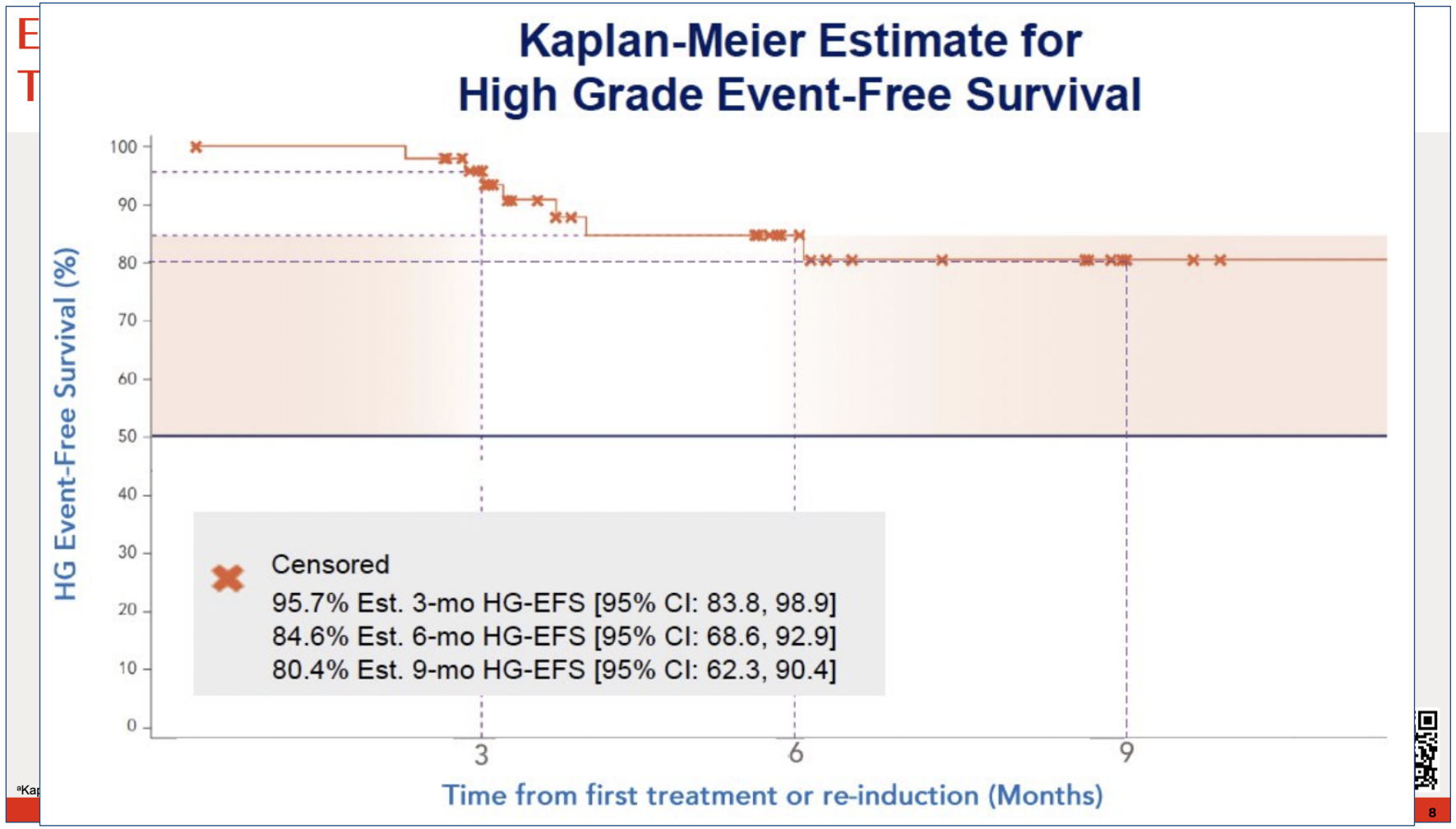
Efficacy data cutoff as of 23JUN2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance..
*CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy. In addition, all patients at 12-month timepoint undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR and detect potential occult disease in the bladder.
Analysis based on both landmark CR rate assessed in clinical trial and CR by Kaplan-Meier estimate.

Emory University School of Medicine
Department of Urology

Joshi SS, SESAUA 2026

@DrFelixGuerrero

High risk BCG unresponsive – papillary only



Vilaseca A, Guerrero-Ramos F, EAU 2026; Narayan V, SESAUA 2026

High risk BCG unresponsive – papillary only

MoonRISe-3: Phase 3 Study of TAR-210 vs Intravesical Chemotherapy in Patients With BCG-treated, *FGFR*-altered Papillary-only HR NMIBC

Key eligibility criteria

- Adults (aged ≥18 years)
- Histologically confirmed **papillary-only HR NMIBC**:
  - High-grade Ta
    —*or*—
    Any T1 (no CIS)
  - Recurrent after BCG
    —*or*—
    Intolerant of BCG
- ECOG performance status of ≤2
- Susceptible *FGFR* mutation or fusion by urine or tumor tissue testing

Stratification factors

- T stage (high-grade Ta or any T1)
- Prior BCG treatment (BCG unresponsive, experienced, or intolerant)
- Choice of intravesical chemotherapy

1:1
(N≈220)

R

TAR-210
(n≈110)
Treatment cycles for 2 years

Investigator's choice of single-agent intravesical chemotherapy
(n≈110)
MMC or gemcitabine
QW for 6 doses (induction) followed by Q4W for 1-2 years (maintenance)

Primary end point

- Disease-free survival

Key secondary end points

- Recurrence-free survival
- Time to next intervention
- Time to disease worsening
- Time to progression
- Overall survival
- Safety and tolerability

NCT06919965

Porten S, Guerrero-Ramos F, SUO 2024; Shore N, Guerrero-Ramos F, AUA 2025

¡Muchas gracias!

felixguerrero@gmail.com

@DrFelixGuerrero