

Year in Review in GU Oncology – A Urologist's perspective



BMUC

UROLOGY - RADIATION ONCOLOGY - MEDICAL ONCOLOGY

**YEAR IN REVIEW
IN GU ONCOLOGY
MEETING 2025**

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New landscape in NMIBC

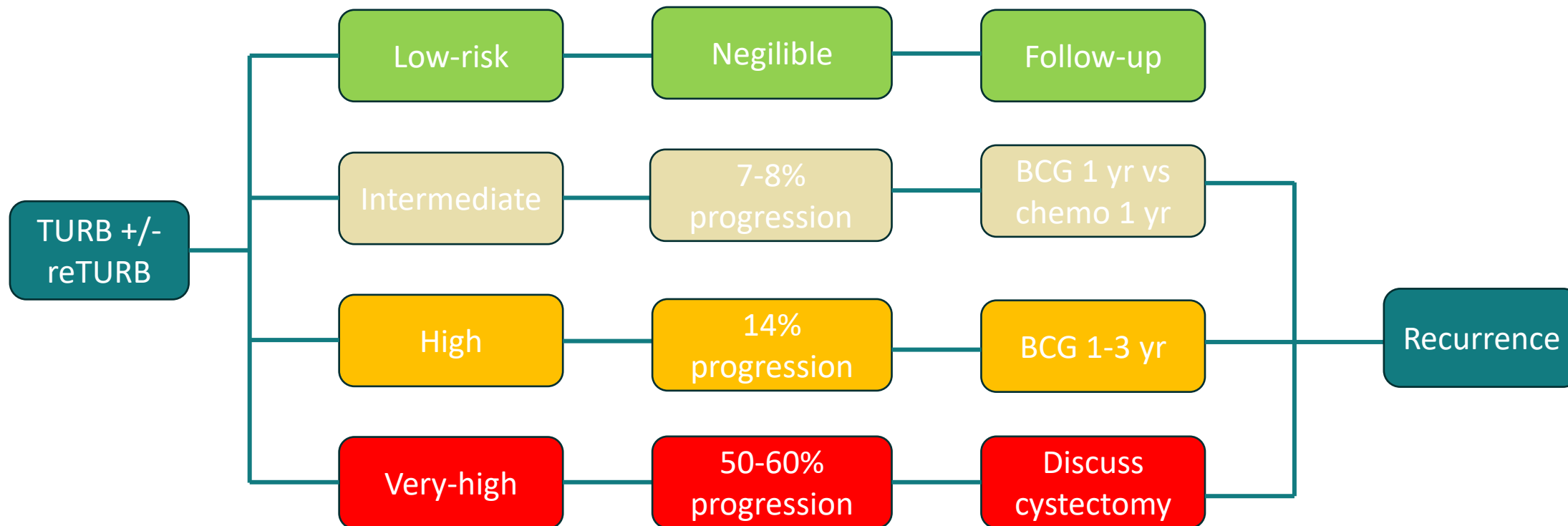
BCG naïve

BCG
unresponsive

New landscape in MIBC

Cost-effectiveness

SoC BCG Naïve



NMIBC – Novel options – BCG naive



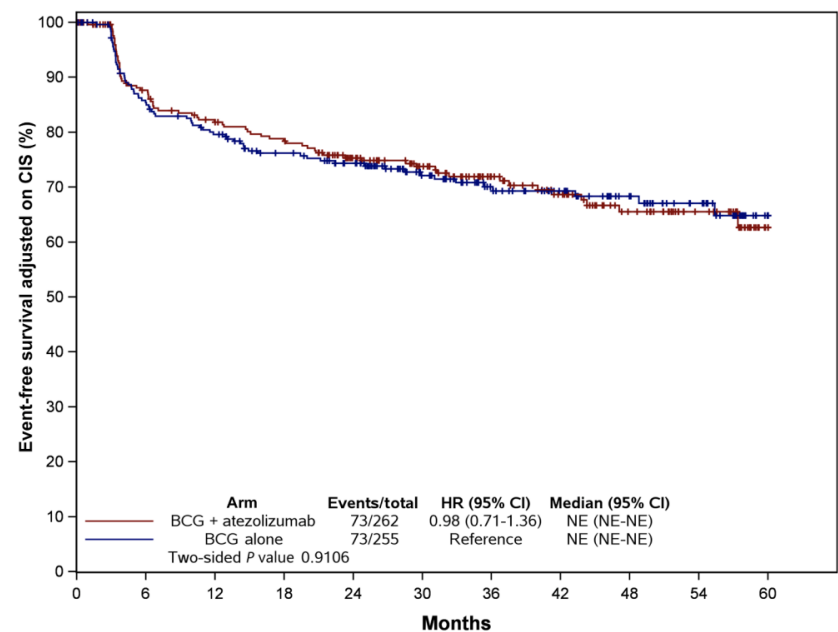
	ALBAN ¹	CREST ²	POTOMAC ³
N=	517 (255 vs 262)	1055 (352 vs 352 vs 351)	1018 (339 vs 339 vs 340)
Design	BCG I + M (control) BCG I + M + 1 yr Atezo (PDL-1)	BCG I + M (control) BCG I + 2 yr sasanlimab BCG I + M + 2 yr sasanlimab (PD-1)	BCG I + M (control) BCG I + 1 y Durvalumab BCG I + M + 1 yr Durvalumab (PDL-1)
Mechanism of Action	Anti PDL-1	Anti PD-1	Anti PDL-1
BCG duration	1 yr	1-3 yrs	2 yr
Mandatory biopsies	No	Yes	No
Median FU (mo)	35	36.3	60.7
Number of BCG instillations	14 (BCG 1 yr)	18/21 (BCG 1-3 yr)	14
Primary endpoint	2-yr EFS = HG/LG relapse, CIS at 6 mo, progression, UTUC, N+, M+, Death	3-yr EFS = HG recurrence, progression, persistent CIS, Death	DFS = recurrence of high-risk disease (HG recurrence, CIS at 6 mo, progression, N/M+, death)
>Grade II TRAEs	9% vs 23%	6% vs 22% vs 29%	4% vs 15% vs 21%
Events	29% vs 28% (HR 0.98) (p=0.91)	25% vs 18% (HR 0.68) (p=0.01)	29% vs 20% (HR 0.68) (p=0.015)
FDA/EMA approval	No	No	No

Novel treatment options for BCG Naïve



ALBAN Trial (Atezolizumab) – Primary outcomes

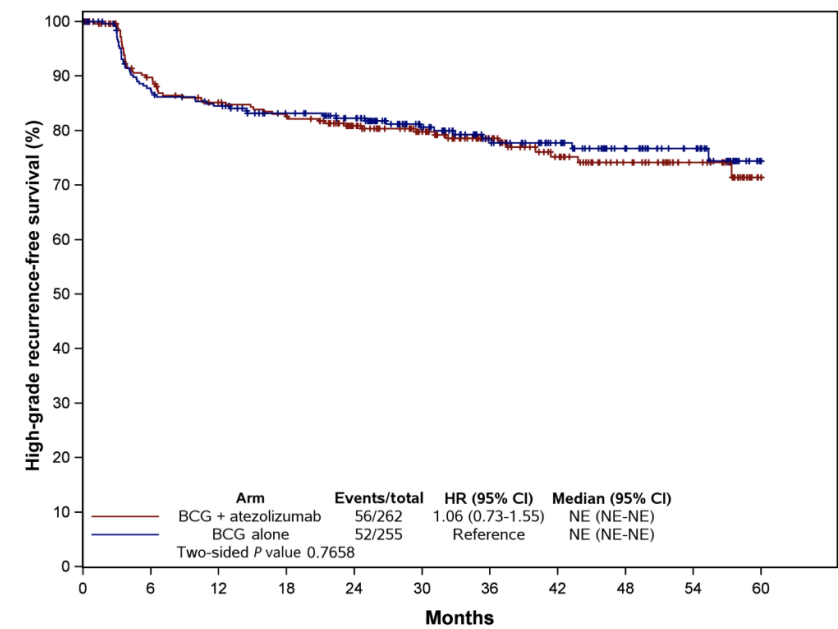
Event-free survival



No. at risk (No. of cumulative events)

BCG + atezolizumab	262 (0)	212 (30)	193 (44)	184 (52)	157 (59)	129 (62)	97 (65)	78 (69)	55 (72)	35 (72)	2 (73)
BCG alone	255 (0)	208 (36)	190 (50)	169 (58)	155 (62)	116 (66)	90 (69)	73 (70)	55 (71)	38 (72)	6 (73)

High-grade Event-free survival



No. at risk (No. of cumulative events)

BCG + atezolizumab	262 (0)	217 (25)	200 (36)	193 (42)	168 (46)	138 (48)	103 (50)	80 (54)	59 (55)	38 (55)	4 (56)
BCG alone	255 (0)	213 (31)	202 (38)	184 (41)	169 (43)	129 (46)	100 (49)	80 (50)	58 (51)	42 (51)	6 (52)

No difference

Novel treatment options for BCG Naïve



ALBAN Trial – Types of events

value	Total (n=146)	BCG alone (n=73)	BCG + Atezolizumab
Local recurrence	122 (83.6%)	60 (82.2%)	62 (84.9%)
Locoregional recurrence	6 (4.1%)	3 (4.1%)	3 (4.1%)
Distant recurrence	3 (2%)	2 (2.7%)	1 (1.4%)
UTUC	2 (1.4%)	2 (2.7%)	0 (0.0%)
Death	13 (8.9%)	6 (8.2%)	7 (9.6%)

No meaningful difference

Novel treatment options for BCG Naïve



ALBAN Trial – Adverse events

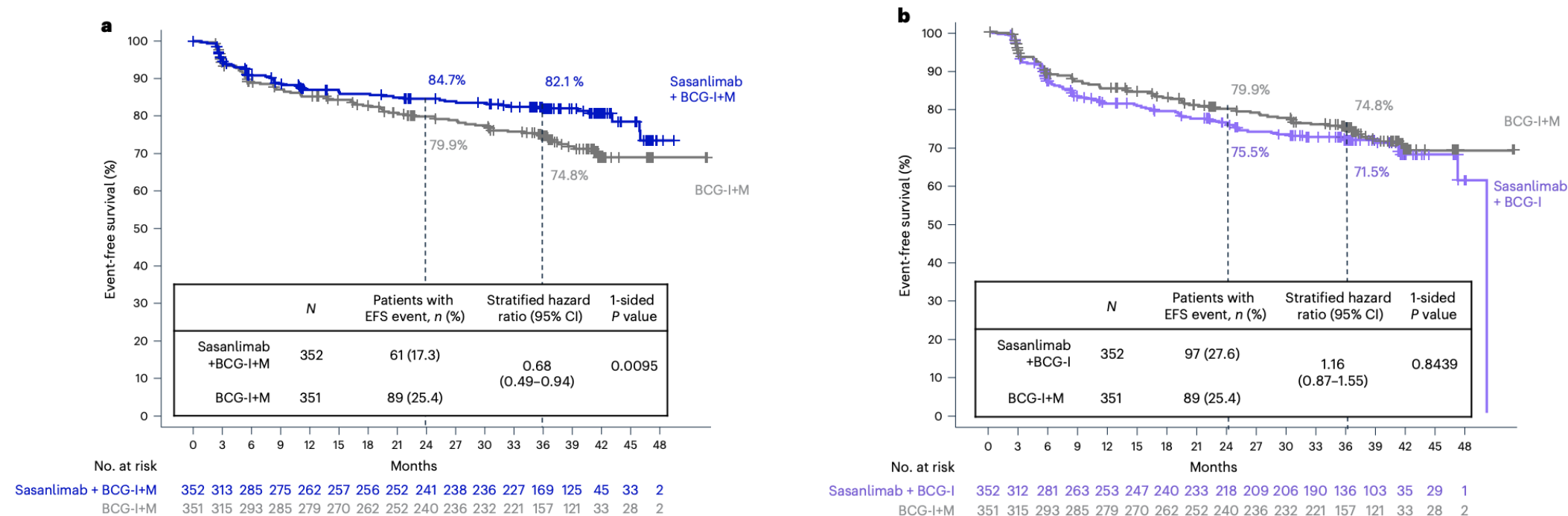
value	BCG alone (n=250)	BCG + Atezolizumab (n=255)
Grade >2 AEs	59 (23.6%)	102 (40.0%)
Grade >2 TRAEs	22 (8.8%)	58 (22.7%)
Serious TRAEs	21 (8.4%)	60 (23.5%)
BCG withdrawal	22 (8.8%)	32 (12.5%)
Atezolizumab withdrawal	0 (0.0%)	41 (16.1%)
BCG + Atezo withdrawal	0 (0.0%)	8 (3.1%)

2-3x more side effects (mainly Arthralgia, fatigue, pollakisuria, pruritus, rash, thyroiditis, UTI)
More patients withdrew from BCG when treated with BCG + Atezolizumab

Novel treatment options for BCG Naïve



CREST trial – Primary outcomes



Statistically significant and clinically meaningful difference – BCG Induction + Maintenance remains important

Novel treatment options for BCG Naïve



CREST trial – Primary outcomes

	Sasanlimab + BCG I + M (n=352)	Sasanlimab + BCG I (n=352)	BCG I+M (=351)
EFS event	61 (17.3%)	97 (27.6%)	89 (25.4%)
Progressive disease	18 (5.1%)	14 (4.0%)	22 (6.3%)
Progression to N+ or M+	3 (0.01%)	2 (0.01%)	7 (0.02%)
Progression to MIBC	7 (0.02%)	3 (0.01%)	7 (0.02%)
Stage progression	7 (0.02%)	9 (0.03%)	7 (0.02%)
Recurrence of high-grade disease	26 (7.4%)	61 (17.3%)	53 (15.1%)
Persistence of CIS	1 (0.3%)	2 (0.6%)	1 (0.3%)

Event-free survival solely driven by local recurrences (both low-grade and high-grade)

Novel treatment options for BCG Naïve



CREST trial – Adverse events

	Sasanlimab + BCG I + M (n=350)	Sasanlimab + BCG I (n=348)	BCG I+M (=349)
Grade >2 AEs	171 (48.9%)	114 (40.5%)	90 (25.8%)
Grade >2 TRAEs	102 (29%)	76 (22%)	22 (6%)
Serious AEs	120 (34.3%)	99 (28.4%)	49 (14%)
Serious TRAEs	62 (17.7%)	43 (12.4%)	5 (1.4%)
Stop of Sasanlimab	92 (26.3%)	58 (16.7%)	-
Stop of BCG	59 (16.9%)	8 (2.3%)	30 (8.6%)
Grade >2 irAE	55 (15.7%)	49 (14.1%)	0

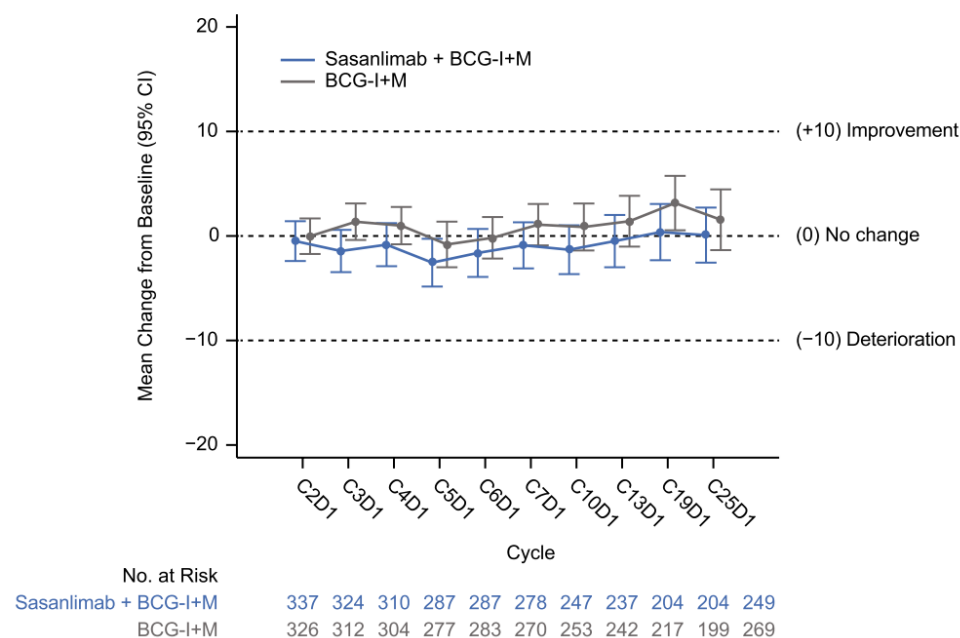
2-5x more side-effects

Impact of increased BCG withdrawal due to Sasanlimab

Novel treatment options for BCG Naïve



CREST trial – QoL



**“It doesn't matter what answers
you get if you ask the wrong
questions”**

Jim Thompson

**No statistically significant difference in QoL,
but trend towards better with BCG alone**

Novel treatment options for BCG Naïve



CREST trial – QoL

Global health status / QoL

Global health status/QoL (revised)[†]

Functional scales

Physical functioning (revised)[†]

Role functioning (revised)[†]

Emotional functioning

Cognitive functioning

Social functioning

Symptom scales / items

Fatigue

~~Nausea and vomiting~~

~~Pain~~

~~Dyspnoea~~

~~Insomnia~~

~~Appetite loss~~

~~Constipation~~

~~Diarrhoea~~



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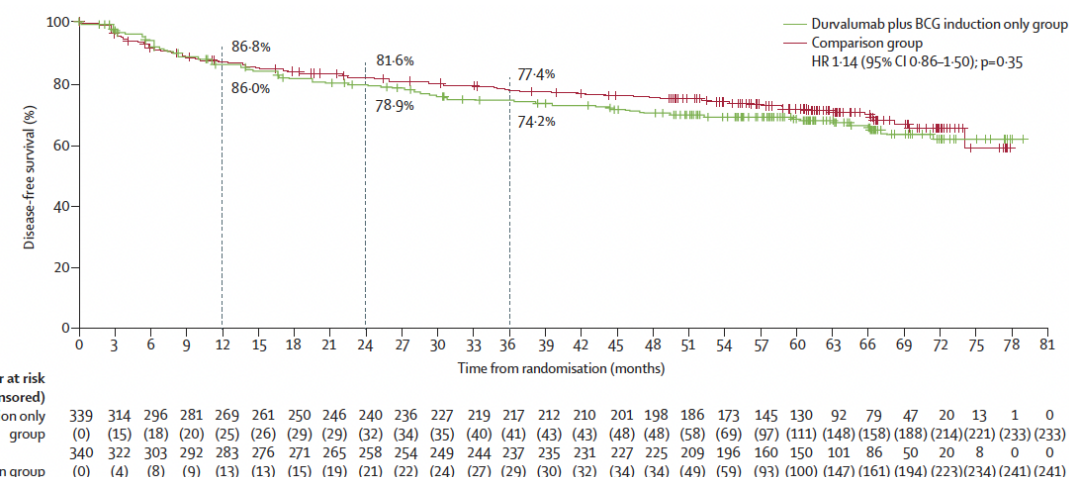
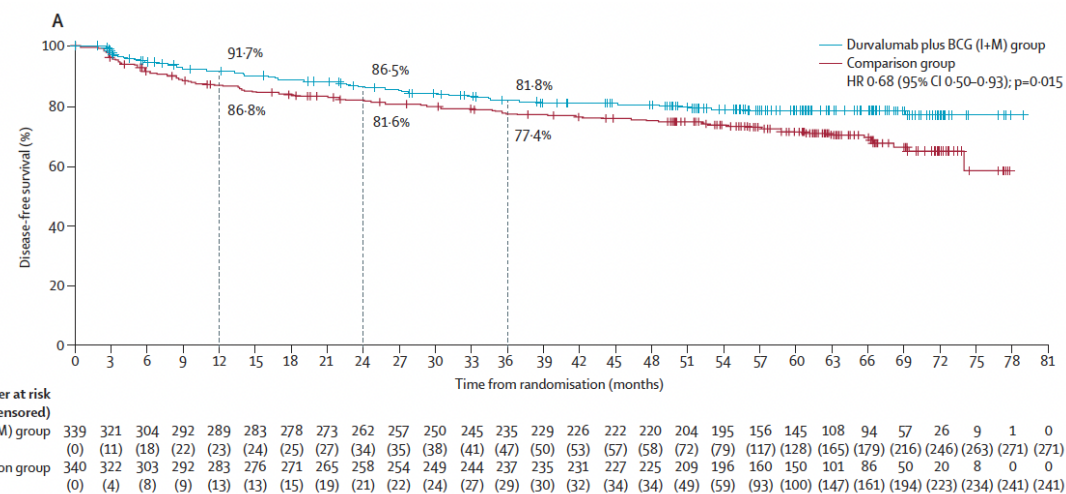
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Novel treatment options for BCG Naïve



POTOMAC – Primary outcomes



Statistically significant en clinically meaningful difference – BCG Induction + Maintenance remains important

Novel treatment options for BCG Naïve



POTOMAC – Primary outcomes

	Durvalumab + BCG I + M (n=339)	Durvalumab + BCG I (n=339)	BCG I+M (n=340)
EFS event	67 (19.8%)	105 (31.0%)	98 (28.8%)
High-risk disease recurrence	53 (15.6%)	87 (25.7%)	69 (20.3%)
High-risk NMIBC	36 (10.6%)	71 (20.9%)	52 (15.3%)
MIBC and/or M+	16 (4.7%)	13 (3.8%)	15 (4.4%)
Persistent CIS	1 (0.3%)	3 (0.9%)	2 (0.6%)

Event-free survival solely driven by local recurrences (both low-grade and high-grade)

Novel treatment options for BCG Naïve



POTOMAC – Adverse events

	Durvalumab + BCG I + M (n=336)	Durvalumab + BCG I (n=337)	BCG I+M (=339)
Grade >2 AEs	113 (34%)	90 (27%)	56 (17%)
Grade >2 TRAEs	71 (21%)	52 (15%)	13 (4%)
Serious AEs	108 (32%)	82 (24%)	63 (19%)
Serious TRAEs	45 (13%)	38 (11%)	13 (4%)
Stop R/ related to durvalumab	54 (16%)	44 (13%)	0 (0%)
Stop R/ related to BCG	55 (16%)	15 (4%)	55 (16%)
Stop R/ due to one or both	109 (32%)	49 (17%)	55 (16%)

2-5x more side-effects

Impact of increased BCG withdrawal due to Sasanlimab

Novel treatment options for BCG Naïve



POTOMAC – Adverse events – Can they be easily resolved?

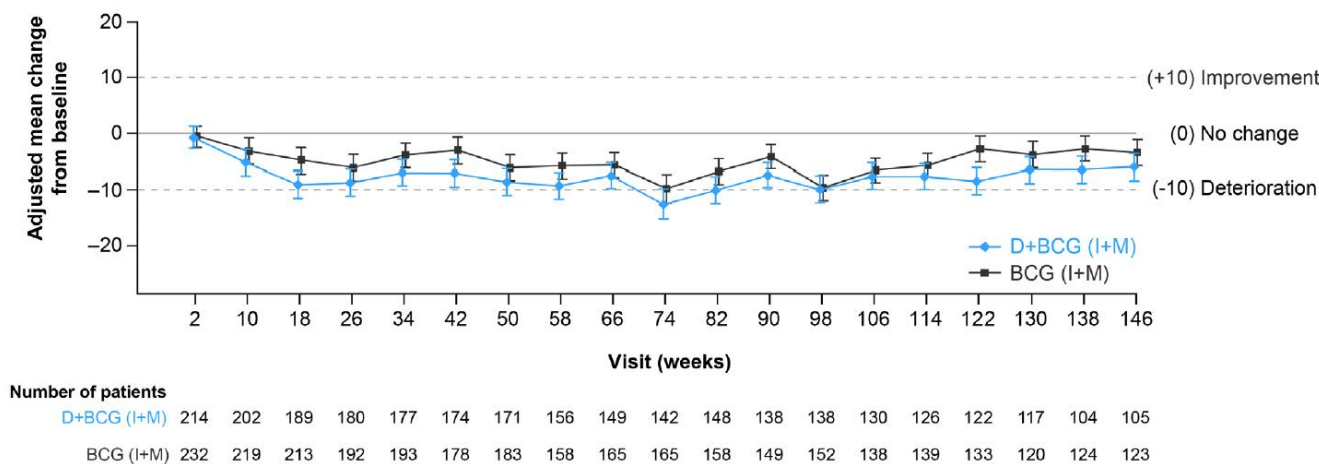
	Durvalumab + BCG I + M (n=336)	Durvalumab + BCG I (n=337)	BCG I+M (=339)
Any immune-mediated AE	91 (27.1%)	113 (33.5%)	4 (1.2%)
Received corticosteroids	55 (60.4%)	55 (48.7%)	3 (75.0%)
Endocrine therapy	49 (53.8%)	72 (63.7%)	1 (25%)
Other immunosuppressants	5 (5.5%)	4 (3.5%)	0
Resolved	43 (47.3%)	54 (47.8%)	2 (50%)
Resolved with sequelae	3 (3.3%)	6 (5.3%)	0
Resolving	15 (16.5%)	17 (15.0%)	1 (25%)
Not resolved	30 (33%)	36 (31.9%)	1 (25%)

14.2% VS 17.5% VS 0.01% of immune related side effects that are not resolved at end of study

Novel treatment options for BCG Naïve



POTOMAC – QoL

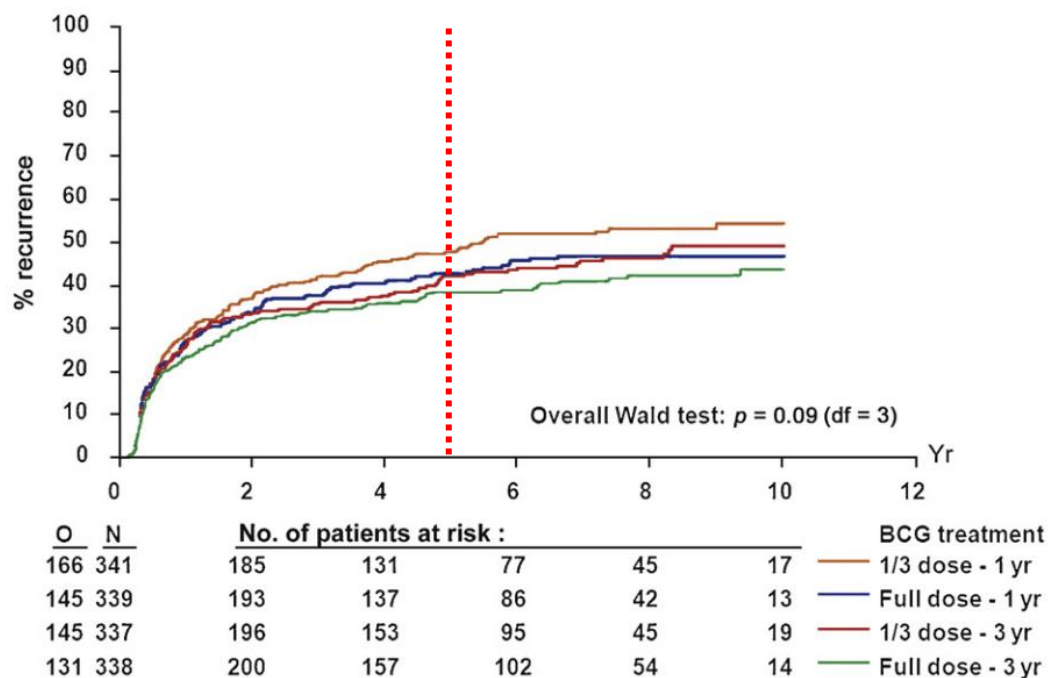


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Novel treatment options for BCG Naïve



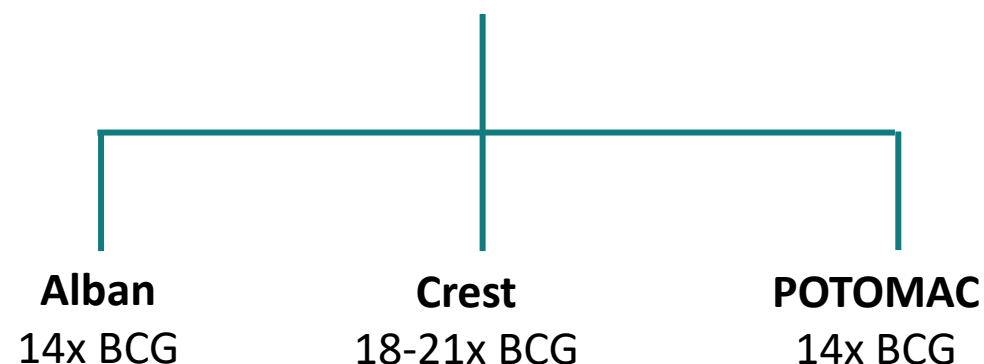
ALBAN / CREST / POTOMAC all agree:
BCG Induction and Maintenance remains essential



5-yr disease free rate:

- 1/3 dose 1 yr: 54.5%
 - 3/3 dose 1 yr: 58.8%
 - 1/3 dose 3 yr: 62.6%
 - 3/3 dose 3 yr: 64.2%
- ARR: 8.1% (for 1/3 dose 1 yr vs 3/3 dose 1 yr)
ARR: 5.4% (for 1/3 dose 3 yr vs 3/3 dose 3 yr)

With 35% of patients completing 3 yrs (= 27x BCG)



Novel treatment options for BCG Naïve



Conclusions

- 3 well conducted RCTs on the role of treatments targeting PD1/PDL1
- 1 negative, 2 positive
- What now?

Novel treatment options for BCG Naïve



Conclusions

- **Conclusions of 2 positive trials**
 - Statistically significant and clinically meaningful with 5-7% reduction of recurrence at 2/3 years: Do you agree?

Novel treatment options for BCG Naïve



Conclusions

- **Conclusions of 2 positive trials**
 - Statistically significant and clinically meaningful with 5-7% reduction of recurrence at 2/3 years: Do you agree? **I do not (effect due to undertreatment with BCG?)**

Novel treatment options for BCG Naïve



Conclusions

- **Conclusions of 2 positive trials**
 - Statistically significant and clinically meaningful with 5-7% reduction of recurrence at 2/3 years: Do you agree? **I do not (effect due to undertreatment with BCG?)**
 - The treatments had a tolerable en manageable toxicity profile: Do you agree?

Novel treatment options for BCG Naïve



Conclusions

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Novel treatment options for BCG Naïve



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- No impact on OS
- No data (yet) on time to cystectomy

Novel treatment options for BCG Naïve



Conclusions

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- No impact on OS
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- BCG maintenance remains important: Do you agree? **I do – rinse hard and long**

Novel treatment options for BCG Naïve



Conclusions

- **Conclusions of 2 positive trials**

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- No impact on OS
- No data (yet) on time to cystectomy
- BCG maintenance remains important: Do you agree? **I do – rinse hard and long**

Final opinion: Limited benefit, too toxic, I hope no FDA/EMA approval will follow



New landscape in NMIBC

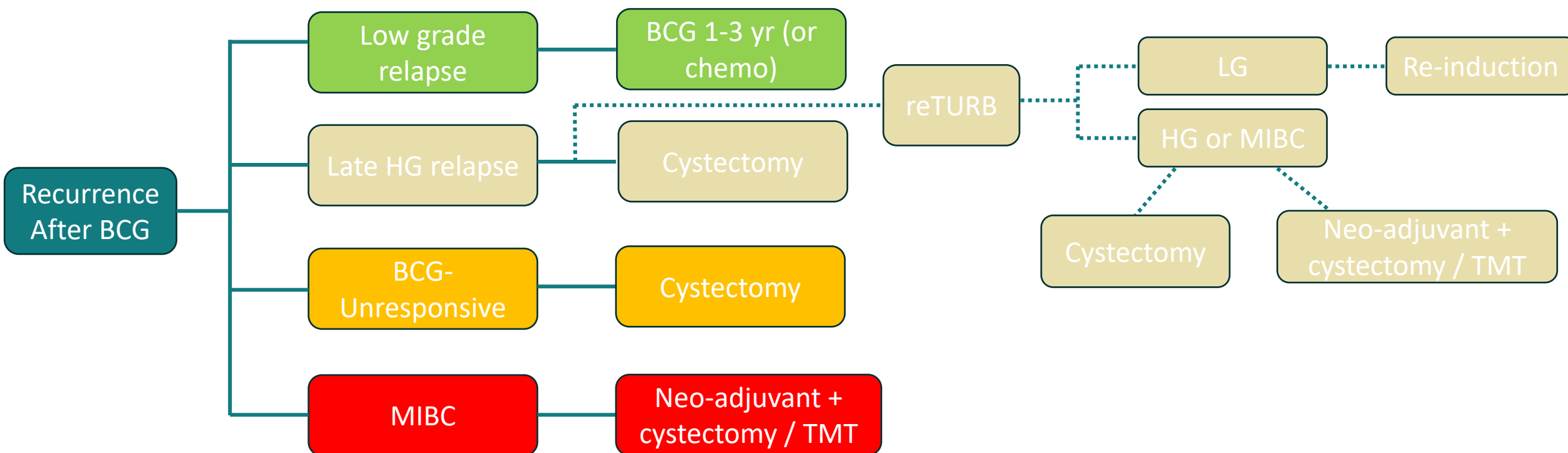
BCG naïve

BCG
unresponsive

New landscape in MIBC

Cost-effectiveness

SoC BCG unresponsive



Unmet need: Additional therapies reducing the risk of progression and need for cystectomy / TMT

NMIBC – Novel options – BCG Unresponsive

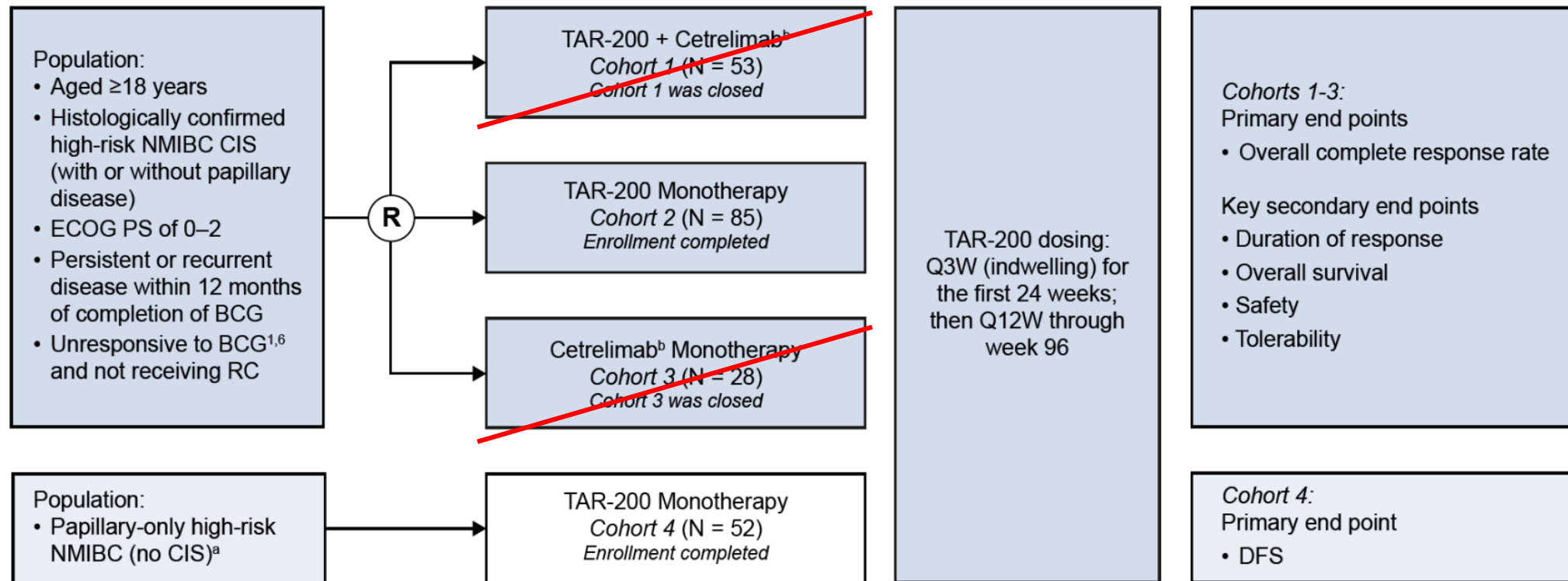


FDA Approved				...
Immune checkpoint inhibition via Pembrolizumab (January 2020) ¹	Viral gene transfer nadofaragene firadenovec (December 2022) ²	IL-15 superagonist Nogapendekin alfa Inbakicept-pmi-In (April 2024) ³	Sustained release of gemcitabine via TAR-200 Sunrise-1 (September 2025) ⁴	Gemcitabine/Docetaxel Intravesical Therapy
EMA Approved	...	...	...	...
No reimbursement	...	...	...	Niet als specifieke combinatie, wel beide als cytostaticum
	Very promising		Very promising	Forgotten?

NMIBC – Novel options – BCG Unresponsive



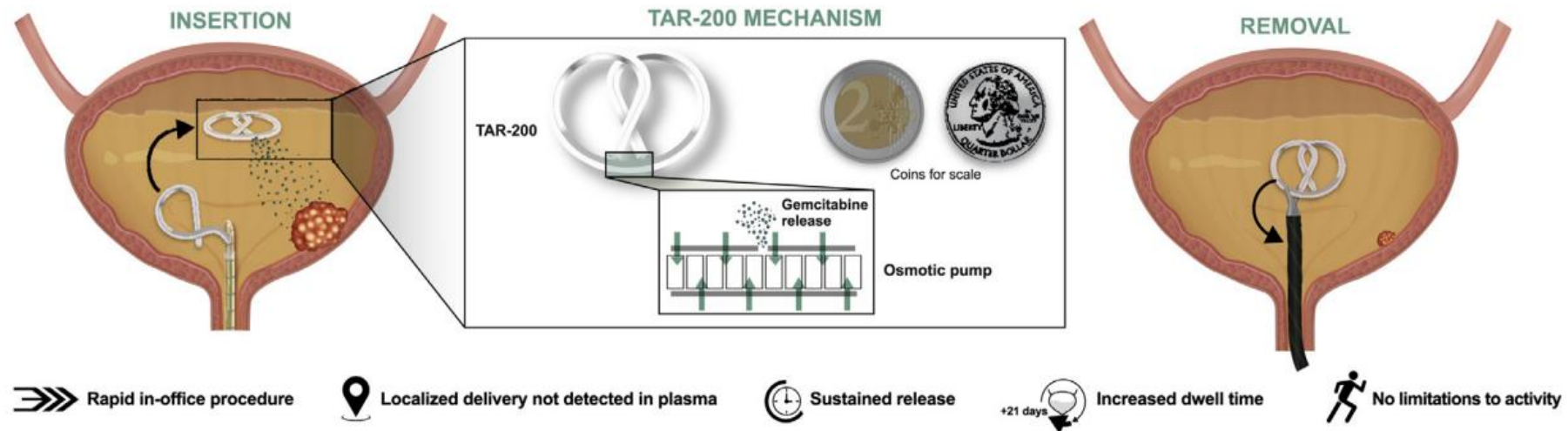
Sunrise-1 study



NMIBC – Novel options – BCG Unresponsive



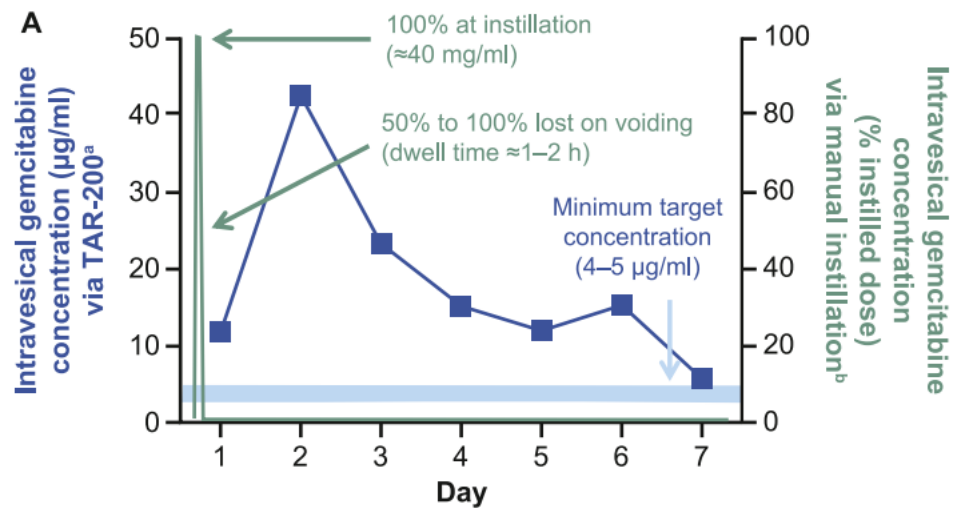
Sunrise-1 study



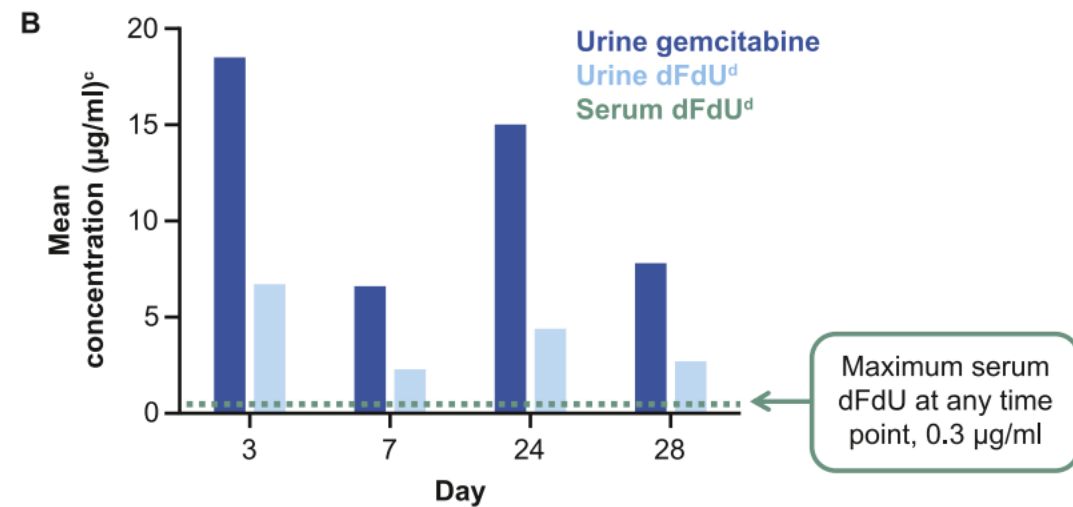
NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study



Prolonged exposure

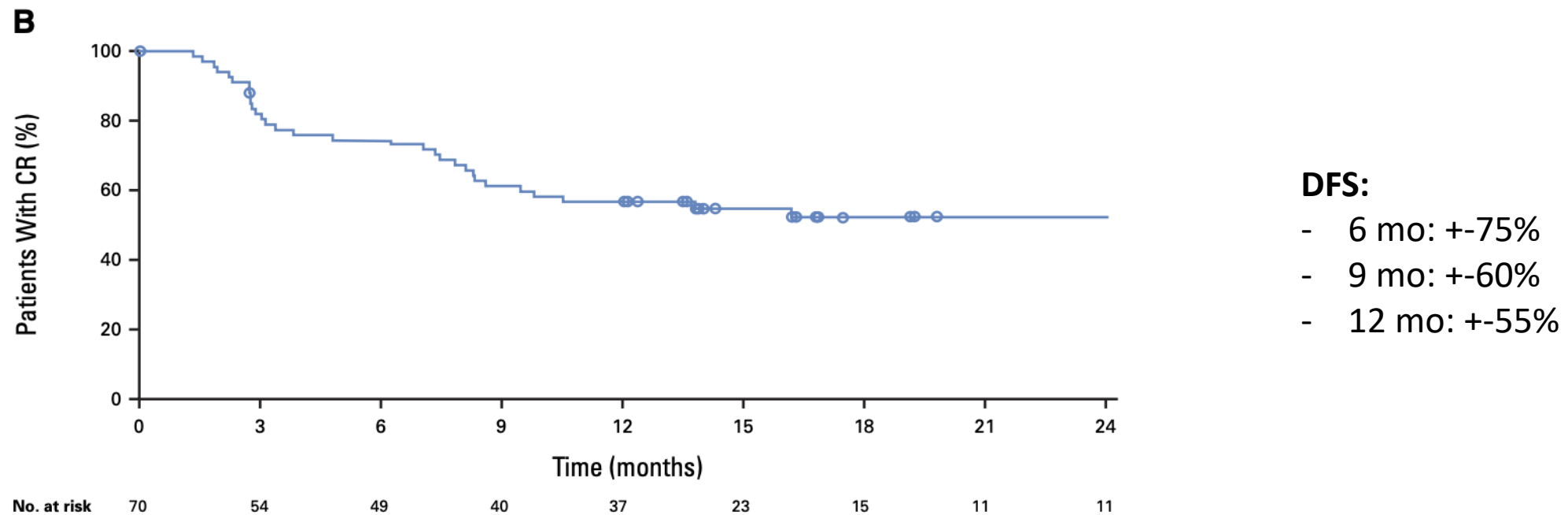


No systemic uptake

NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study – Cohort 2

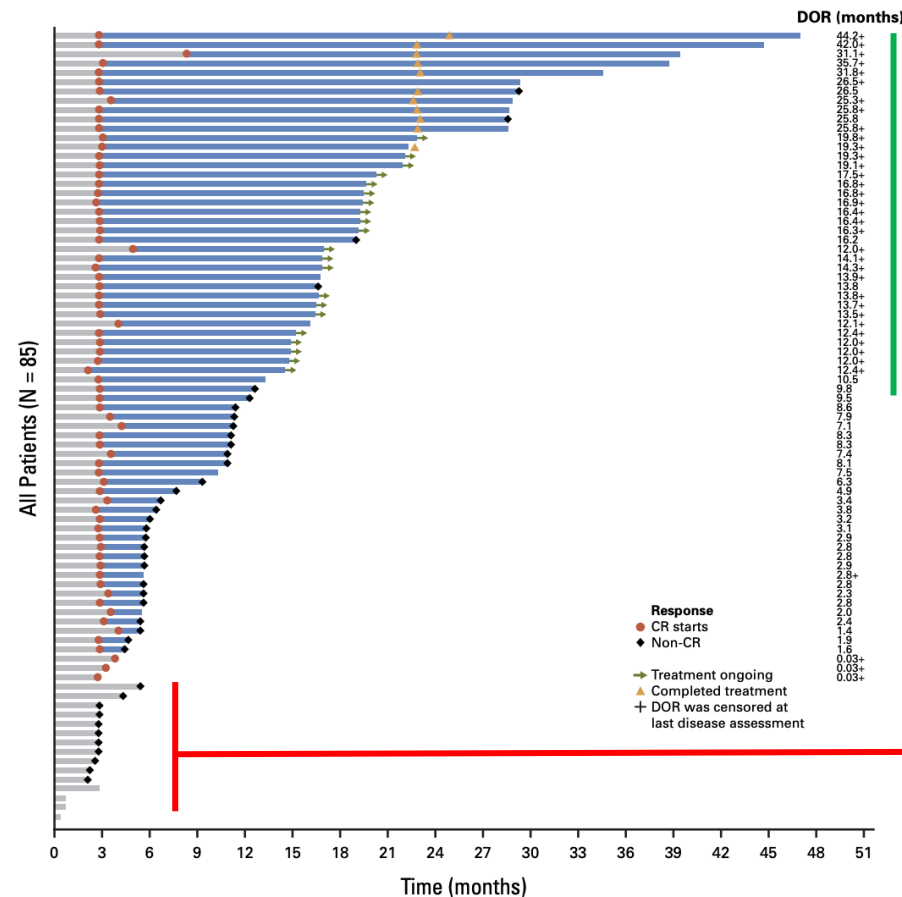


Recurrence-free survival – CAVE: KM only for responders

NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study – Cohort 2



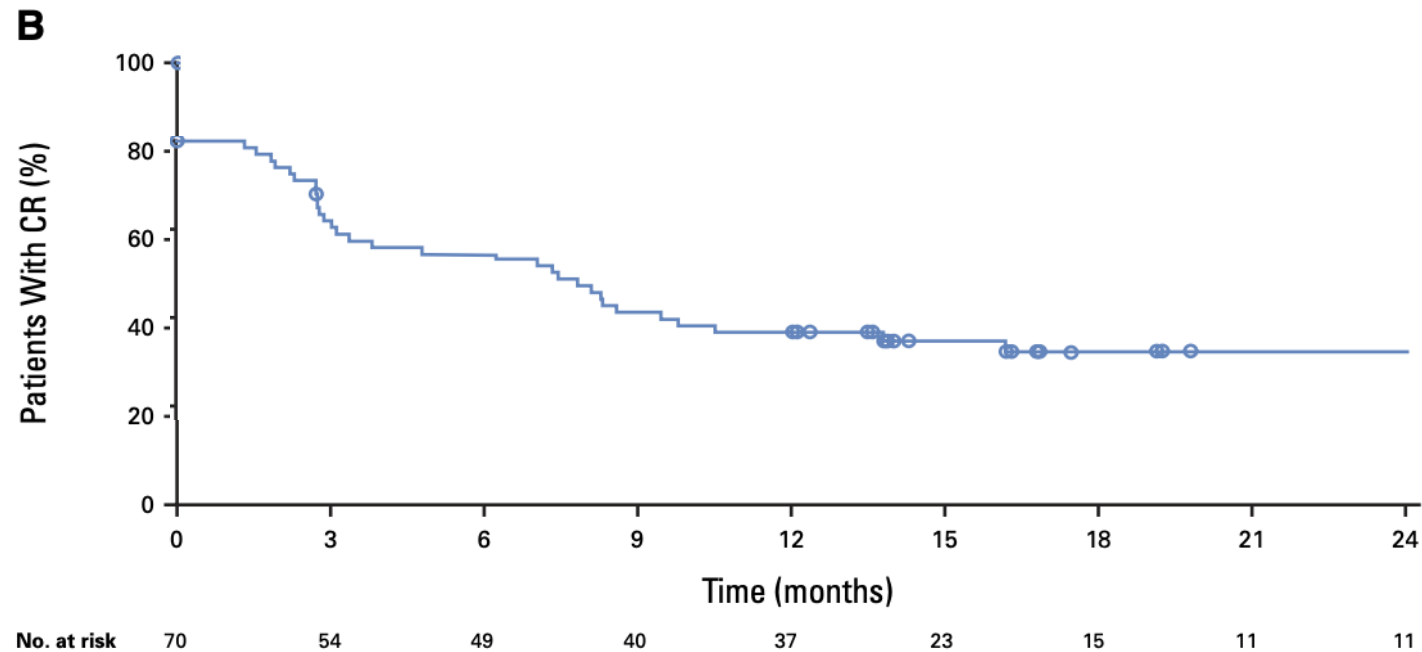
Long-term response seems durable

These patients not included in KM analysis

NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study – Cohort 2



RFS:

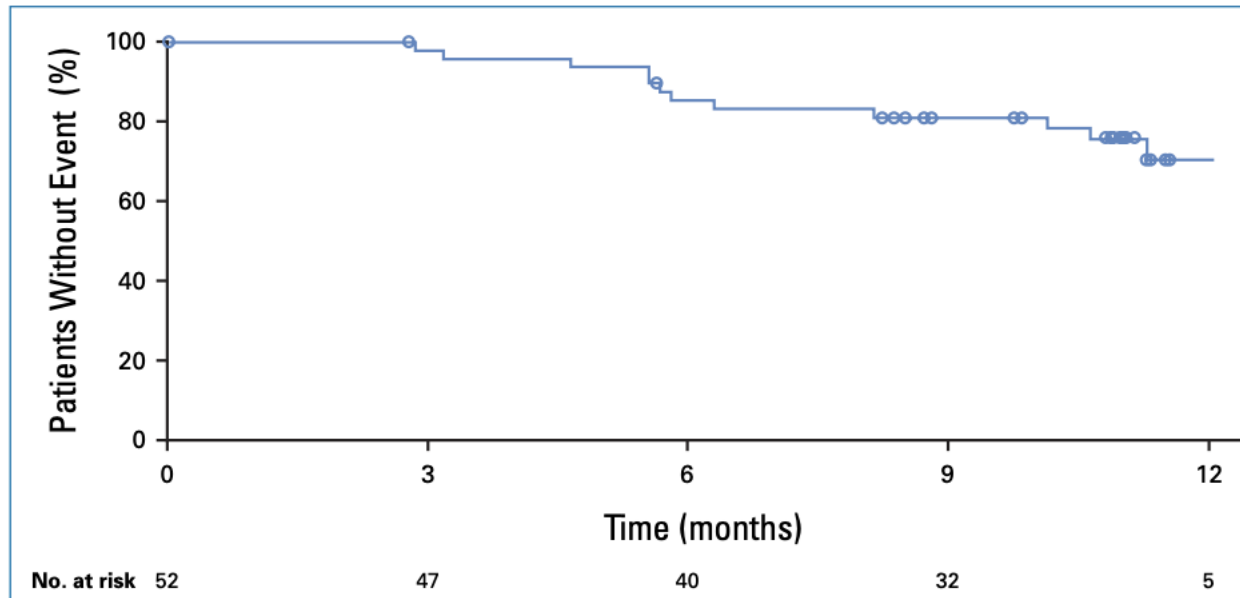
- 6 mo: +- 55%
- 9 mo: +-42%
- 12 mo: +-38%

Recurrence-free survival – How it should look

NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study – Cohort 4



DFS:

- 6 mo: 85.3%
- 9 mo 81.1%
- 12 mo: 70.2%

Event-free survival

NMIBC – Novel options – BCG Unresponsive



Sunrise-1 study – AEs

Cohort 2: TAR-200 Monotherapy (N = 85) ^a					
Patients With ≥1 Event	Any Grade, No. (%)	Grade ≥3, No. (%)			
Treatment-related AEs ^b	71 (83.5)	11 (12.9) ^c			
Most frequent treatment-related AEs ^d					
Pollakiuria	37 (43.5)	0	Urinary retention	4 (4.7)	1 (1.2)
Dysuria	34 (40.0)	0	Cystitis	3 (3.5)	1 (1.2)
Micturition urgency	21 (24.7)	0	Lower urinary tract symptoms	3 (3.5)	0
UTI	18 (21.2)	1 (1.2)	Pelvic pain	3 (3.5)	0
Hematuria	14 (16.5)	0	Abdominal pain	2 (2.4)	0
Urinary tract pain	9 (10.6)	4 (4.7)	Abdominal pain lower	2 (2.4)	0
Bladder pain	7 (8.2)	2 (2.4)	Asthenia	2 (2.4)	0
Bladder spasm	7 (8.2)	0	Constipation	2 (2.4)	0
Noninfective cystitis	6 (7.1)	0	Fatigue	2 (2.4)	0
Urinary incontinence	5 (5.9)	0	Penile pain	2 (2.4)	0
Nocturia	4 (4.7)	0	Perineal pain	2 (2.4)	0
Urethral pain	4 (4.7)	0	Urethral injury	2 (2.4)	0
Urinary retention	4 (4.7)	1 (1.2)	Vulvovaginal pain	2 (2.4)	0
			Treatment-related AEs leading to TAR-200 interruption ^e	27 (31.8) ^f	
			Treatment-related AEs leading to TAR-200 discontinuation	3 (3.5) ^g	

NMIBC – Novel options – BCG Unresponsive



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	Very promising		Very promising	Forgotten?

NMIBC – Novel options – BCG Unresponsive



Do not forget about the past

Sequential Intravesical Gemcitabine and Docetaxel for the Salvage Treatment of Non-Muscle Invasive Bladder Cancer

[Ryan L Steinberg](#)¹, [Lewis J Thomas](#)¹, [Michael A O'Donnell](#)^{1,*}, [Kenneth G Nepple](#)¹

► Author information ► Copyright and License information

PMCID: PMC6218180 PMID: [30561441](#)

- Pilot study: 45 patiënten refractair aan intravesicale therapie
- 12 mo recurrence free survival: 50-55%
- 24 mo recurrence free survival: +- 30%

Clinical-Bladder cancer

Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for non-muscle invasive bladder cancer

[Phani T. Chevuru](#) M.D. ^{a #}, [Ian M. McElree](#) B.S. ^{a #}, [Sarah L. Mott](#) M.S. ^c, [Ryan L. Steinberg](#) M.D. ^b, [Michael A. O'Donnell](#) M.D. ^b, [Vignesh T. Packiam](#) M.D. ^b  

- 97 patiënten, retrospective
- 5-yr: 30% free of high-grade recurrence
- 5-yr: 70% progression free survival
- 5-yr: 75% cancer specific survival

NMIBC – Novel options – BCG Unresponsive



The future seems bright for BCG unresponsive disease

- For now none of the new therapies EMA approved
- In case of approval, which one will be the preferred one?
- Could sequencing therapies further postpone the need for cystectomy?
- Do not forget about Gem-Doc intravesical therapy in patients refusing SoC treatment (cystectomy)

But will we (and our government) be able to pay for all these new treatments?



New landscape in NMIBC

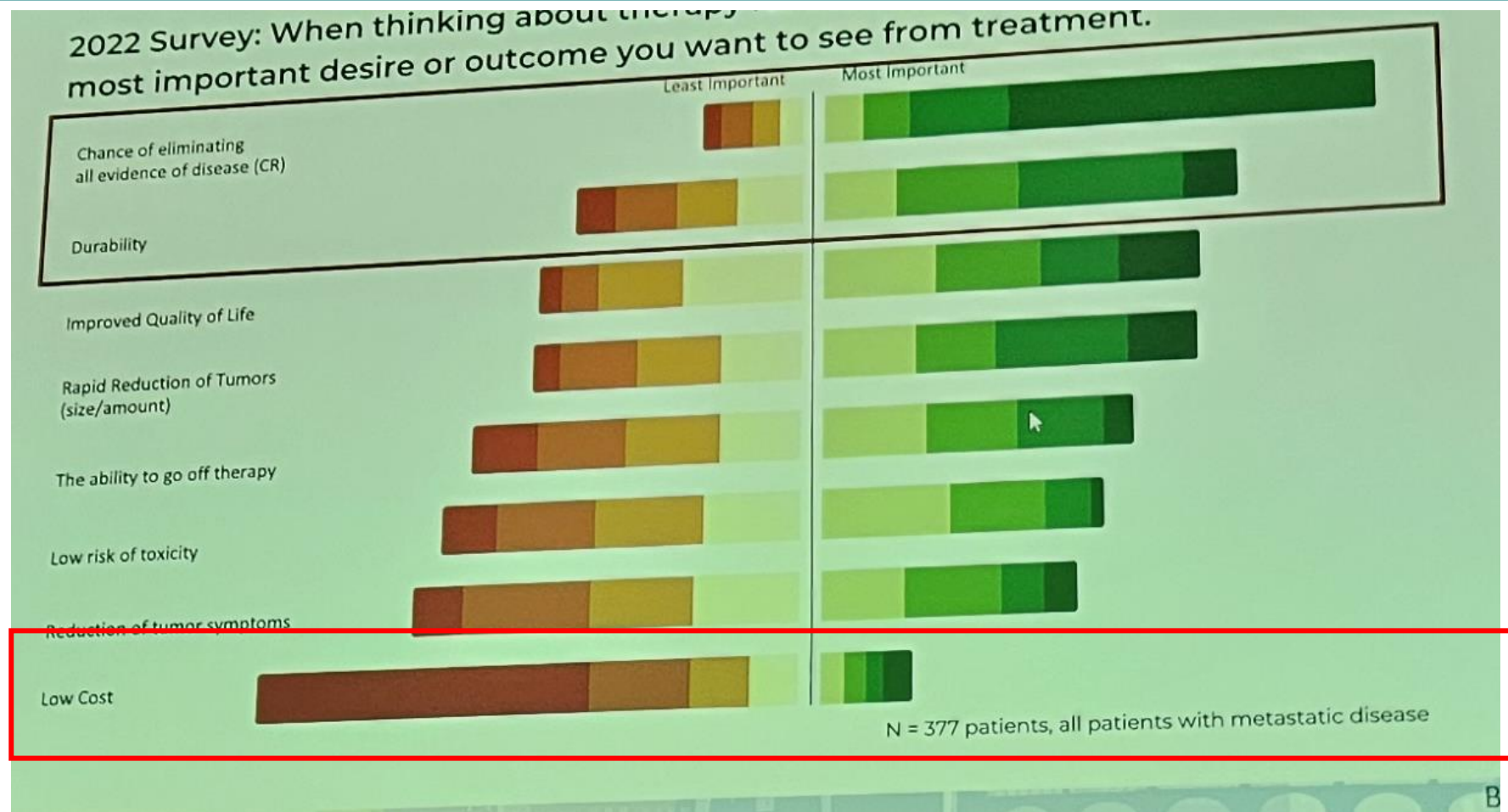
BCG naïve

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New landscape in MIBC

Cost-effectiveness

Cost of novel therapies



Patients do not care about the cost, but our government does

Cost of novel therapies



Index patient 1: 1L BST or upfront RC				
Index Patient 1^a	Cost (5-year USD)	Effectiveness (5-year QALY)	ICER (USD/QALY)	
Gemcitabine/Docetaxel	78,539	3.95	Ref.	
Radical Cystectomy	96,909	3.78	-109,912	
Pembrolizumab	226,879	3.82	-1,137,869	
Nadofaragene	296,318	3.84	-2,154,264	
NAI-BCG	529,801	3.85	-4,685,203	
Index Patient 2^b				
	Cost (5-year USD)	Effectiveness (5-year QALY)	ICER (USD/QALY)	
Radical Cystectomy	96,909	3.78	Ref.	
Gemcitabine/Docetaxel	156,579	3.92	412,530	
Pembrolizumab	347,016	3.90	-8,575,398	
Nadofaragene	391,001	3.92	-77,480,806	
NAI-BCG	688,820	3.88	-11,125,110	
Index Patient 3^c				
	Cost (5-year USD)	Effectiveness (5-year QALY)	ICER (USD/QALY)	
Pembrolizumab	419,022	3.88	Ref.	
Nadofaragene	449,307	3.90	1,469,775	
NAI-BCG	704,172	3.83	-3,847,835	

QALY = quality adjusted life-year, with the value of 1 representing one year in perfect health
ICER= Incremental cost-effectiveness ratio, calculated as incremental cost divided by incremental effectiveness. The treatment is considered cost effective if the ICER was below the willingness to pay threshold.
NMB = Net monetary benefit calculated as willingness to pay [WTP] X effectiveness

Gem-Doce is most cost effective if patients want to undergo maximum 1 line of treatment before cystectomy

Cystectomy is most cost effective if patients want to undergo 2 lines of treatment.

Pembrolizumab is most cost effective if patients want to undergo only FDA approved treatment and refuse cystectomy

Cost of novel therapies



Cost Analysis of treatments for BCC

	Drug cost and doses		
	Drug acquisition cost per dose (USD)	Total doses for 1 year treatment	Drug acquisition cost for 1 year treatment
Gemcitabine/Docetaxel	\$ 49.9	15	\$ 749
Pembrolizumab	\$ 12,058	17	\$ 204,986
Nadofaragene	\$ 63,342	4	\$253,368
Nogapendekin/BCG	\$ 38,027	15	\$570,405
Gemcitabine intravesical system (TAR-200)	\$ 69,000*	10	\$690,000

- Not the same for Europe (much more costly in the US)
- Belgium reimbursement will cover this
- But the tax payer will still need to pay

Cost of novel therapies



Conclusion

For now, cystectomy remains the SoC for BCG unresponsive disease.

Explain your patient that Gem-Doce exists als an inferior (but bladder sparing) option.

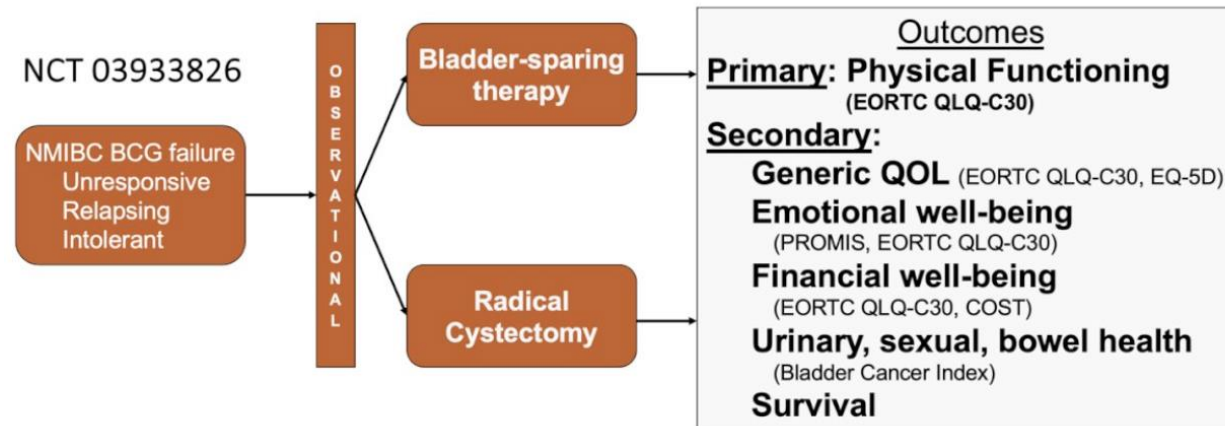
The future will show which novel treatments will be reimbursed.

Cost of novel therapies



What about cystectomy? Is it such a morbid therapy as everyone thinks?

AUA 2025: Radical Cystectomy vs Bladder-Sparing Therapy for Recurrent High-Grade NMIBC: Results from the Comparison of Intravesical Therapy and Surgery as Treatment (CISTO) Study

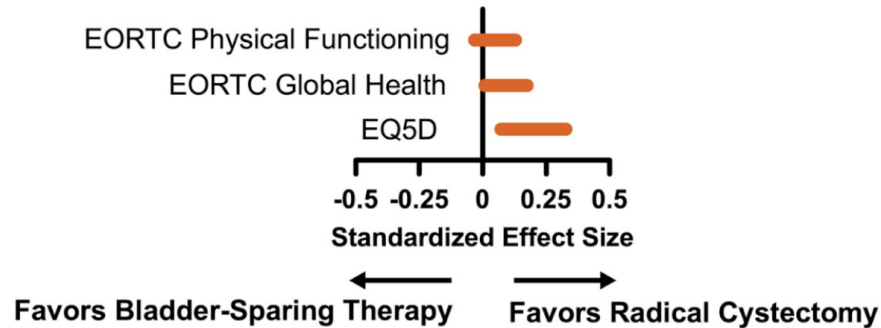


Hypothesis: patients undergoing radical cystectomy experience worse health-related QOL at 12 months compared to those who chose bladder-sparing therapy.

Cost of novel therapies

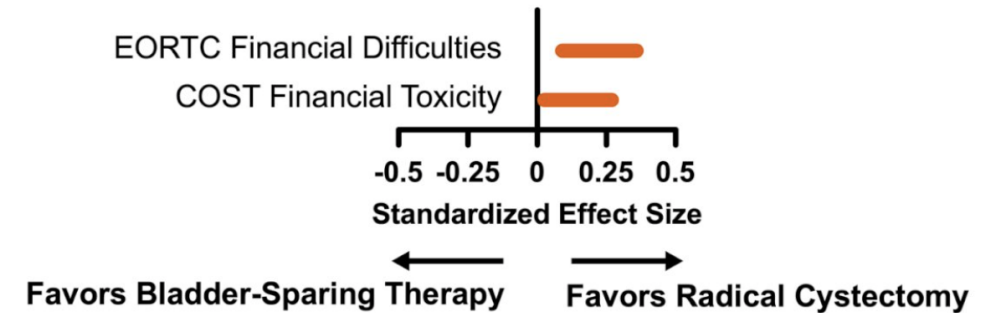


Results: General Quality of Life



QoL: favors radical cystectomy

Results: Financial Well-Being Outcomes



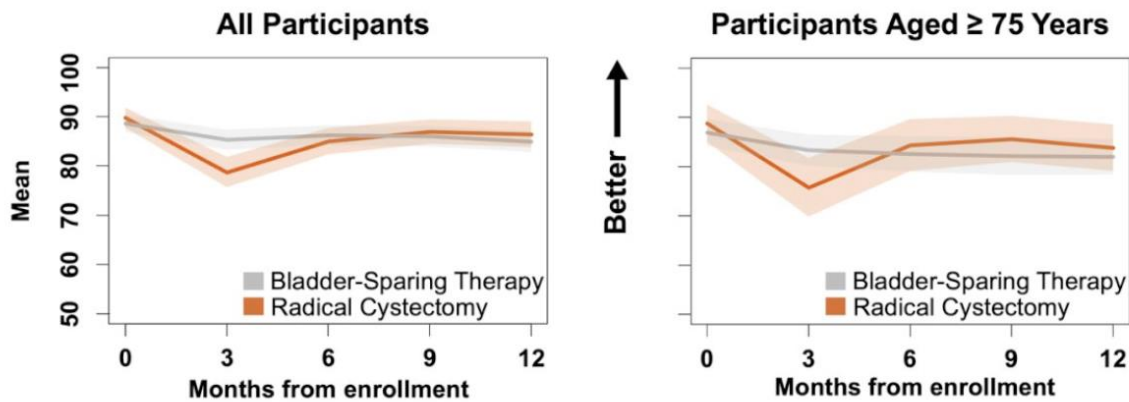
Financial well being: favors cystectomy

Emotional well being: favors radical cystectomy (figure not shown)

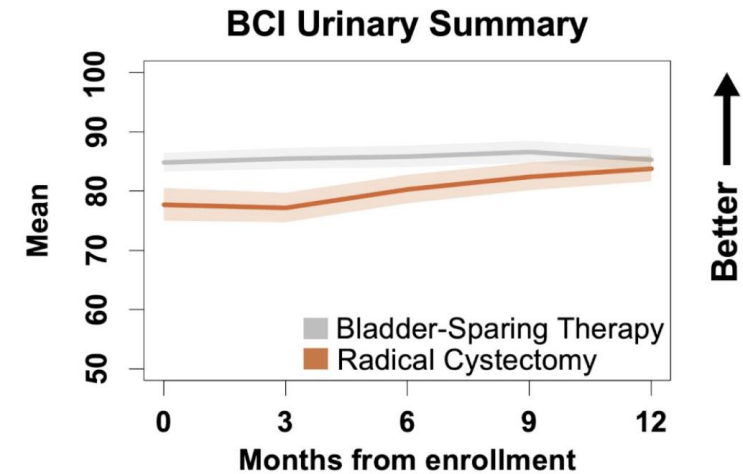
Cost of novel therapies



Results: Longitudinal Physical Functioning



Physical functioning: Declined at 3m, normalised at 6 mo, even slightly better for elderly.



Urinary health: worse during the first year, then normalizes

Cost of novel therapies



Summary of 12-Month Outcomes

Favors BST	No Difference	Favors RC
Bowel health Sexual health	Physical functioning • Overall • By age Role functioning Social functioning Urinary health	Physical functioning • Patients w/ CIS • Unpartnered Cognitive functioning Mental health Financial health

Finally we have data that cystectomy causes a temporary decrease in functional functioning and urinary health (due to surgical morbidity and getting used to their stoma/neobladder)

But patients who keep their bladder have clearly more benefits than harms compared to bladder sparing treatments (anxiety for cystoscopies, urine cytologies, biopsies, urinary symptoms due to intravesical treatments)



New landscape in NMIBC

BCG naïve

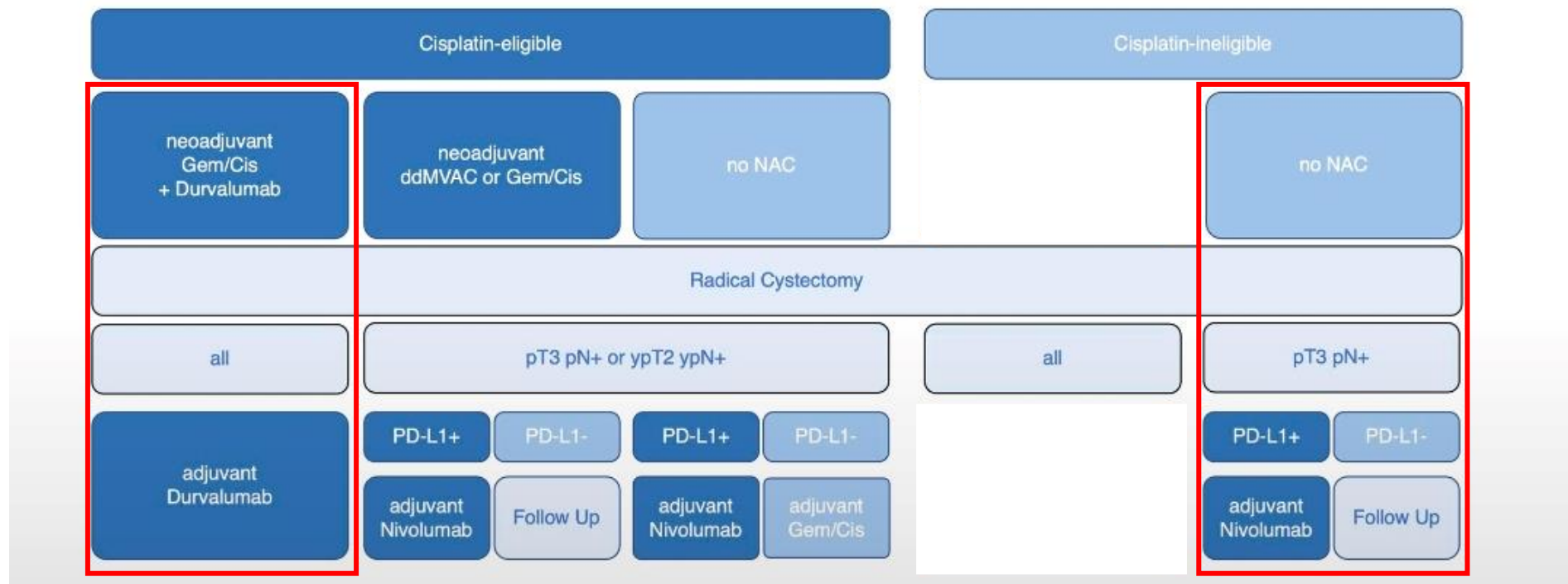
BCG
unresponsive

New landscape in MIBC

Cost-effectiveness



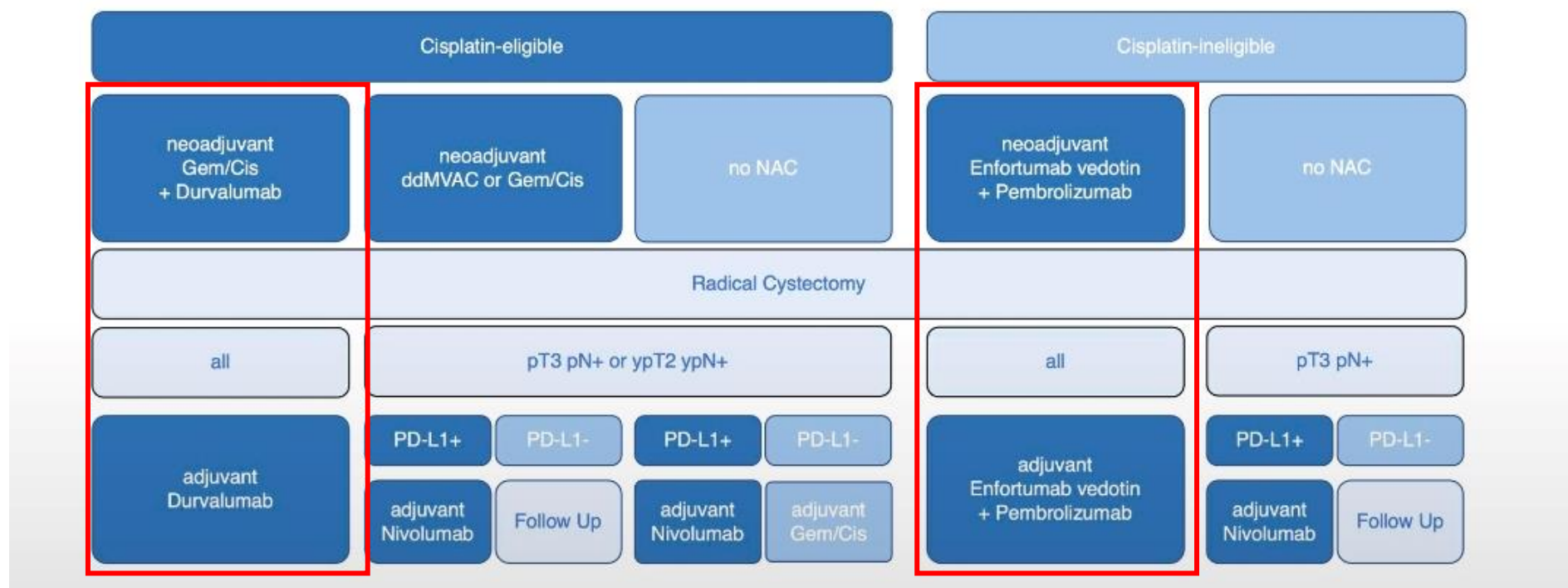
Perioperative Therapy **after** ESMO 2025



NIAGARA



Perioperative Therapy **after** ESMO 2025



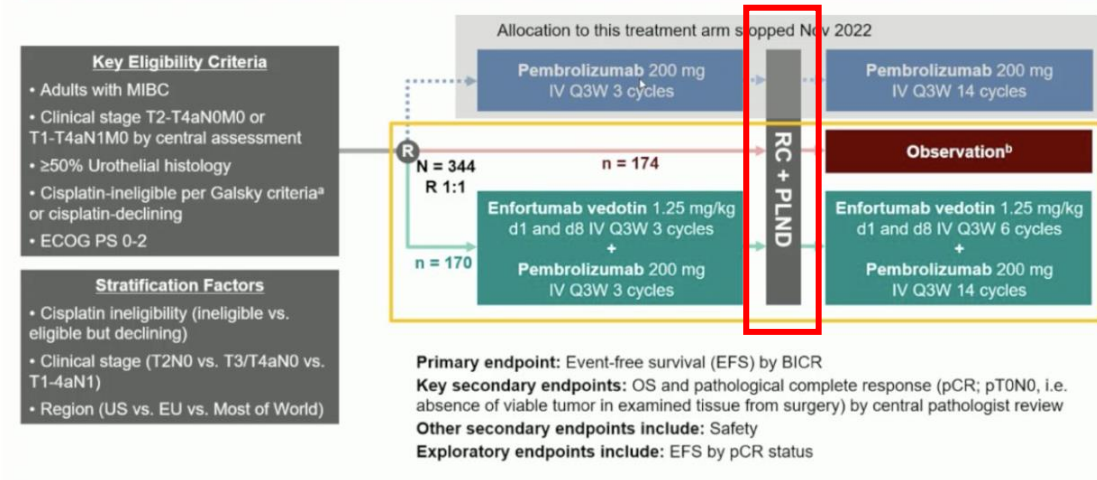
NIAGARA

Keynote-905

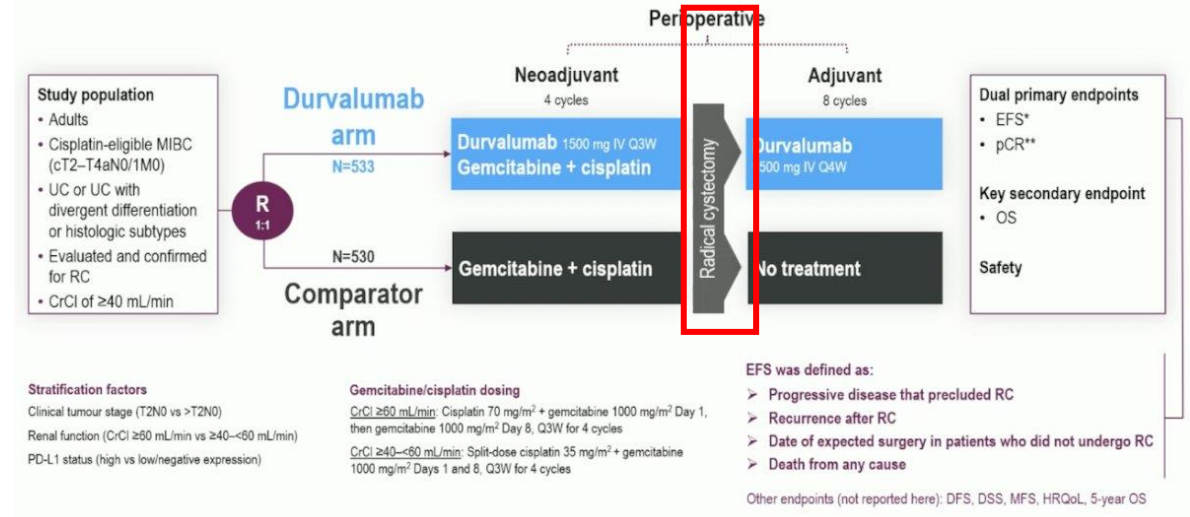
MIBC – Upcoming SoC



KEYNOTE-905/EV-303 Study (NCT03924895)

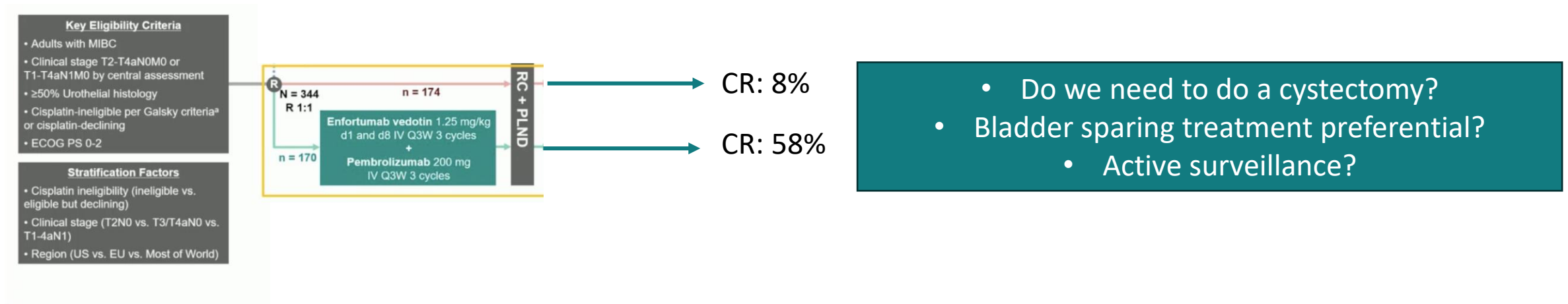


NIAGARA: Study Design



Do not forget: Radical Cystectomy remains the SoC for muscle invasive bladder cancer
With the results of the Keynote-905 even more so due to excellent response

MIBC – Keynote-905 – Complete response rate



For now the answer remains NO:

- In previous natural history studies (in very selected patients) who achieved cT0 disease, only 30-50% remained free of bladder cancer.
- cCR = not pCR – NAC: 30-40% pCR who had cCR at time of cystectomy.

MIBC – Cystectomy remains SoC in the new era



Goals for surgeons: improve surgery

Surgical techniques

Robot-assisted versus open

Bricker versus Neobladder

Reduction in complications

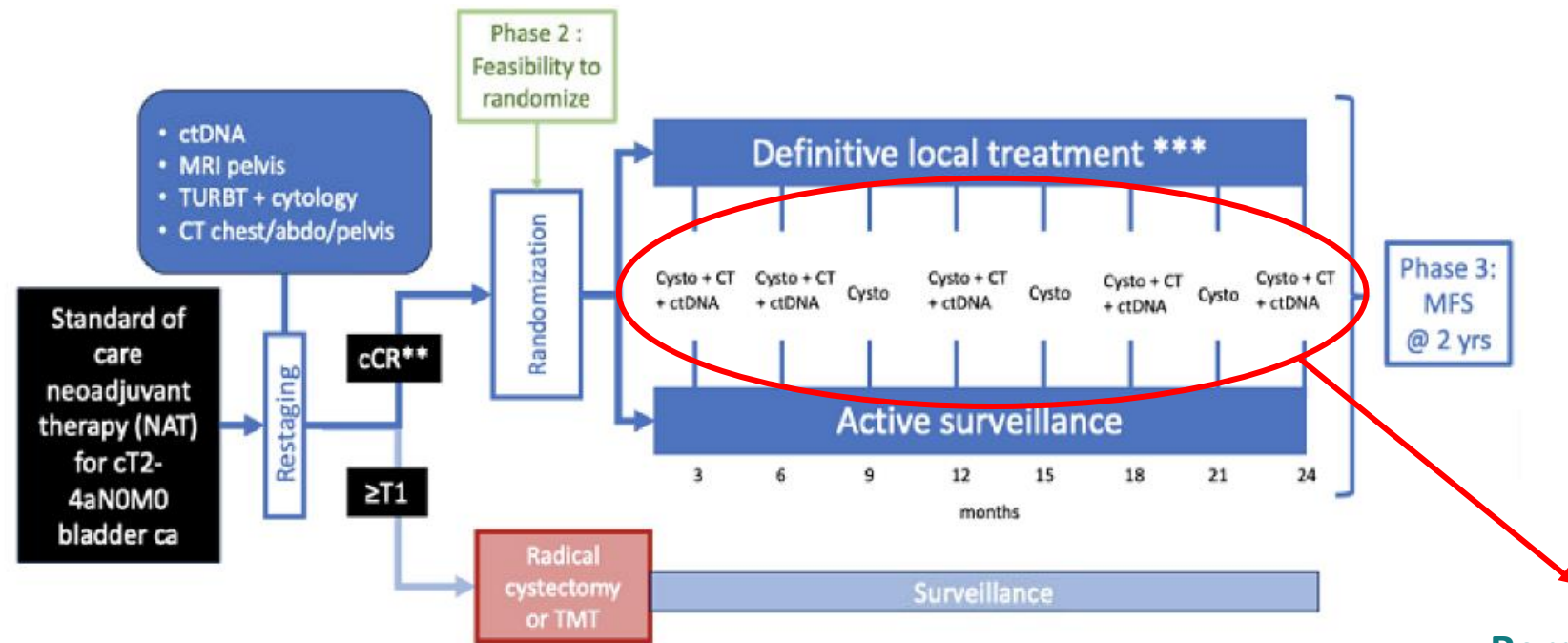
Prophylactic antibiotics to prevent infections postop (furadantine postop pos RCT)

Develop Care Pathways

ENHANCE trial (BJUI)



MIBC – Future - Neo-Blast



Remember CISTO trial

**Definition of cCR:

- Negative MRI (VI-RADS 0-1-2)
- Negative repeat TURBT (< cT1, no extensive CIS)
- Negative ctDNA
- No mets (negative conventional CT/MRI or PET-CT)

Exploratory: Negative utDNA

*NAT = any SOC regimen approved at time of enrolment (Cisplatin, EV, IO, etc.)

*** Patient/investigator's choice; Radical cystectomy or TMT

Definitions: cCR (clinical complete response, as defined in protocol), CT (computerized tomography), ctDNA (cell-free tumor DNA), MIBC (muscle invasive bladder cancer), MRI (magnetic resonance imaging), NAT (neoadjuvant therapy), RC (radical cystectomy), SOC (standard of care), TMT (trimodal therapy including TURBT, chemotherapy and radiation), TURBT (transurethral resection of bladder tumor), utDNA (urine tumor DNA)

Final conclusions: What changed in 2025 for BCa



A Urologist's point of view

- **NMIBC BCG Naïve:** Novel treatments slightly reducing local recurrences, but the harms are too high
- **NMIBC BCG Unresponsive:** Bright future ahead for bladder sparing treatments with less harms than the BCG naïve treatment options. Do not forget about Gem-Doce.
- **MIBC:** KEYNOTE-905 will completely change the way we treat patients with MIBC peri-operatively (once reimbursed)
- **Keynote-905 has exceptional pCR,** but future trials will need to show that bladder sparing treatment or surveillance will be safe
- **Both in NMIBC and MIBC** the Standard of Care treatment remains cystectomy en financieel het meest houdbaar voor de maatschappij
- **Cystectomy** is not as morbid as previously thought (CRISTO trial). Goal of surgeons to improve even more!