Uro-oncologie

11/06/2024

Webinar post-ASCO

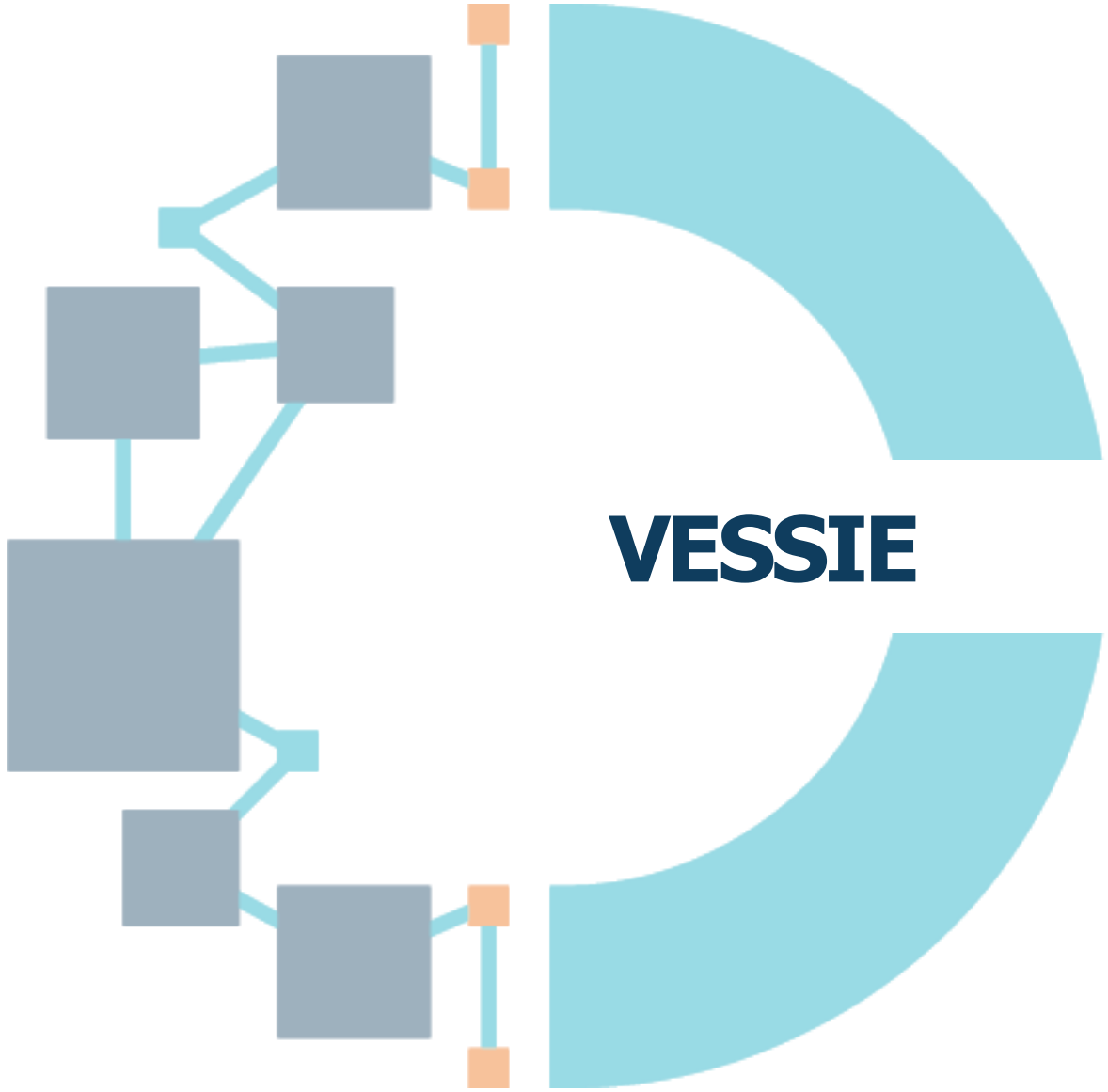
Dr Sabrina Falkowski

Oncologue médicale

Polyclinique de Limoges - IMRO

Liens d’intérêts

- Astellas
- BMS
- Grünenthal
- Ipsen
- Johnson&Johnson
- Merck
- MSD
- Pfizer



VESSIE

Tumeur de l'ouraque métastatique

FOLFIRINOX modifié = Nouveau SOC

Phase II ULTIMA

Carcinome de l'ouraque en rechute ou métastatique
Maladie mesurable

N=21

Oxaliplatine 85 mg/m2 + Irinotecan 150 mg/m2 + Leucovorin 400 mg/m2 + 5-FU 2400 mg/m2 + PegGCSF / 2 semaines

12 cycles ou PD ou toxicité

suivi med: 15,2 mois

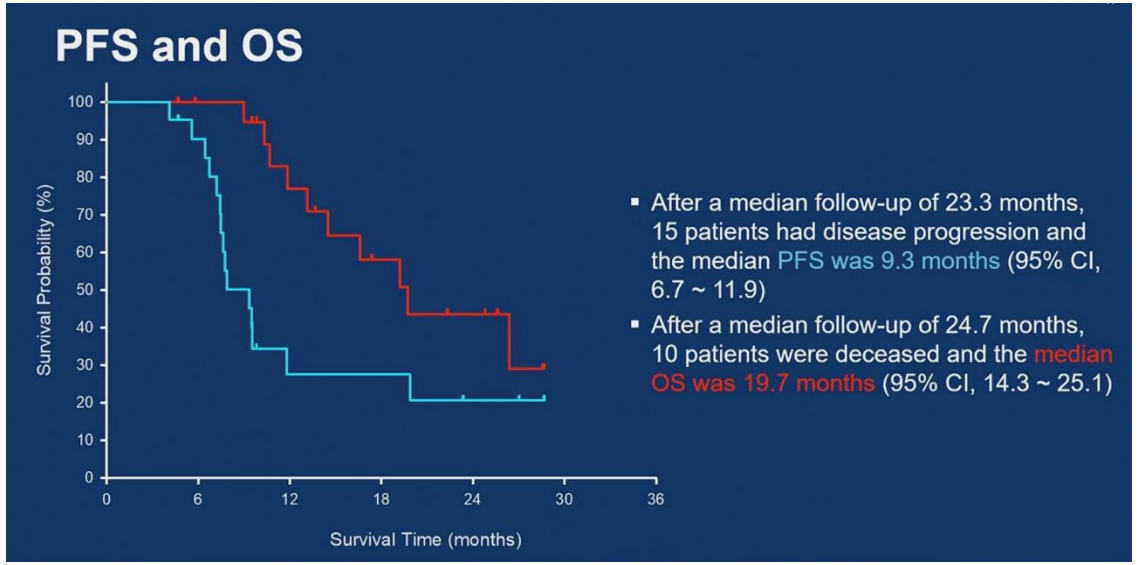
Critère principal :
- RO selon investigateur

Critères secondaires :
- SSP
- Survie globale
- Incidence NF
- Qualité de vie

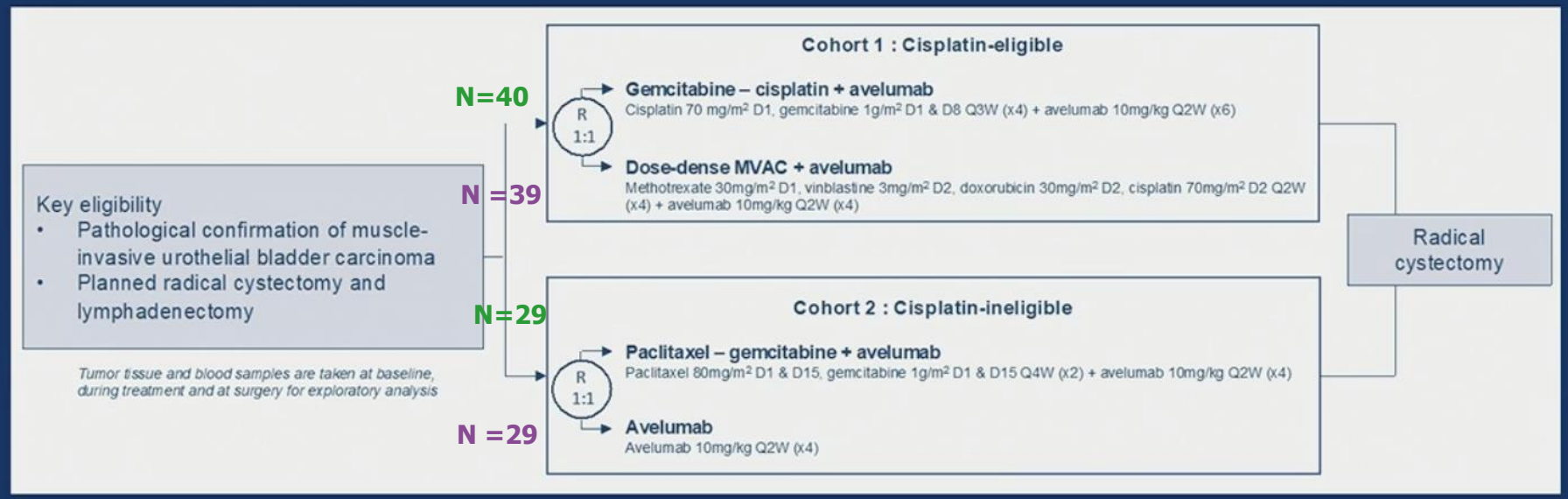
Loc II pulm (47,6%), Gag (38,1%), péritonéales (33,3%)

	No. of pts/percentage
Complete Response (CR)	2(9.5%)
Partial Response (PR)	11(52.4%)
Stable Disease (SD)	8(38.1%)
Progressive Disease (PD)	0

Overall response rate was 61.9% (95% CI, 41.1-82.7)

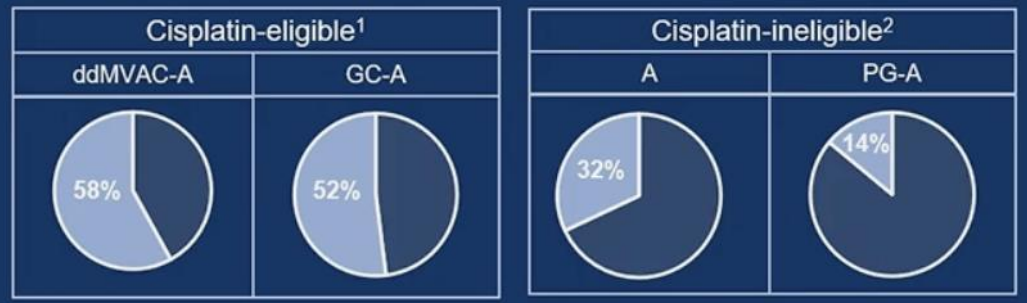


AURA : a multi-centric non comparative randomized phase II trial investigating neoadjuvant avelumab alone or in combination with chemotherapy



Primary Endpoint:

- Proportion of patients achieving a pathological complete response (pCR) ypT0/TisN0



[1]Martinez Chanza N et al. ,ESMO 2021; [2]Martinez Chanza N et al., ASCO 2022

AURA

Données de SSM et de SG

	MVACdd -Ave	GemCis-Ave	PG - Ave	Ave
Survie sans maladie à 12 mois	97% (83-100)	86 (70-94)	52% (32-69)	68% (47-82)
Population ypTO à 12 mois	100 %	100%		
Survie sans maladie à 36 mois	77% (55-89)	68 (46-82)	-	-
Population ypTO à 36 moiS	100%	78%		
SG à 12 mois	95% (81-99)	84 % (67-92)	67% (46-81)	75% (55-87)
SG à 36 mois	87% (40-76)	61% (40-76)	-	-

MVAC-DD+Ave > GC+ Avé
-> en SSM
-> en SG

Pas de bénéfice à CT+Avé vs Avé seul pour les cisplatine unfit
->en SSM et SG

AURA

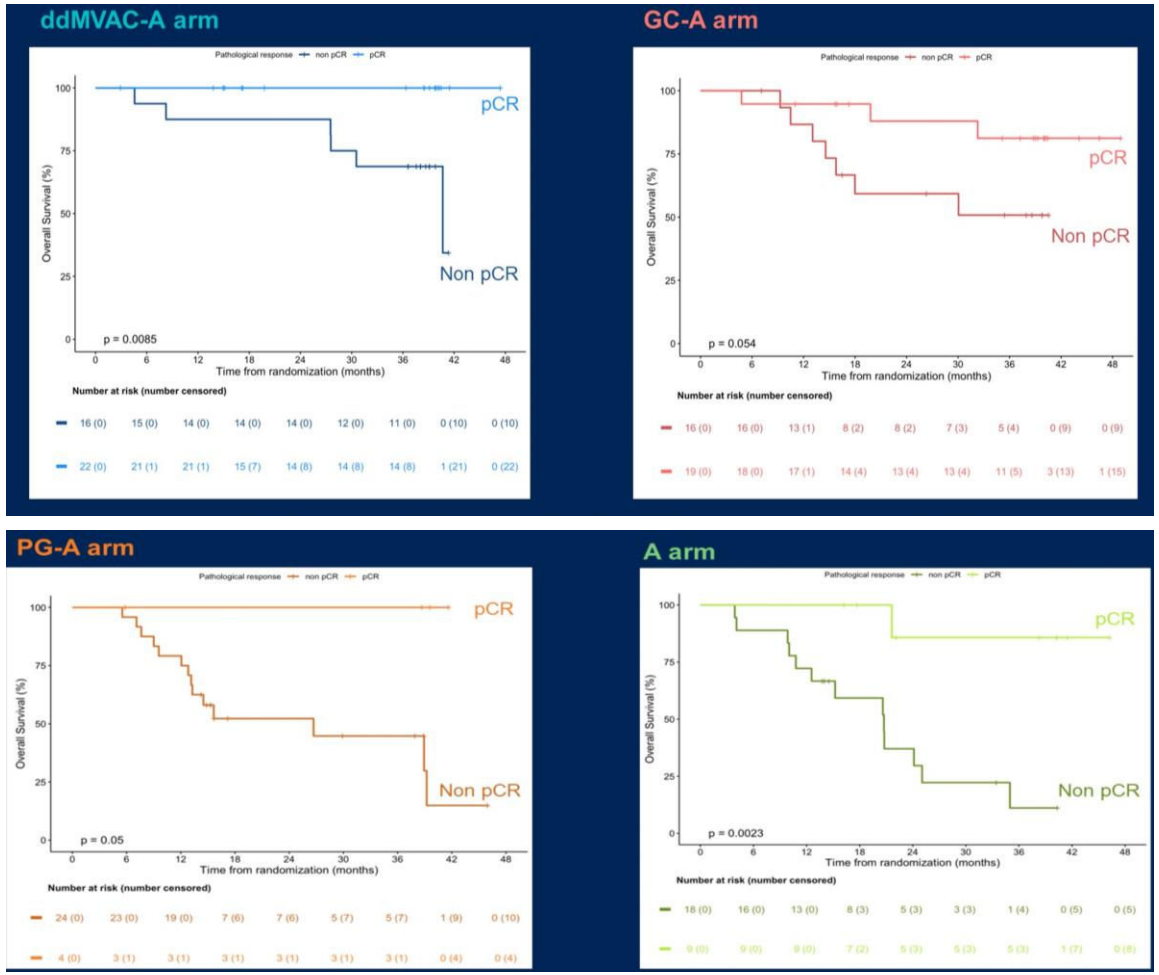
Réponse histologique complète = Marqueur d'une meilleure SG

Cisplatine éligibles

Survie globale selon la réponse
pRC / nonpCR

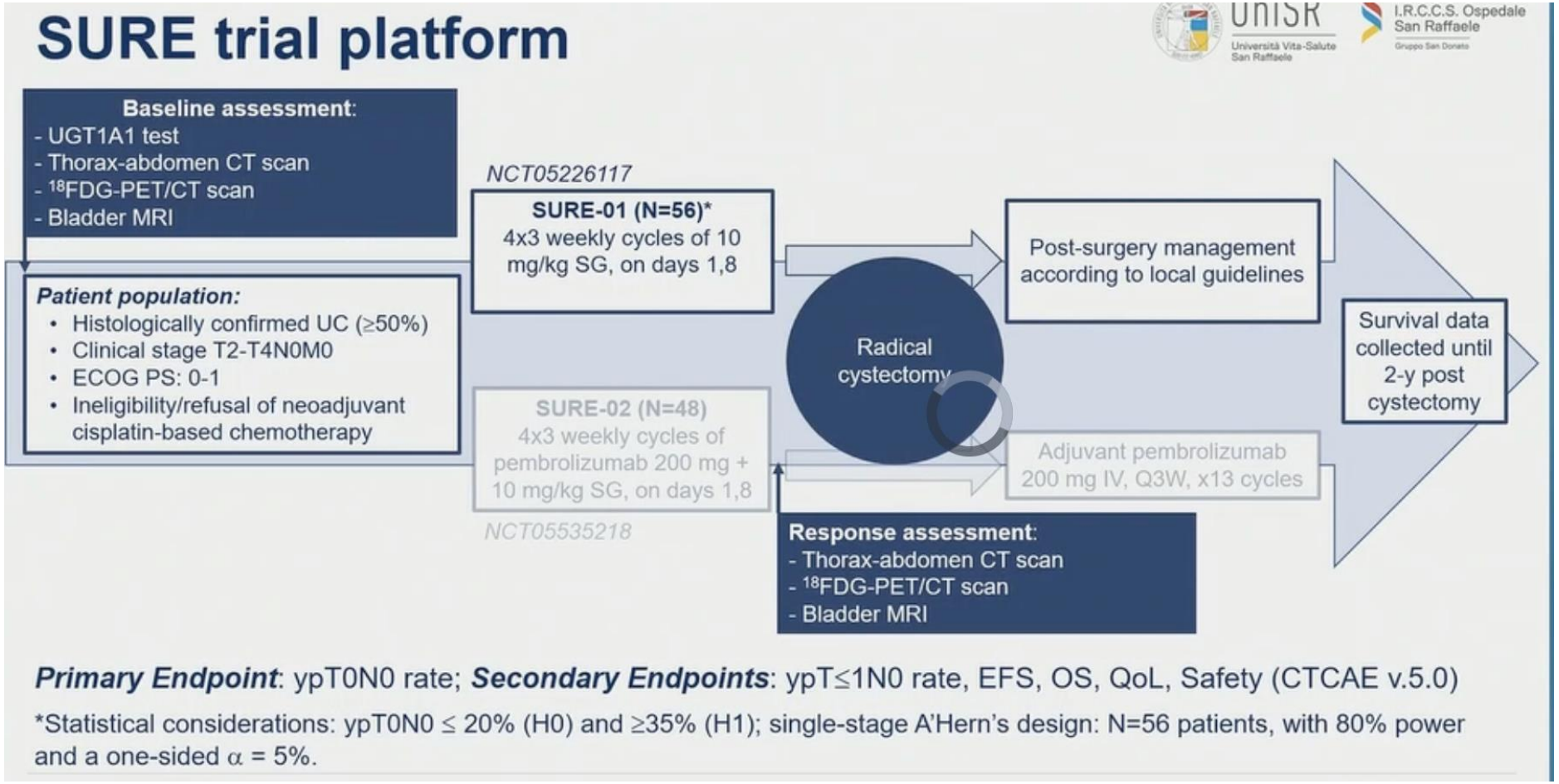
Cisplatine inéligibles

Survie globale selon la réponse
pCR / non pCR



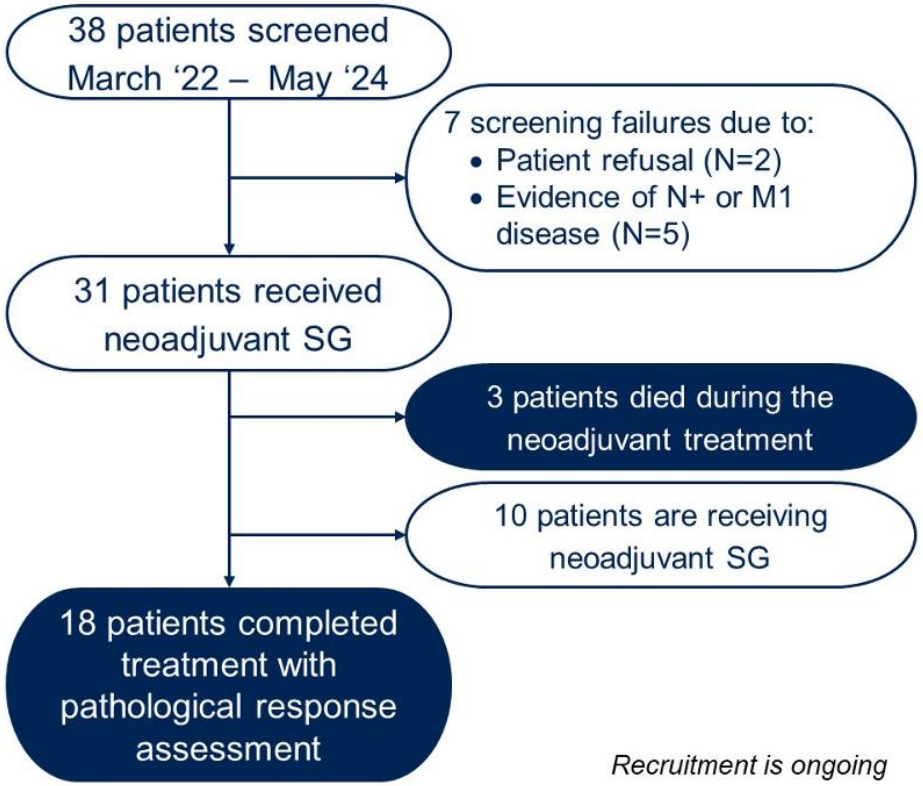
SURE-01 – Phase II - néoadjuvant

Sacituzumab govitecan, ADC Trop-2 + inhibiteur de topoisomérase



SURE-01

2ème ADC potentiellement efficace, toxique sur PNN, Hb et diarrhées



Outcome	N (%)
Total N=11 RC-evaluable patients	
• ypT0N0 (95%CI)	4 (36.4; 14.9–64.8)
• ypT≤1N0 (95%CI)	5 (45.4; 21.2–72.0)
Total N=21 ITT patients	
• **ypT0N0-x (95%CI)**	**10 (47.6; 28.3–67.6)**

7 pts en RC clinique (refus de chirurgie)

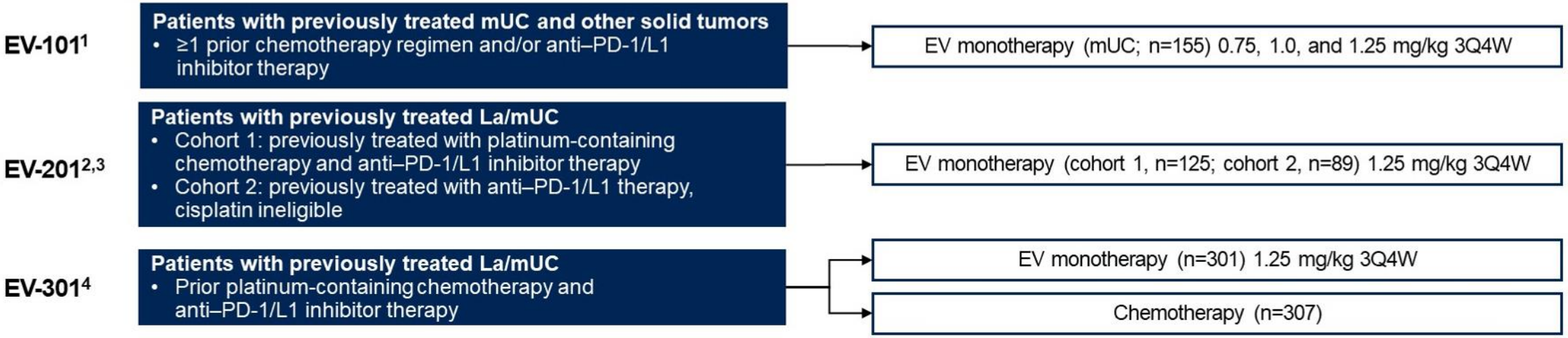
Due à toxicité : **Modification protocole réduction posologie à 7,5 mg/kg + GCSF**

TRAEs	ITT population N (%)	SG 10 mg/kg N (%)	SG 7.5 mg/kg* N (%)
• TRAEs leading to SG interruption:	4 (19.0)	4 (19.0)	0
• Sepsis (G3)	1 (4.8)	1 (4.8)	0
• Neutropenia (G3)	2 (9.5)	2 (9.5)	0
• Neutropenia (G4)	1 (4.8)	1 (4.8)	0
• TRAEs leading to dose reduction:	7 (33.3)	6 (28.6)	1 (4.8)
• Anemia (G3)	1 (4.8)	1 (4.8)	0
• Diarrhea (G3)	1 (4.8)	1 (4.8)	0
• Neutropenia (G3)	5 (23.9)	4 (19.0)	1 (4.8)
• TRAEs leading to SG discontinuation:	1 (4.8)	1 (4.8)	0
• Sepsis (G5)	1 (4.8)	1 (4.8)	0

Enfortumab vedotin

Données d'exposition – efficacité - toxicité en monothérapie

Analyse post-Hoc



Pharmacocinétique évaluée par dosages itératifs lors des 2 premiers cycles et pré-doses durant les cycles ultérieurs.

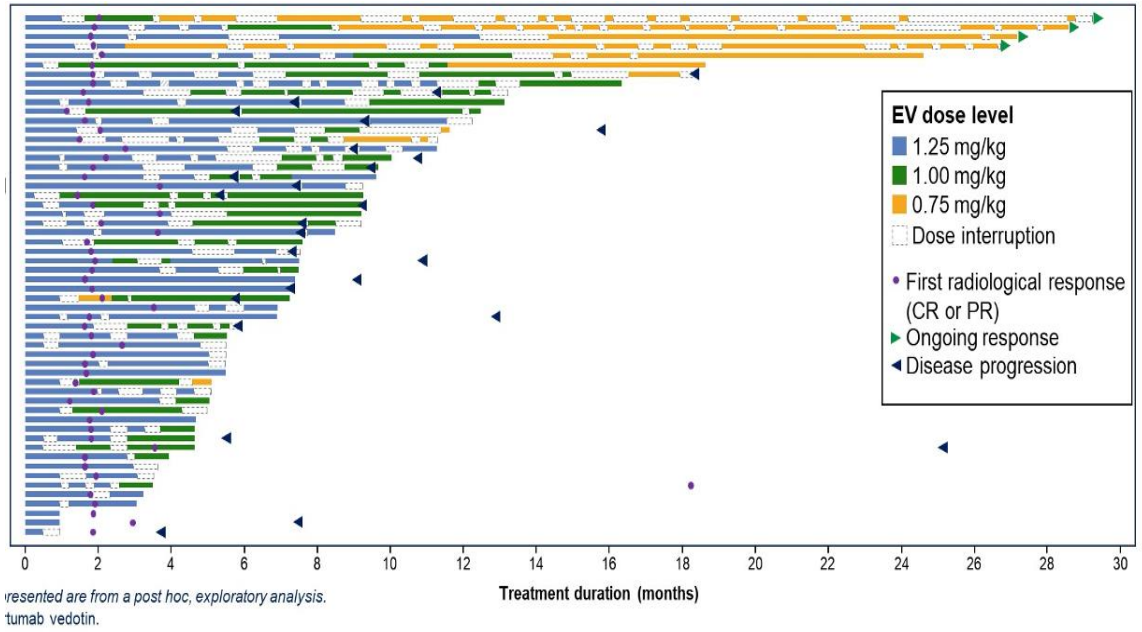
Objectifs : Déterminer une concentration d'exposition optimale, contrôler l'efficacité des adaptations de doses sur les TRO, SSM, SG et durée de traitement.

Petrylak D et al. Abstr 4503

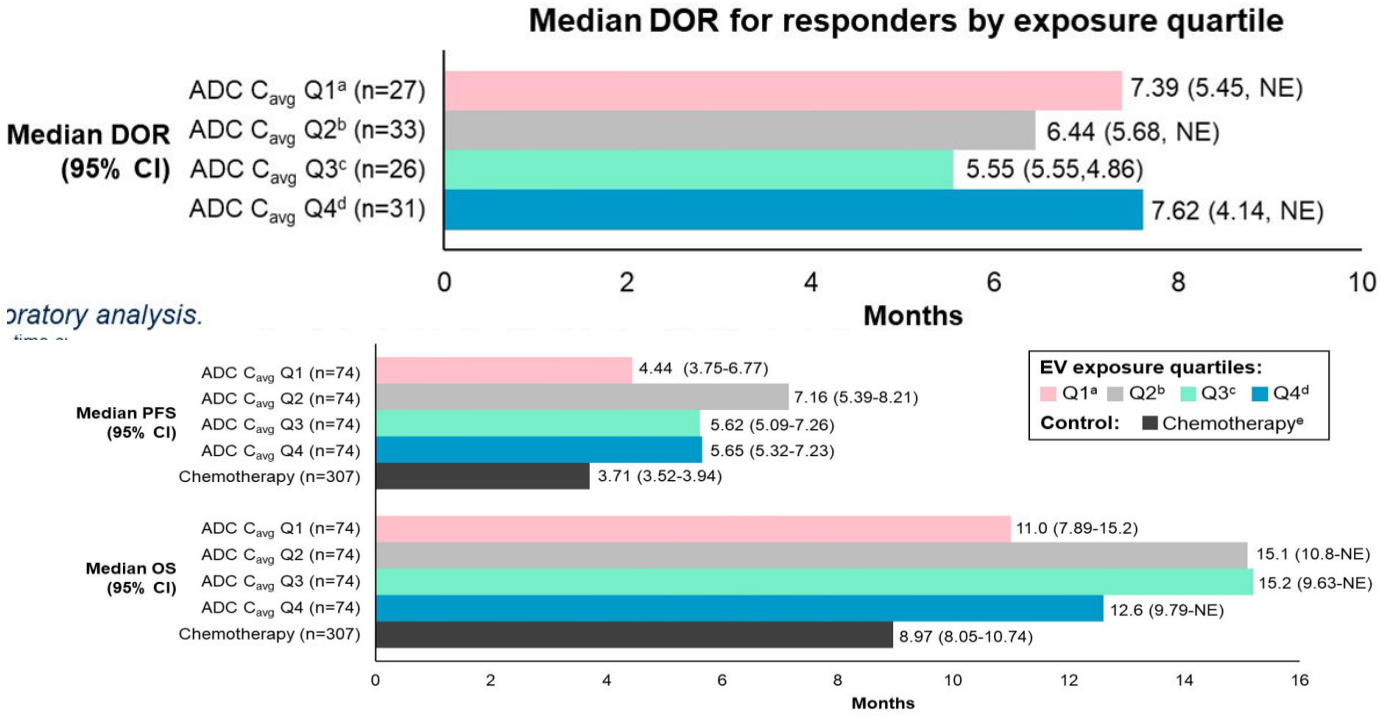
Enfortumab vedotin

Maintien bénéfice SSP , SG , durée de réponse malgré réduction de dose et exposition

	ADC C_{avg} Q1[a] (n=74)	ADC C_{avg} Q2[b] (n=74)	ADC C_{avg} Q3[c] (n=74)	ADC C_{avg} Q4[d] (n=74)
Median EV ADI (mg/kg/4 week)[e] (range)	2.37 (1.15, 3.77)	2.96 (1.57, 3.82)	3.26 (2.36, 3.86)	3.59 (2.50, 3.93)



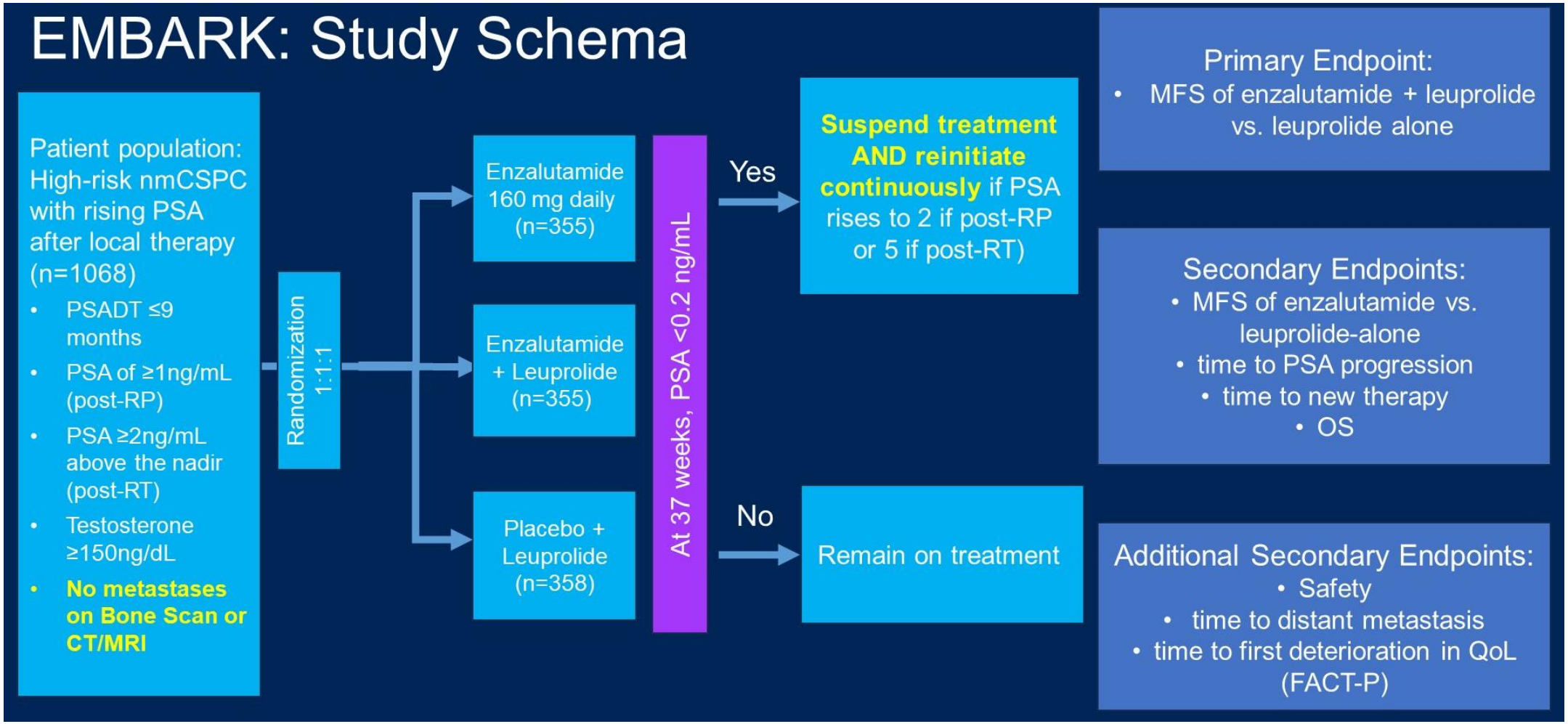
resented are from a post hoc, exploratory analysis.
tumab vedotin.



➢ **Opportunités d'optimisation par des schémas modifiés**

PROSTATE

Rising PSA

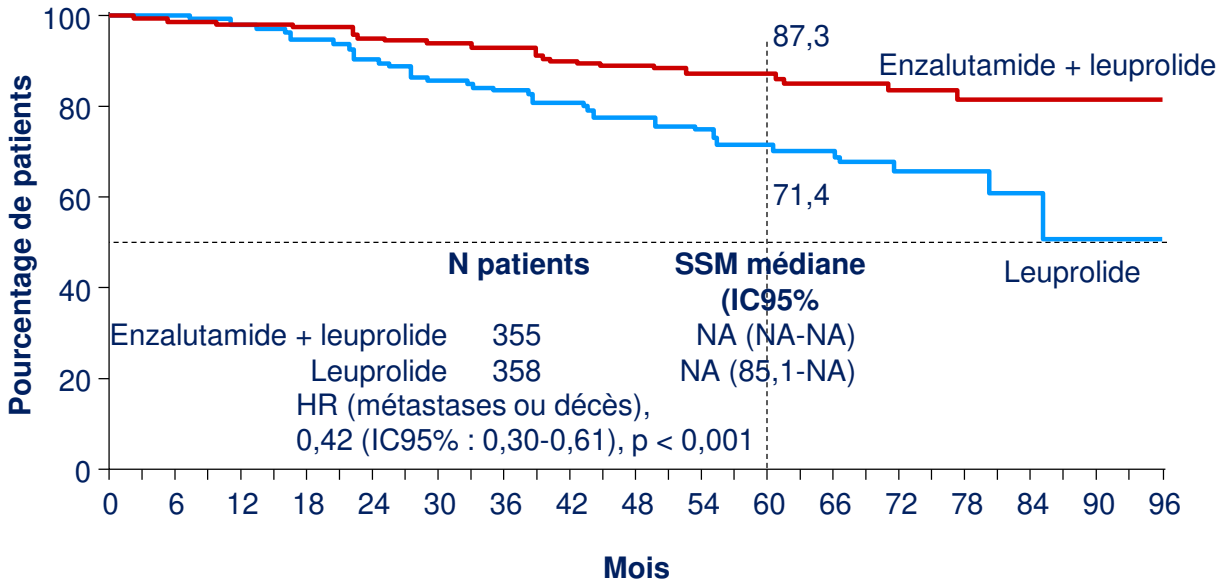


Freedland S et al Abst 5005, ASCO 2024

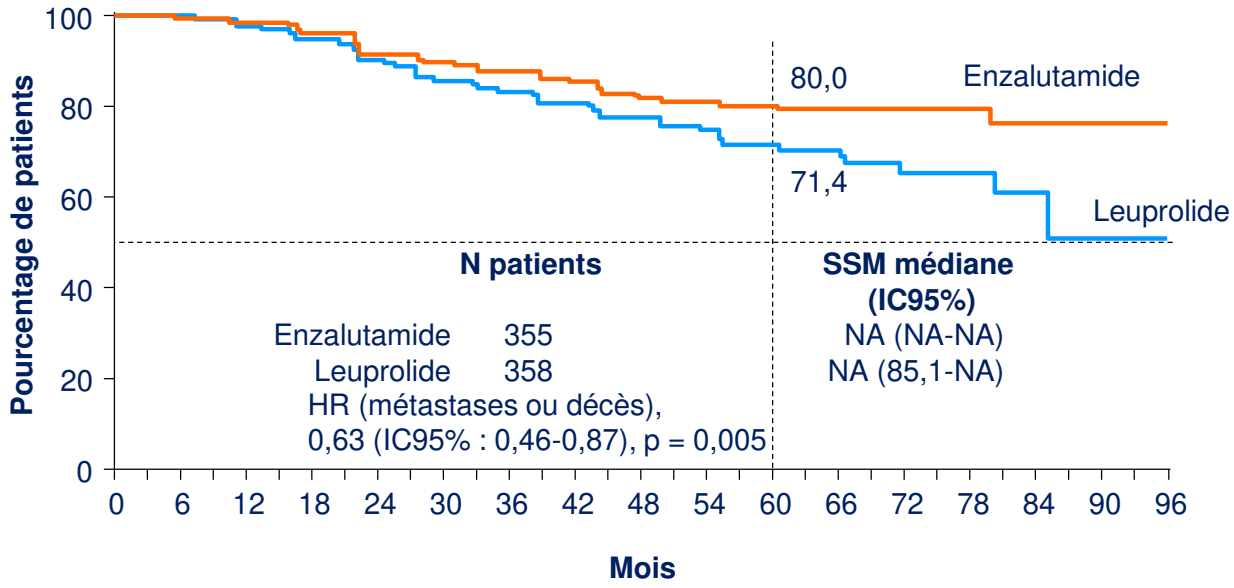
Rising PSA

EMBARK : Survie sans métastase

Enzalutamide + leuprolide vs leuprolide



Enzalutamide monothérapie vs leuprolide

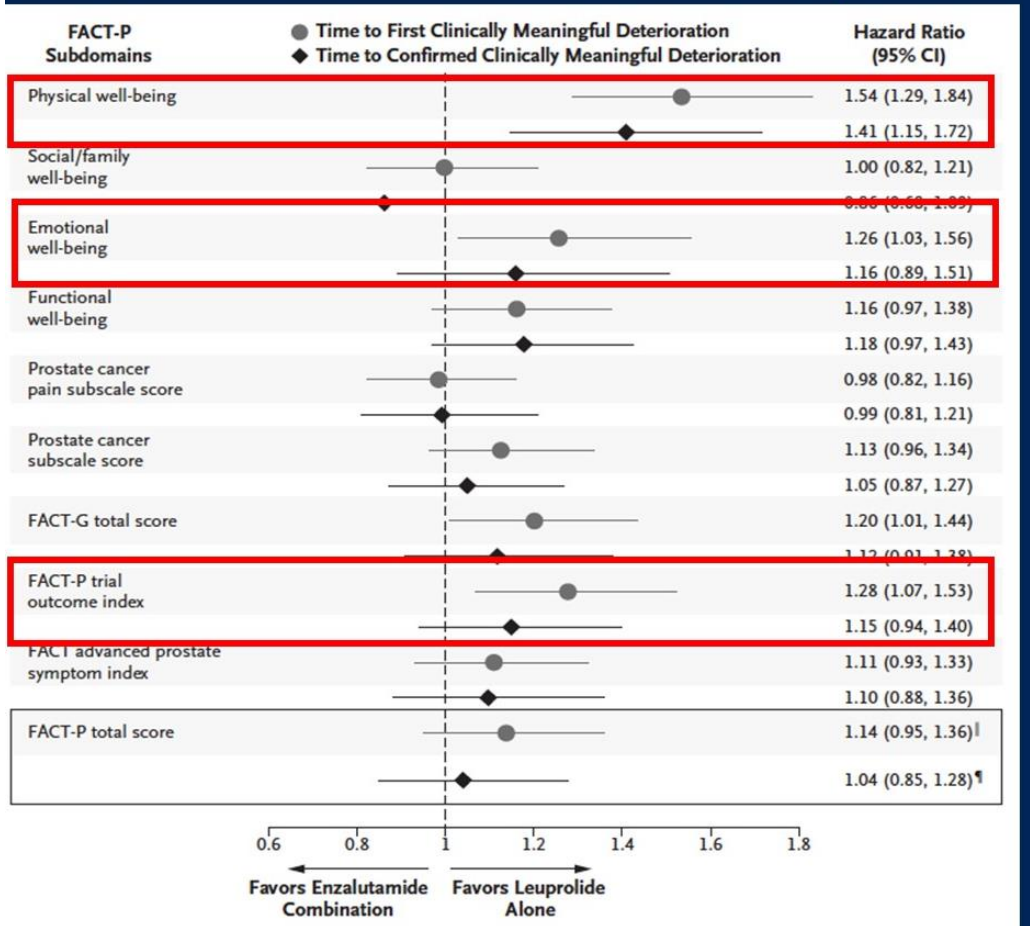


Freedland S et al , NEJM 2023

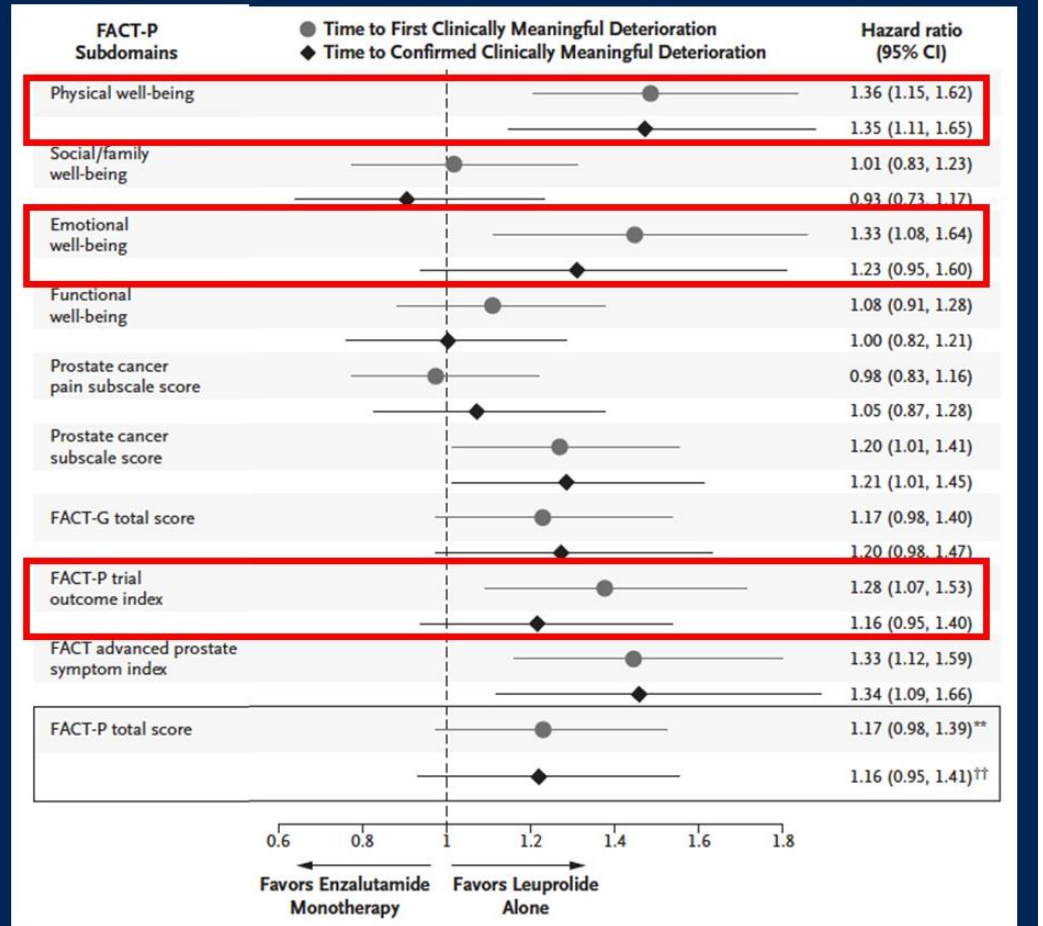
Rising PSA

EMBARK: Intensification n'a pas d'impact sur la QdV

Enzalutamide Combination / Leuprolide



Enzalutamide Monotherapy / Leuprolide



Rising PSA

EMBARK: Blocage du RA en monothérapie a des effets secondaires distincts de l'ADT

Event	Enzalutamide + Leuprolide (N=353, (%))		Leuprolide Alone (N=354, (%))		Enzalutamide Monotherapy (N=354, (%))	
	Any Grade	Grade≥3	**Any Grade**	Grade≥3	**Any Grade**	Grade≥3
Hot flash	243 (68.8)	2 (0.6)	203 (57.3)	3 (0.8)	77 (**21.8**)	1 (0.3)
Fatigue	151 (**42.8**)	12 (3.4)	116 (32.8)	5 (1.4)	165 (**46.6**)	14 (4)
Nipple Pain	11(3.1)	0	4 (1.1)	0	54 (**15.3**)	0
Gynecomastia	29 (8.2)	0	32 (9)	0	159 (**44.9**)	1 (0.3)
Ischemic heart disease	19 (5.4)	14 (4.0)	20 (5.6)	11 (3.1)	32 (**9.0**)	21 (5.9)
Fracture	65 (**18.4**)	14 (4)	48 (13)	9 (2.5)	39 (11)	7 (2)
Cognitive impairment	53 (**15**)	2 (0.6)	23 (6.5)	2 (0.6)	50 (**14.1**)	0

- **Patients avec un PSADT plus long et PSA plus faible peuvent être surveillés en toute sécurité**

mCRPC

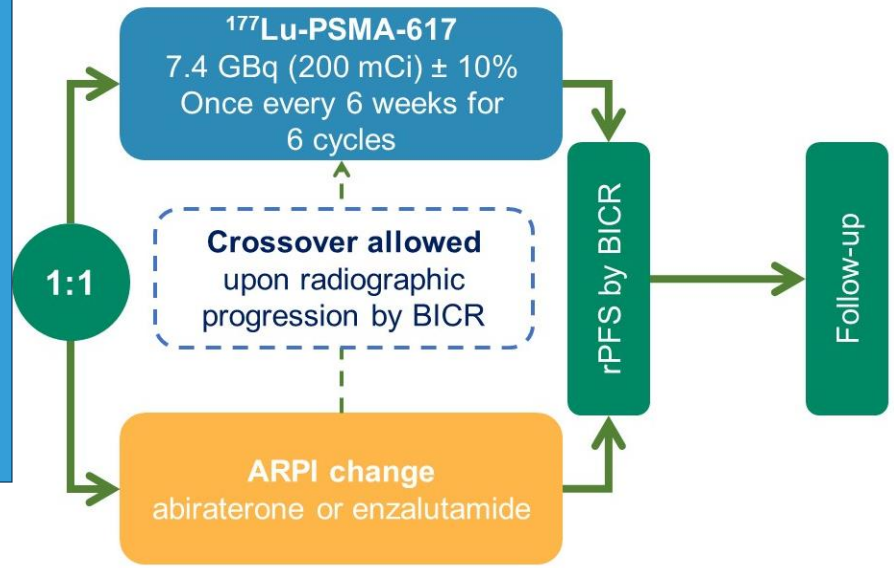
PSMAfore : Evaluation de la qualité de vie et de la douleur

PRIMARY ENDPOINT
rPFS
BICR per PCWG3/RECIST v1.1

KEY SECONDARY ENDPOINT
OS

PATIENT-REPORTED OUTCOMES
(Secondary and exploratory endpoints)
Time-to-worsening in HRQoL and pain

Critères d'inclusion
- mCRPC en progression
- ≥ 1 lésion positive au PET ^{63} Ga –PSMA-11
- Progression après ARPI
- Pouvant recevoir un ARPI
- Taxanes seulement en mHSPC
- Non candidat pour un iPARP
- ECOG 0-1



Stratification factors
- Prior ARPI setting (castration-resistant vs hormone-sensitive)
- BPI-SF worst pain intensity score (0–3 vs > 3)

HRQoL

Prostate cancer-specific	Generic
Functional Assessment of Cancer Therapy-Prostate (FACT-P) • Outputs include: ▪ Total score ▪ Subscales: ○ Physical well-being ○ Functional well-being ○ Emotional well-being ○ Social/family well-being	**EuroQol 5-Dimension 5-Level (EQ-5D-5L)** • Outputs include: ▪ Utility score

Chronic pain

Brief Pain Inventory – Short Form (BPI-SF)
- Outputs include time to worsening in:
  - Pain intensity
  - Pain severity (worst pain intensity)
  - Pain interference

Questionnaire qualité de vie et douleurs

(Evaluation des données à la 2nde analyse intermédiare 21 juin 2023)

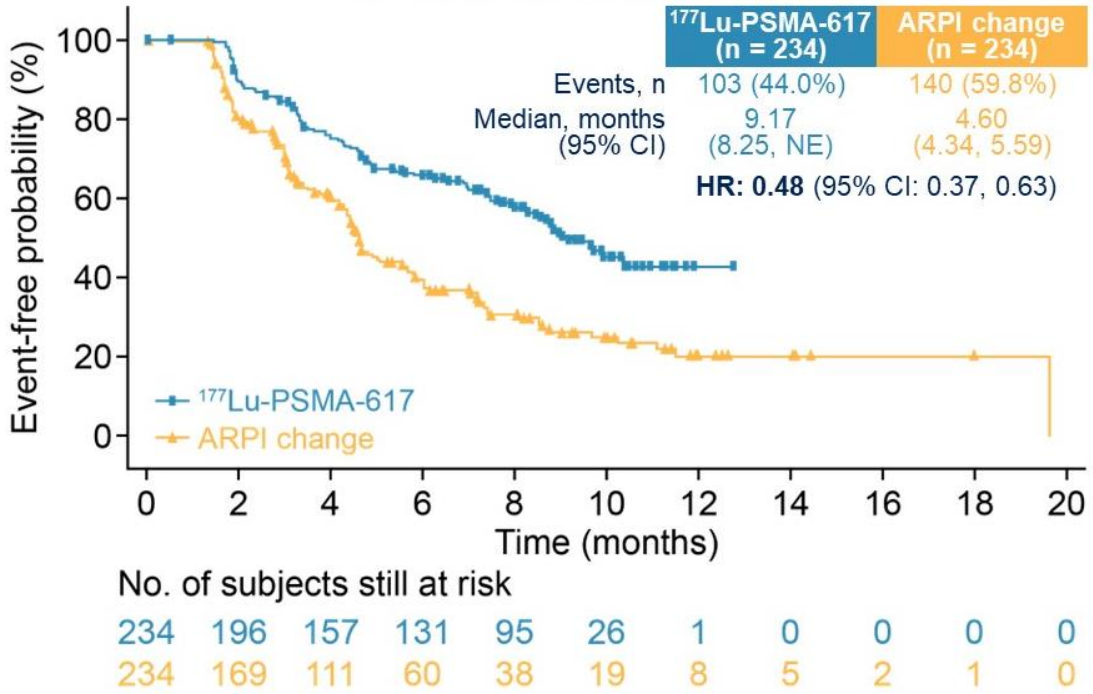
Fizazi K et al, Abst 5003 ASCO 2024

mCRPC

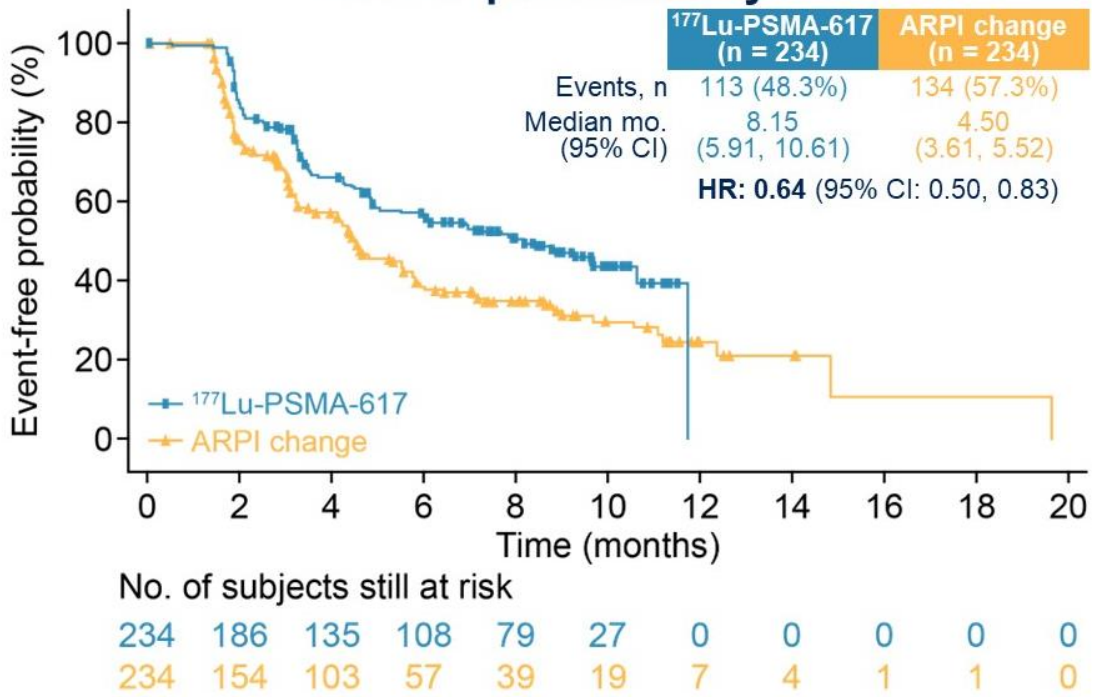
PSMAfore: ^{177}Lu PSMA-617 retarde la dégradation liée au cancer

***Post hoc* analysis:**
Non-composite time to worsening in FACT-P and BPI-SF excluding clinical progression and death

FACT-P total score



BPI-SF pain intensity

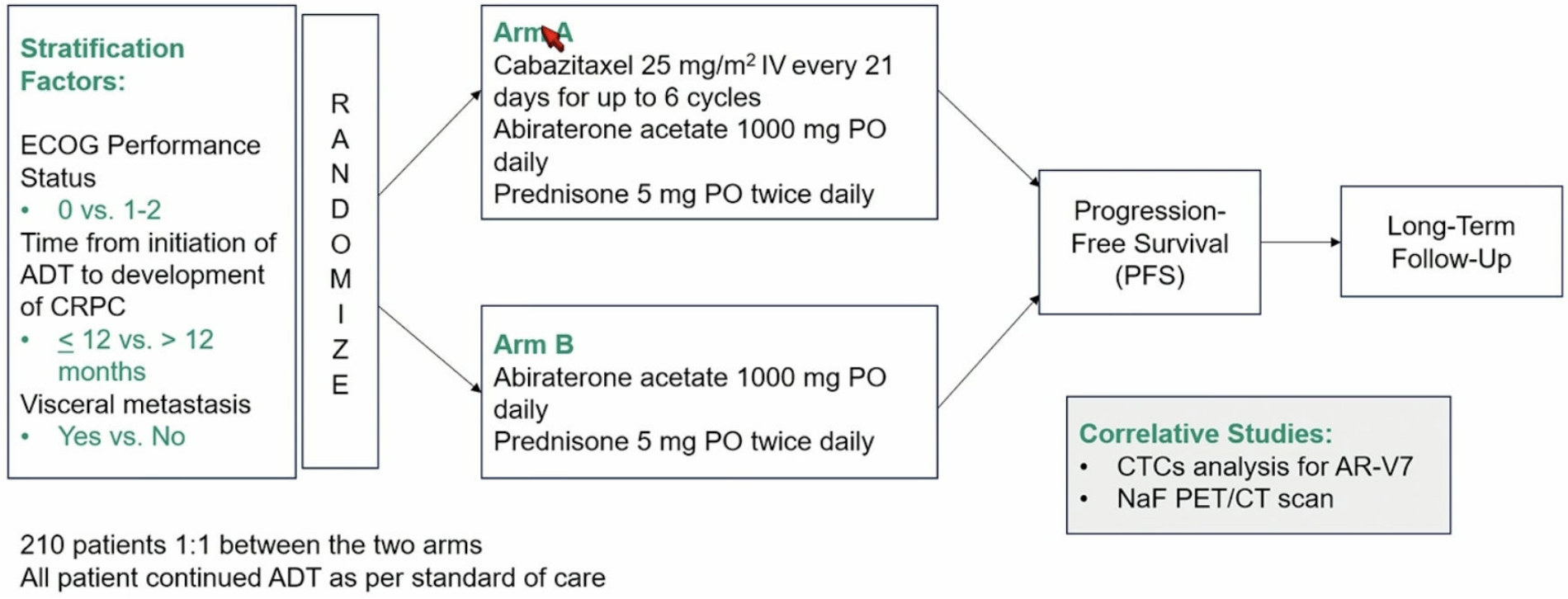


Clinical progression was investigator-assessed as: cancer-related pain escalation, immediate need for new treatment, ECOG status deterioration or progression requiring treatment discontinuation
ARPI, androgen receptor pathway inhibitor; BPI-SF, Brief Pain Inventory – Short Form; CI, confidence interval; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HR, hazard ratio; HRQoL, health-related quality of life; NE, not estimable; PSMA, prostate-specific membrane antigen

mCRPC

CHAARTED 2 : Abiratérone +/- cabazitaxel - Phase 2

Patients naif ARPI et traité par au moins 3 cycles de docetaxel en phase mHSPC



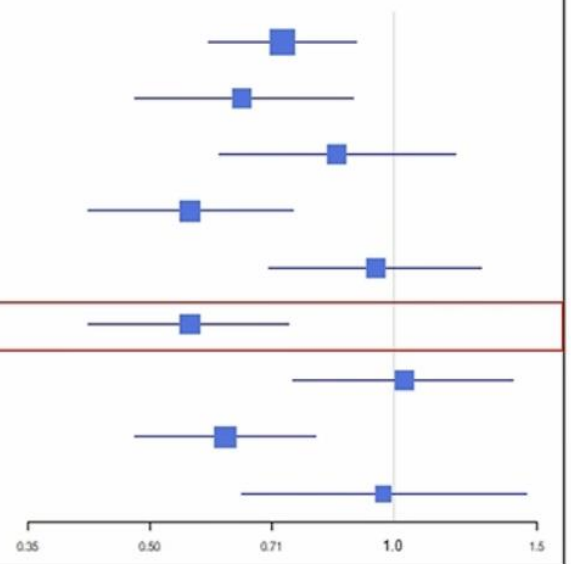
Kriakopoulos K et al , Abst 5000, ASCO 2024

mCRPC

CHAARTED 2 : Abiratérone +/- cabazitaxel - Phase 2

PFS Analysis by Subgroup

Subgroup	N	Median PFS (Cabazitaxel)	Median PFS (Abiraterone)	HR
All Patients	223	14.9	9.9	0.73
Age < 65	112	15.6	9.8	0.65
Age >= 65	111	10.7	9.9	0.85
ECOG PS of 0	130	20.9	10.1	0.56
ECOG PS of 1-2	93	9	6.3	0.95
Time from ADT to CRPC <= 12 months	114	12.9	5.1	0.56
Time from ADT to CRPC > 12 months	109	18.6	17.2	1.03
Without Visceral Metastasis	169	18.1	10.1	0.62
With Visceral Metastasis	54	9.6	7.1	0.97



- Age <65:
  5.8 months difference
- ECOG PS 0:
  10.8 months difference
- Time to CRPC of ≤ 12 months:
  7.8 months difference

Confirmation de faire CT en 3L après HT si récidive à <12mois?

mCRPC

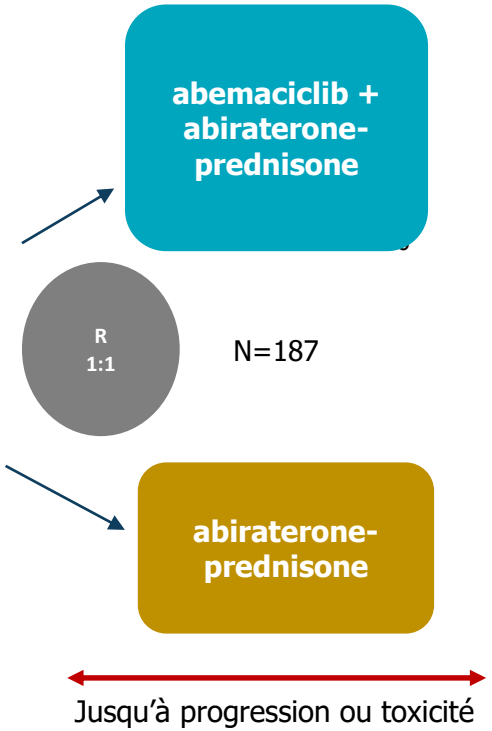
CYCLONE 2 – Abemaciclib + Abiraterone-P vs Abiraterone-P

Abemaciclib – inhibiteur de tyrosine kinase de CDK4/6

Population :
- Progression radio/bio sous DA
- ECOG 0-1
- Docetaxel autorisé au stade mHSPC
- Pas d'ARPI antérieure

Stratification :
- Docetaxel en situation HSe (O/N)
- maladie mesurable (O/N),
- progression radio à l'inclusion (O/N).

Scanners / 8 semaines



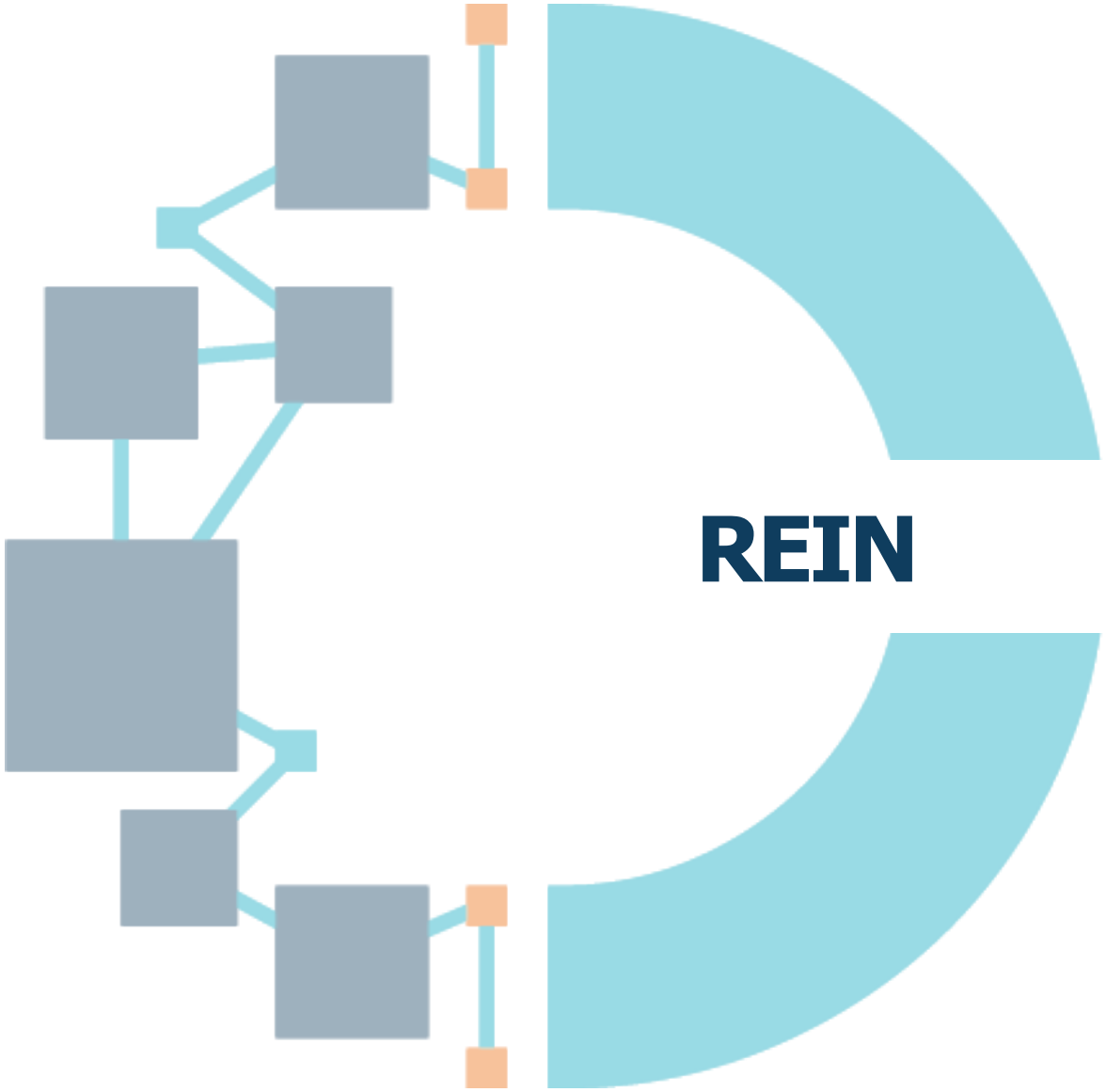
Critère principal :
- SSP radio (RECIST / PCWG3) Invest

Critères secondaires :
- SSP radio (BIRC)
- Survie globale
- Réponse objective
- Temps avant progression
- Temps avant progression PSA
- Temps avant aggravation des douleurs
- Qualité de vie
- PK

- Essai négatif sur tous les critères :

- **Survie sans progression**
- **Temps avant détérioration de la douleur**
- **Temps avant progression symptomatique**
- **Survie sans progression PSA**

- Sur-toxicité avec réduction de dose et arrêt de traitement



REIN

Entre 2016-2023 – 611 pts favorables - 165 très favorable (26,9%)

Zarba M et al. Abstr 4514

Groupe favorable/ très favorable

Définition et Objectifs

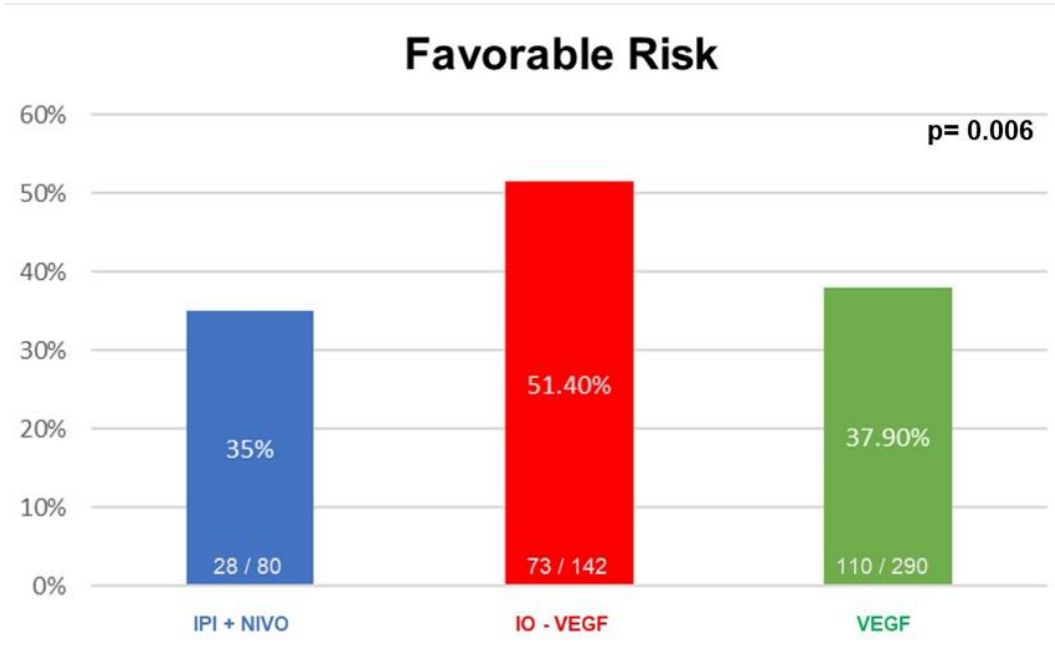
- *Groupe pronostic très favorable* : intervalle dg/tt ≥ 3 ans + KPS 90-100% **ET** pas de loc II cérébrale , osseuse ou hépatique

- *Objectifs:* survie à 2 ans, durée de ttt et temps avant le prochain traitement

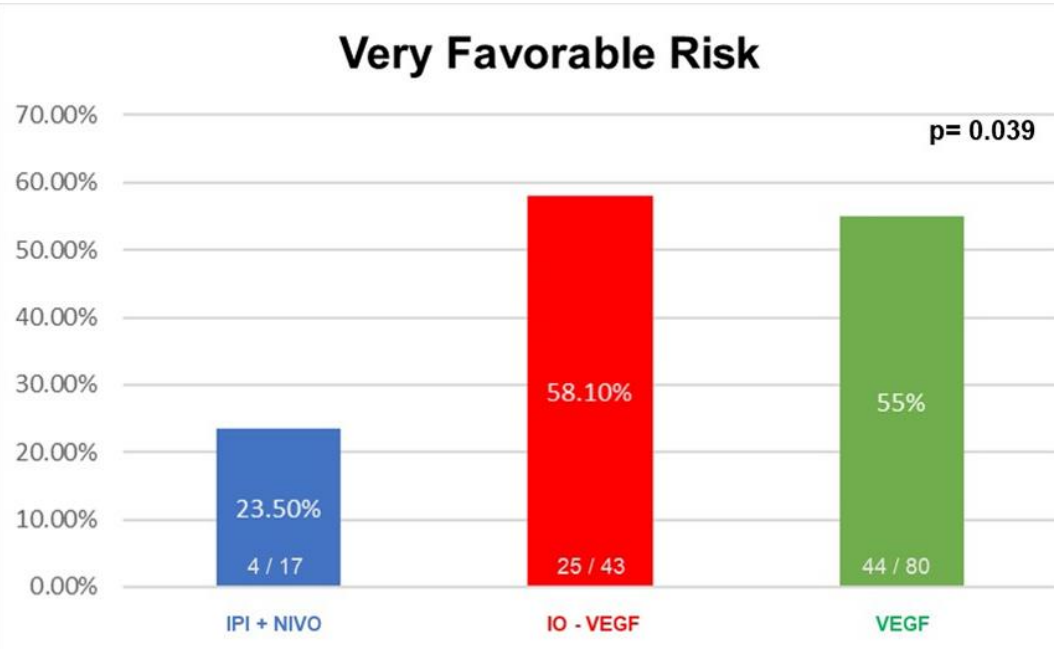
Caractéristiques des populations

Répartition des ttt reçus

65% M+ pulmonaires; 77% ayant + d'un seul site M+



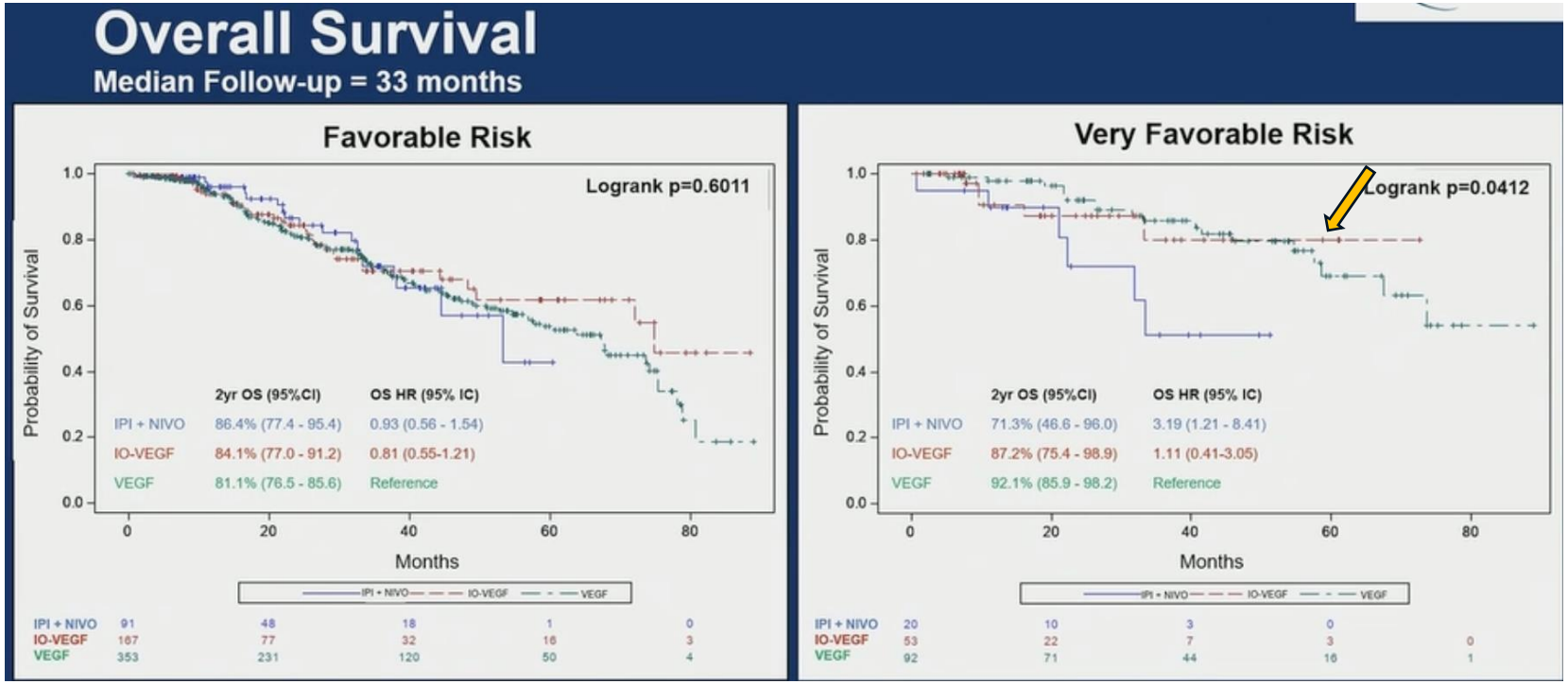
60% M+ pulmonaires; 70% ayant + d'un seul site M+



Survie globale

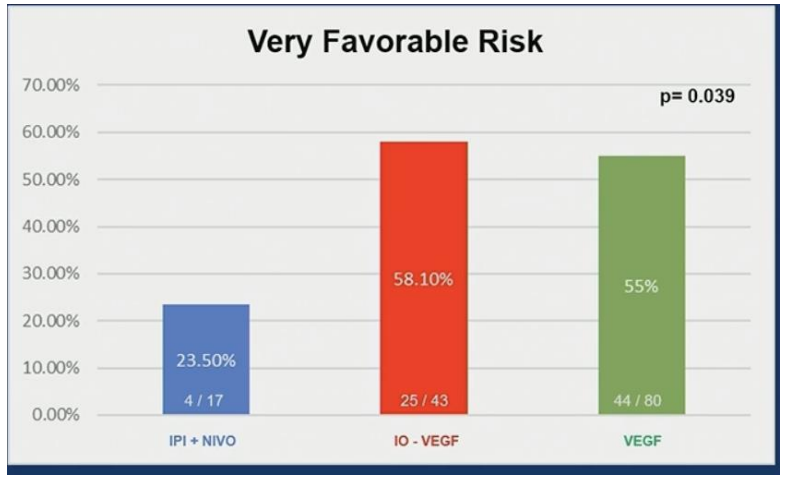
Favorable: Confirmation de l'absence de bénéfice de SG

Très favorable: Effet délétère de IO/IO

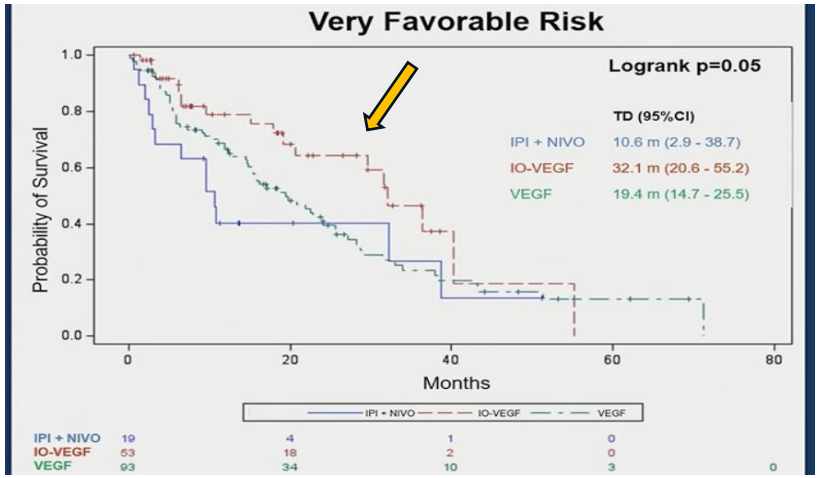


Groupe très favorable

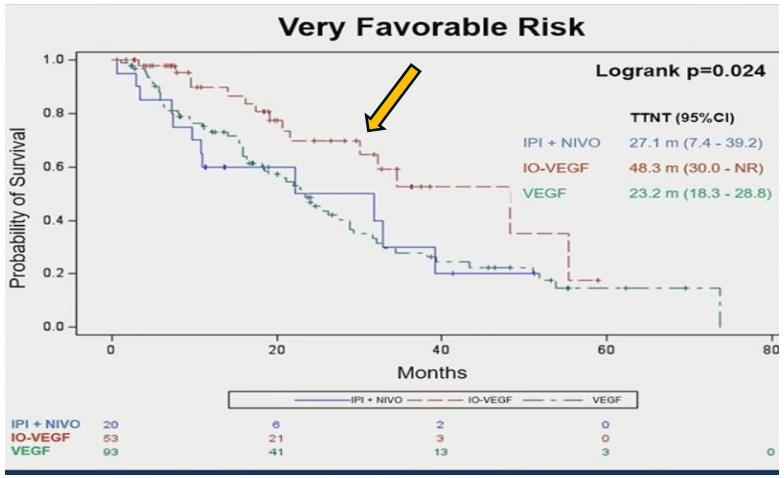
Bénéfice de la combo TKI/IO vs TKI



Taux de réponse



Durée de ttt



Temps avant prochain ttt

BIOMARQUEURS

Biomarker analyses in patients with advanced renal cell carcinoma from the phase 3 CLEAR trial

Robert J. Motzer[1], Camillo Porta[2], Masatoshi Eto[3], Thomas E. Hutson[4], Sun Young Rha[5], Jaime R. Merchan[6], Eric Winquist[7], Howard Gurney[8], Viktor Grünwald[9], Saby George[10], Julia Markensohn[11], Joseph E. Burgents[11], Razvan Cristescu[11], Yudai Narita[12], Cixin S. He[13], Ziming Zhao[13], Chinyere E. Okpara[14], Yukinori Minoshima[12], and Toni K. Choueiri[15]

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Biomarker Analysis of the Phase 3 KEYNOTE-426 Study: Pembrolizumab Plus Axitinib Versus Sunitinib for Advanced Renal Cell Carcinoma

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Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010, a randomized Phase 3 study of adjuvant atezolizumab vs placebo in patients with renal cell carcinoma at increased risk of recurrence after resection

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BIOMARQUEURS

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Expression de PD-L1
Mutations tumorales somatiques
Signatures d'expression génique

= Non discrimant

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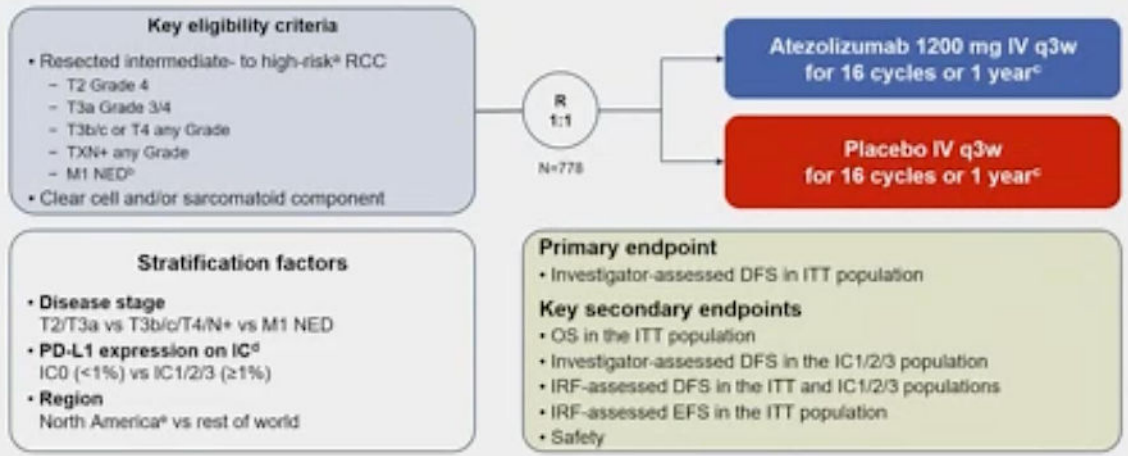
IMmotion010 Study design (NCT03024996)



EFS, event-free survival; IC, tumour-infiltrating immune cells; IRF, independent review facility; ITT, intention to treat; IV, intravenous; NED, no evidence of disease; OS, overall survival; q3w, every 3 weeks; R, randomized; TNM, tumor, node, metastasis. [a]Per TNM grading system or status post metastasectomy. [b]Including patients with synchronous metastasectomy and patients with metachronous metastasectomy ≥12 months after primary surgery. [c]Whichever occurred first. [d]Per VENTANA SP142 immunohistochemistry assay. [e]Not including Mexico.

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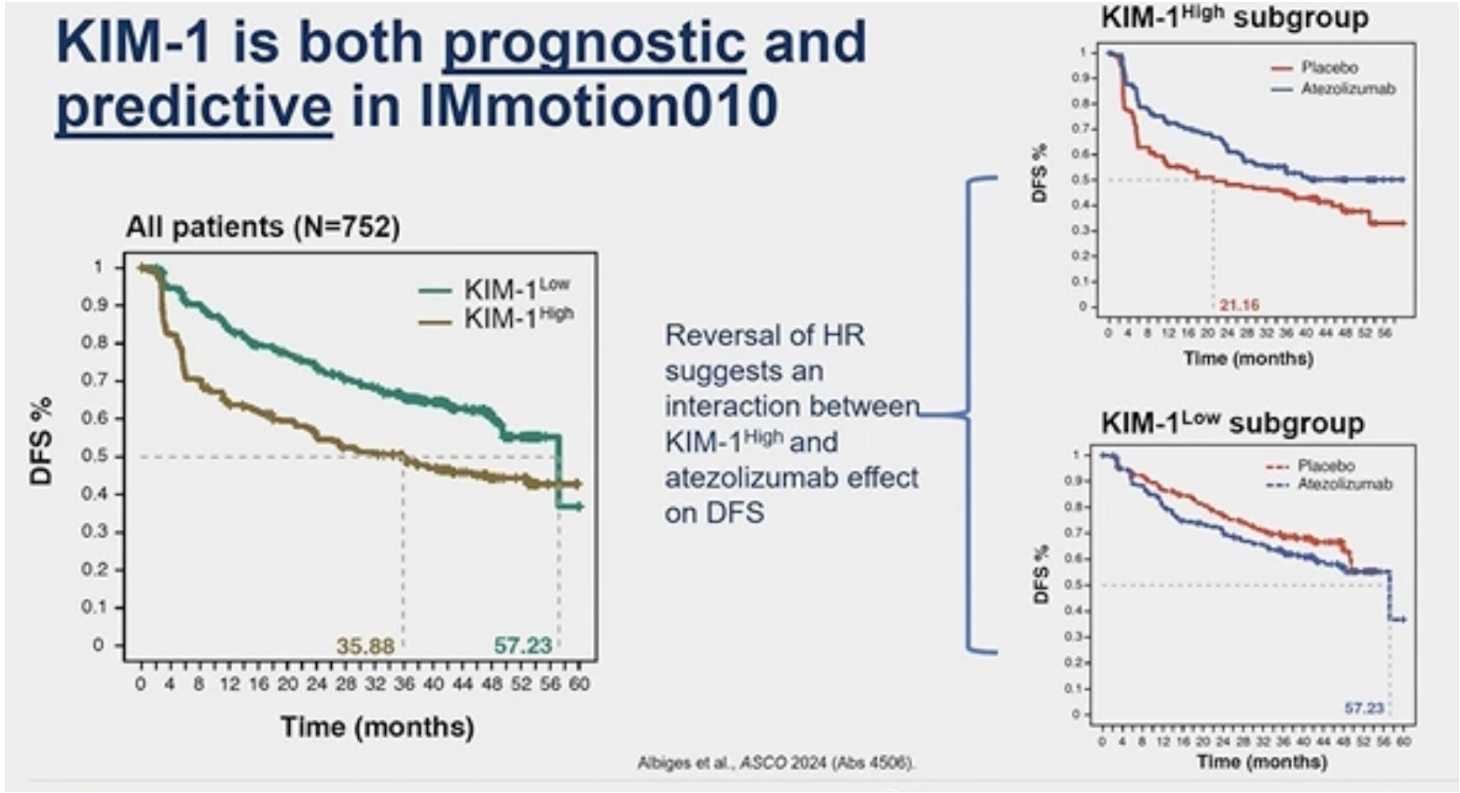
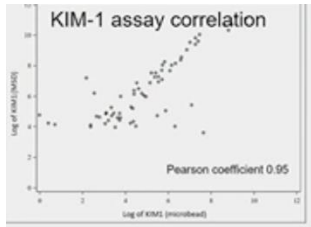
KIM-1

Glycoprotéine présente serum/plasma => Biomarqueur pour IO en adjuvant?





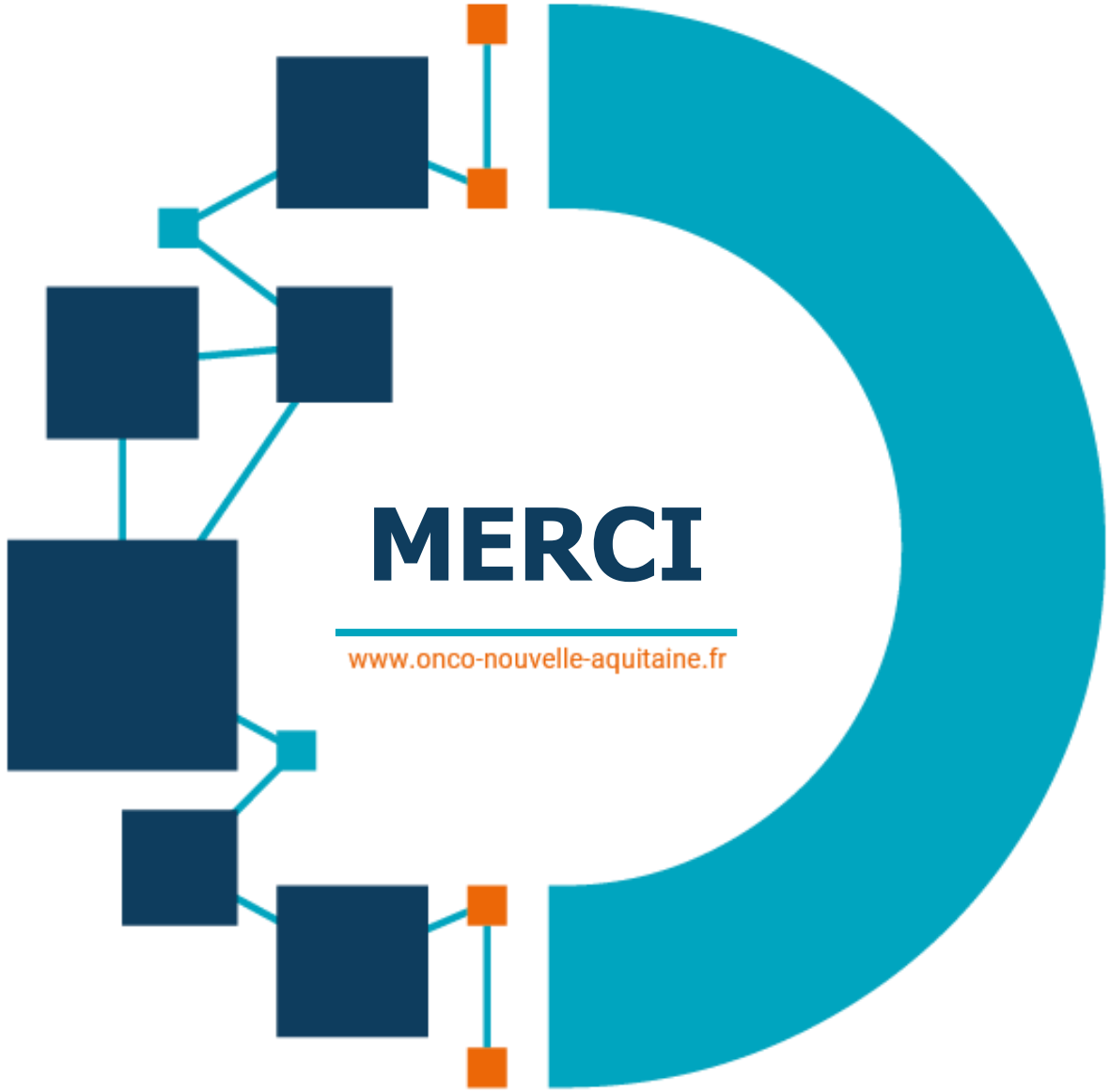
Trial	Median KIM-1	Assay used
ASSURE	76 pg/mL	Luminex bead-based
CheckMate 914 (Part A)	102 pg/mL	Electrochemiluminescence
IMmotion010	73 pg/mL	Electrochemiluminescence

Xu et al., JCO 2024 (Supplemental Figures).

- Nécessité de standardisation des techniques et des cut-off
- Validation prospective nécessaire

Les points à retenir

- *Vessie*
  - Ouraque, ULTIMA => mFolfirinox: Nouveau standard en 1L M+
  - Néoadjuvant, AURA, unfit : Pas de bénéfice à l'adjonction de CT p/r IO
  - Néoadjuvant, AURA, réponse histologique complète = Marqueur de SG
- *Prostate*
  - Embark: + de gynécomastie avec enza seul, + de bouffées avec ADT, pas de changement sur qualité de vie
  - PSMAfore: ^{177} Lu PSMA-617 retarde la dégradation liée au cancer, pas d'amélioration SG (mais cross-over++)
- *Rein*
  - KIM 1 : Futur biomarqueur circulant pronostic et prédictif pour l' IO en adjuvant?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