



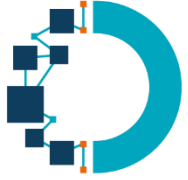
Recherche Clinique : Place des urologues dans les essais des TVNIM et TVIM

Mardi 03 octobre 2023

Limoges

Eddy VALGUEBLASSE
Urologue
Polyclinique de Limoges

Actualités dans la prise en charge des cancers urologiques

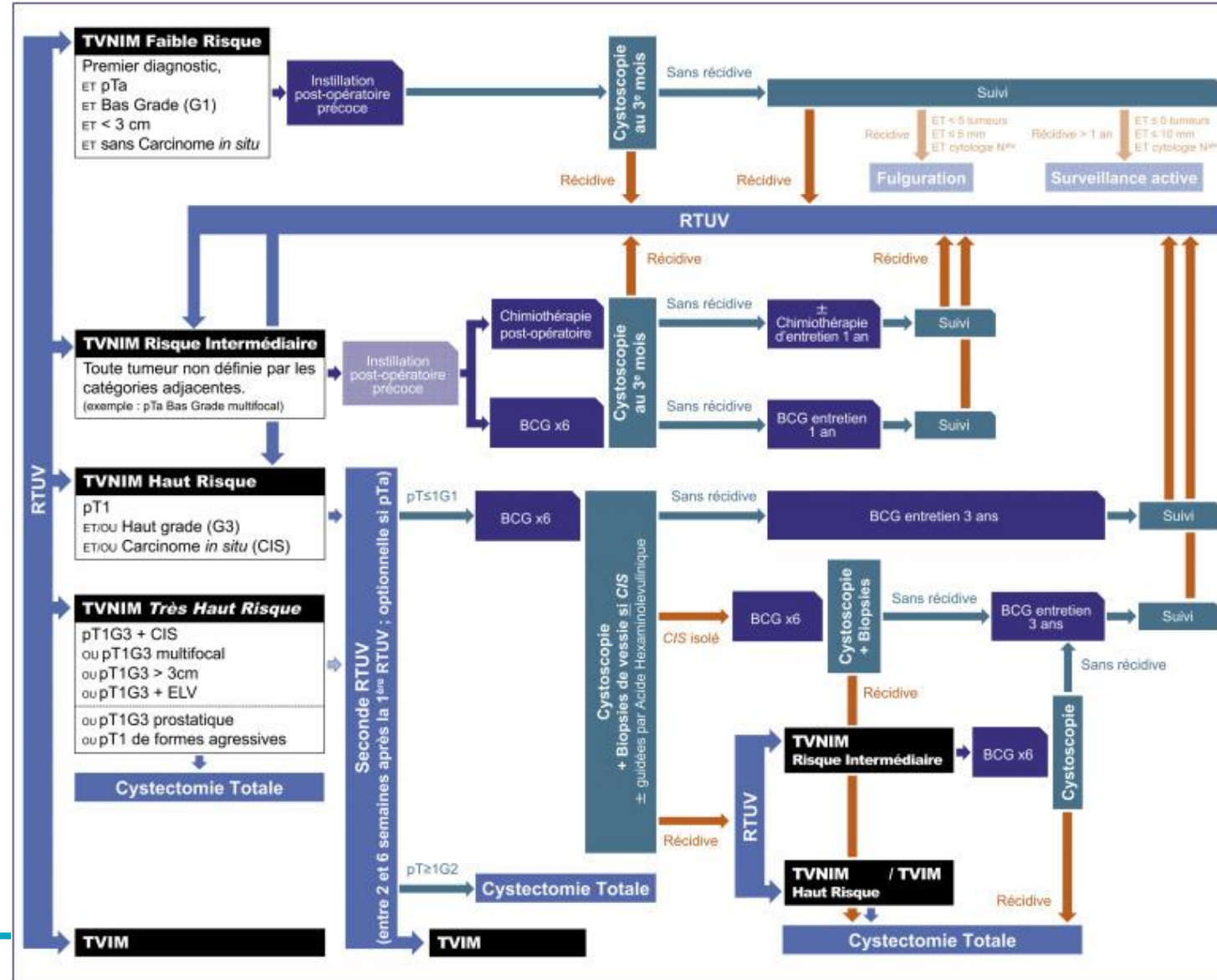


Liens d'intérêts

- Aucun pour la présentation



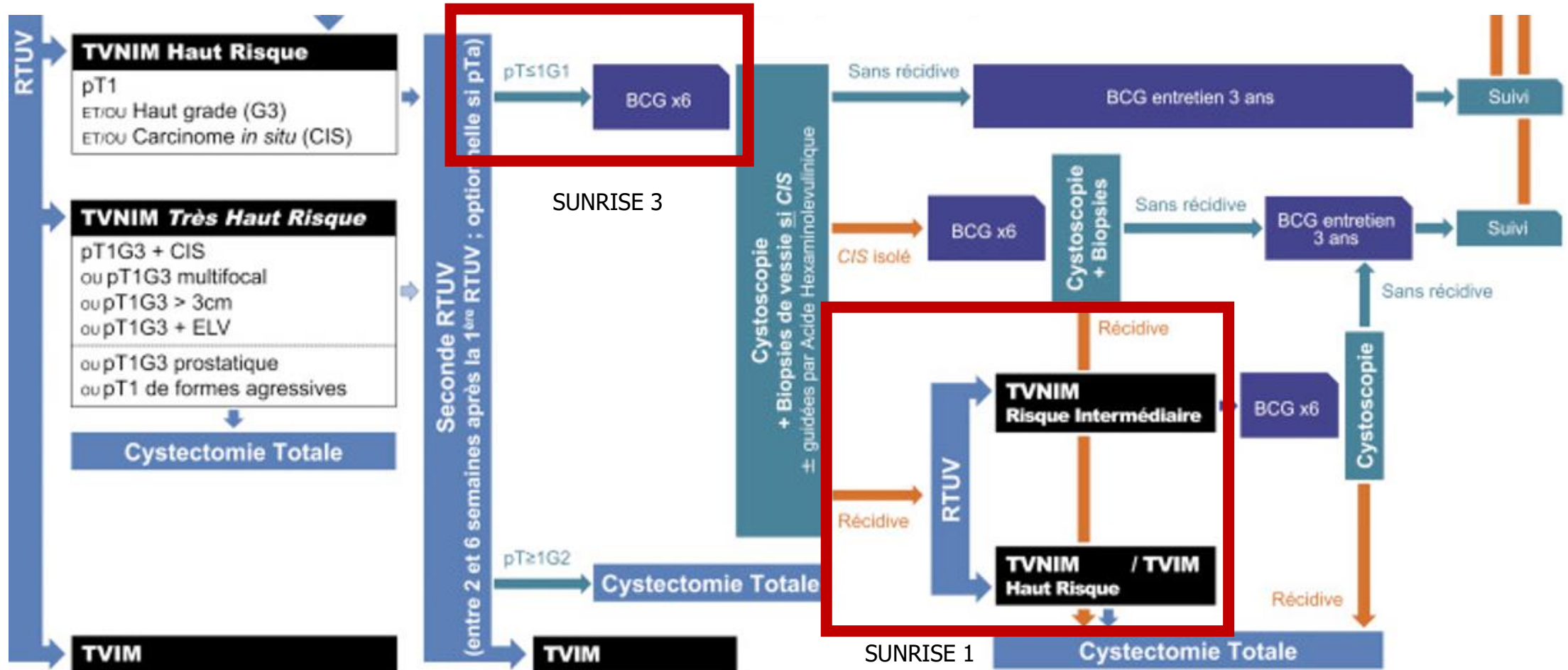
Recommandations AFU dans les TVNIM





Les essais dans les TVNIM : place de l'urologue

Programme SUNRISE (essais industriels) de phase II et III



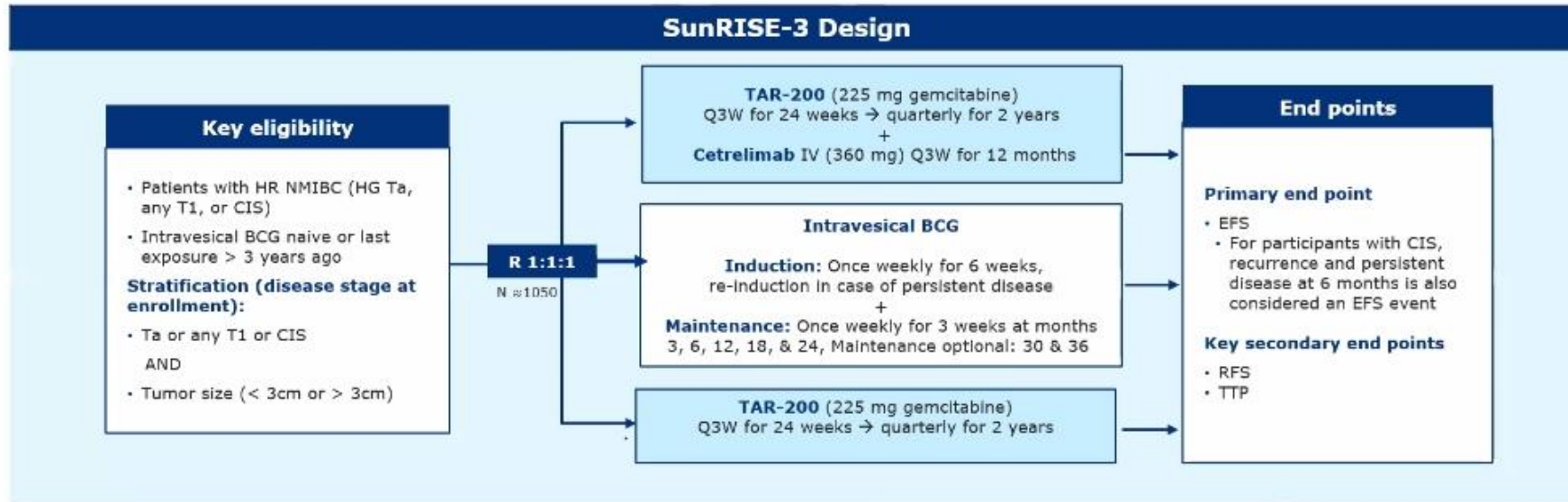


TVNIM : BCG vs ttt expérimental

TAR200 +/- immunothérapie

SunRISe-3

SunRISe-3 is a prospective, randomized, **phase 3 study** that will provide efficacy and safety data for TAR-200 + cetrelimab vs SoC BCG for patients with BCG-naïve HR NMIBC¹



Statut de l'étude :

○ 128/1050 pts recrutés

En France

- Centres activés : 12/19
- Patients screenés: 1
- Patients randomisés: 1

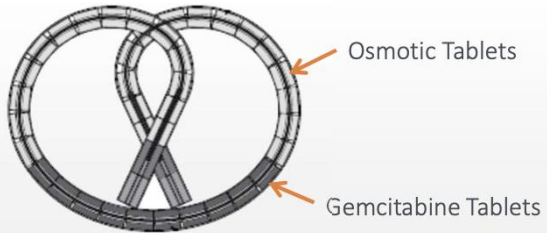
1.NCT05714202. ClinicalTrials.gov. Accessed 17 March 2023.



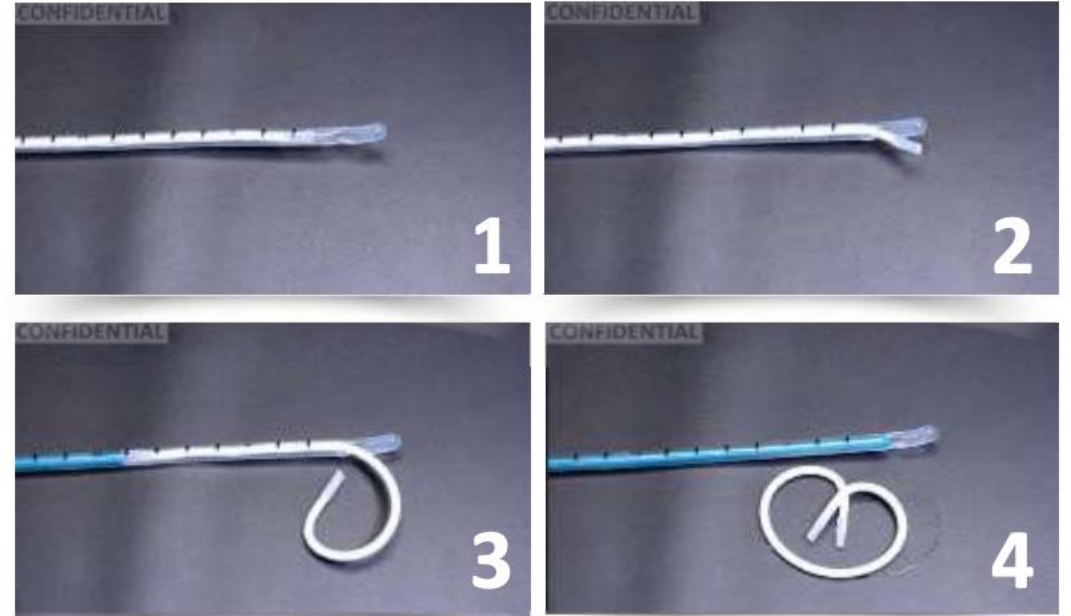
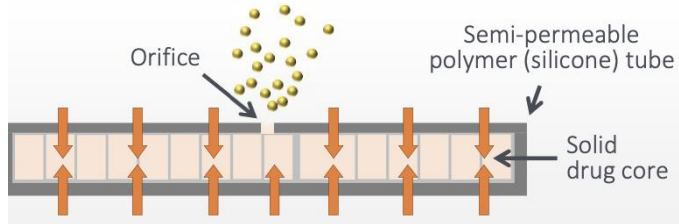
Place de l'urologue dans le bras expérimental

TAR 200 : chimio intra-vésicale

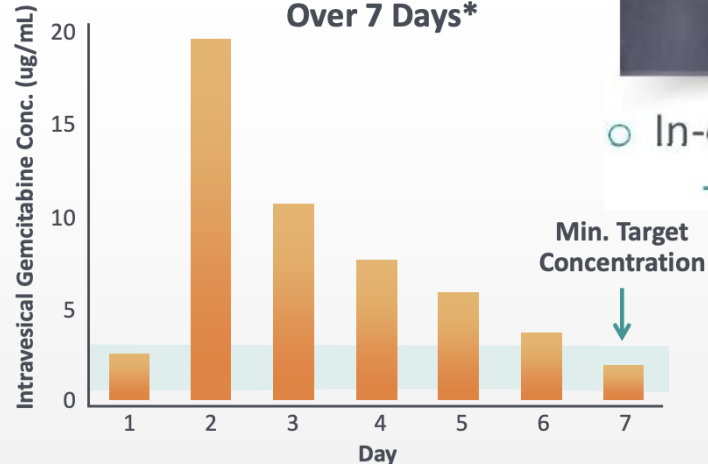
Two Minitablet Design



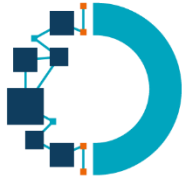
Osmotic System



Gemcitabine Urine Conc. Over 7 Days*



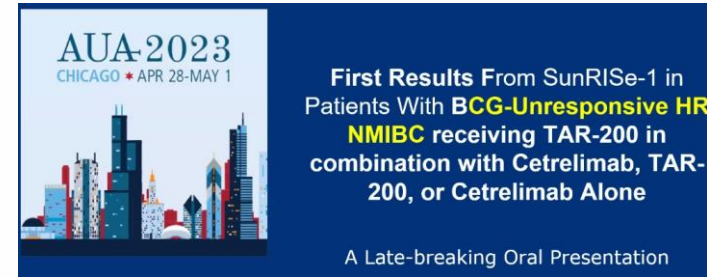
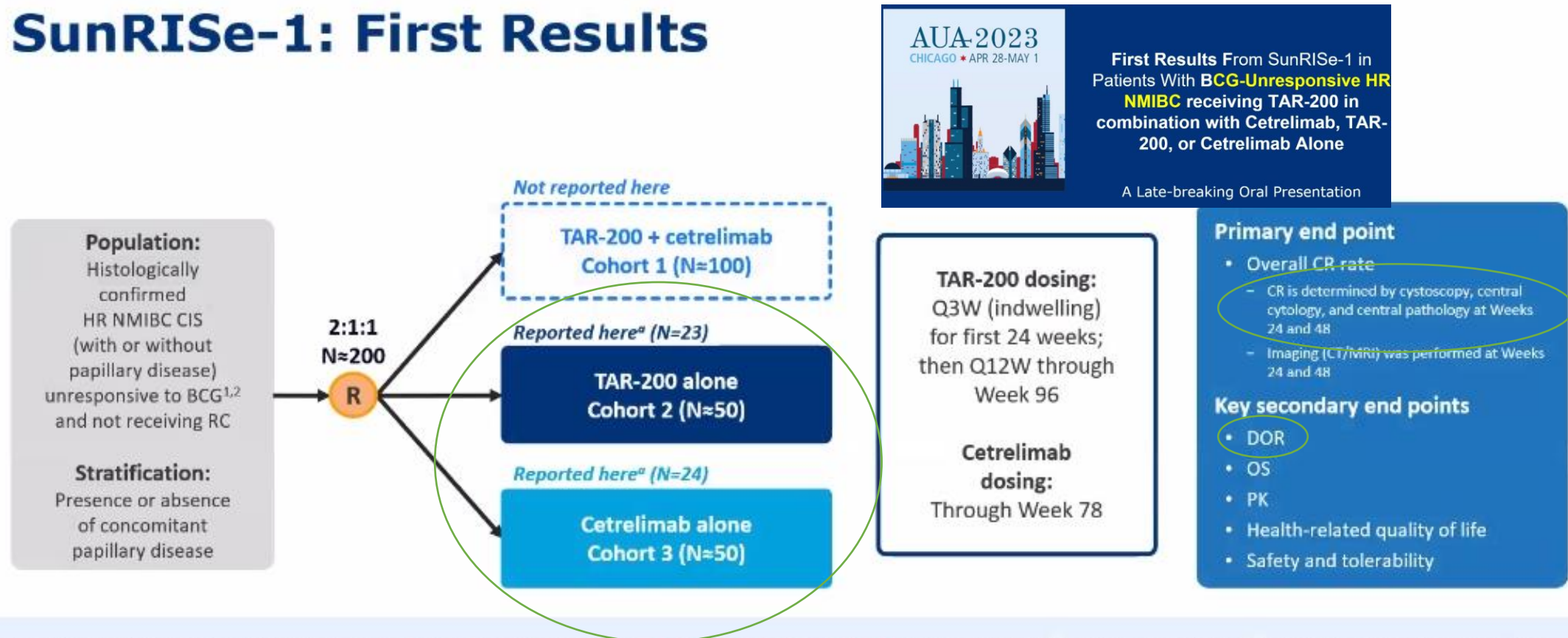
- In-office dosing and retrieval using existing procedures
- Catheterization, cystoscope, no anesthesia



TVNIM résistante à la BCG thérapie

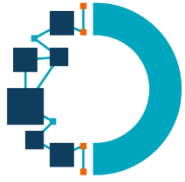
Résultats préliminaires de la Sunrise 1 (fin d'inclusion en nov 2023)

SunRISe-1: First Results



Here we report **first results** from the **TAR-200 monotherapy** and **cetrelimab monotherapy** groups of SunRISe-1 from a planned futility analysis (N=47 patients)

- Clinical cutoff: April 4, 2023
- IDMC review of safety data: April 14, 2023

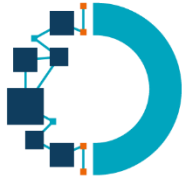


Caractéristiques des patients

Characteristics	TAR-200 (N=23)	Cetrelimab (N=24)
Age, years, median (range)	72.0 (40-81)	70.0 (51-88)
Sex, male, %	82.6	79.2
Race, %		
White	69.6	83.3
Asian	0	4.2
Black or African American	4.3	0
Not reported	26.1	8.3
Unknown	0	4.2
ECOG performance status 0, %	95.7	95.8

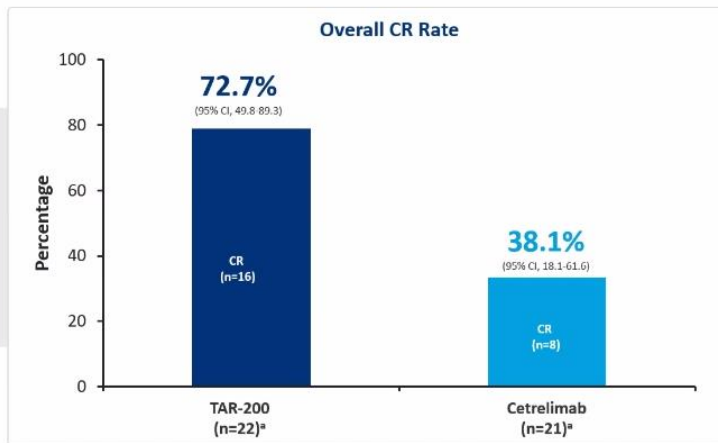
Baseline characteristics were well balanced between groups

Characteristics	TAR-200 (N=23)	Cetrelimab (N=24)
Tumor stage, %		
CIS only	69.6	65.2
CIS + papillary disease	30.4	34.7
Total doses of prior BCG, n, median (range)	12 (7-24)	12 (7-30)
Time from last BCG to CIS diagnosis, months, median (range)	3.0 (1-22)	3.1 (0-11)
Reason for not receiving RC, %		
Declined	95.7	100
Ineligible	4.3	0



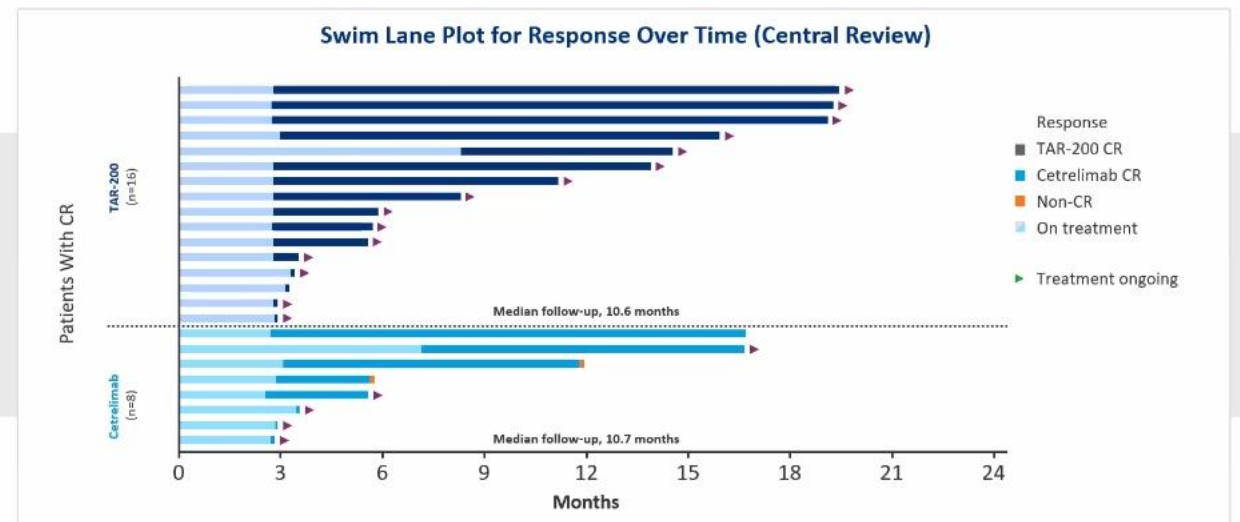
Données d'efficacité et de durée de réponse

Efficacy of TAR-200 and Cetrelimab **monotherapies**:
73% of evaluable patients achieved CR with TAR-200



CR is based on cystoscopy and centrally assessed urine cytology and biopsy at Weeks 24 and 48

Median DOR with TAR-200 has not been reached after median follow-up of **~11 months**

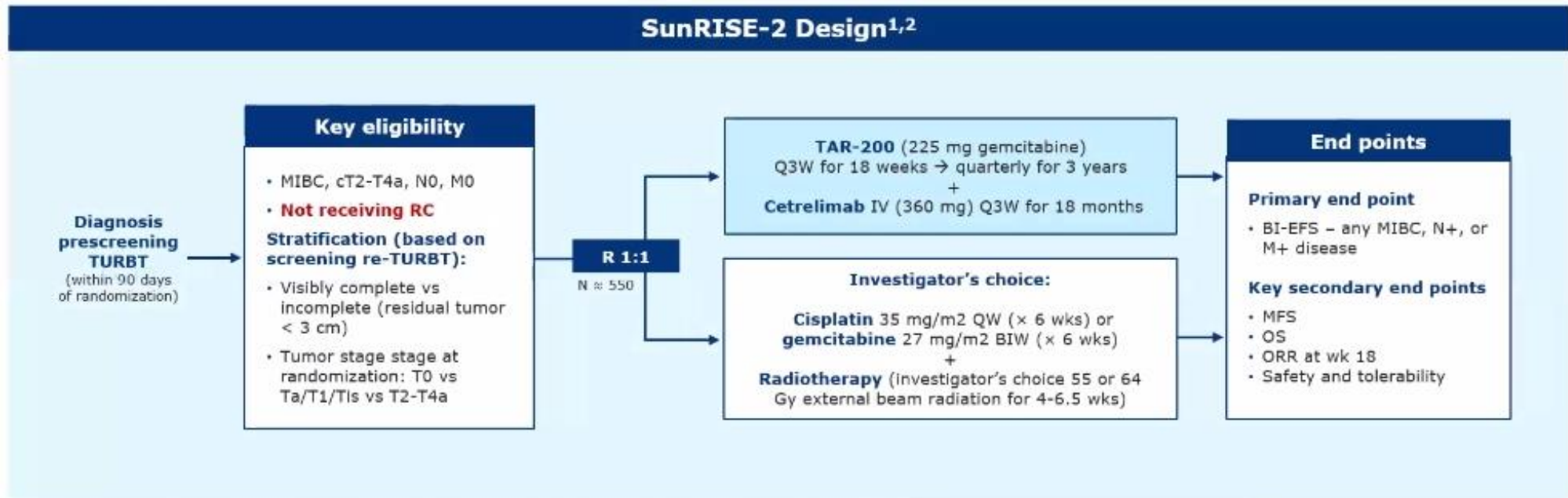




TVIM : place de l'urologue dans le ttt plurimodal

SUNRISE 2 : Refus de cystectomie ou inéligible à la chimio

SunRISe-2 is a prospective, multicenter, open-label, randomized **phase 3 study** evaluating the efficacy and safety of TAR-200 + cetrelimab vs SoC chemoradiotherapy in patients with MIBC who are ineligible for or refuse RC^{1,2}

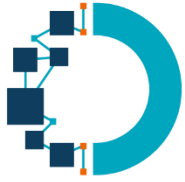


Statut de l'étude :

- 238/550 pts recrutés

En France

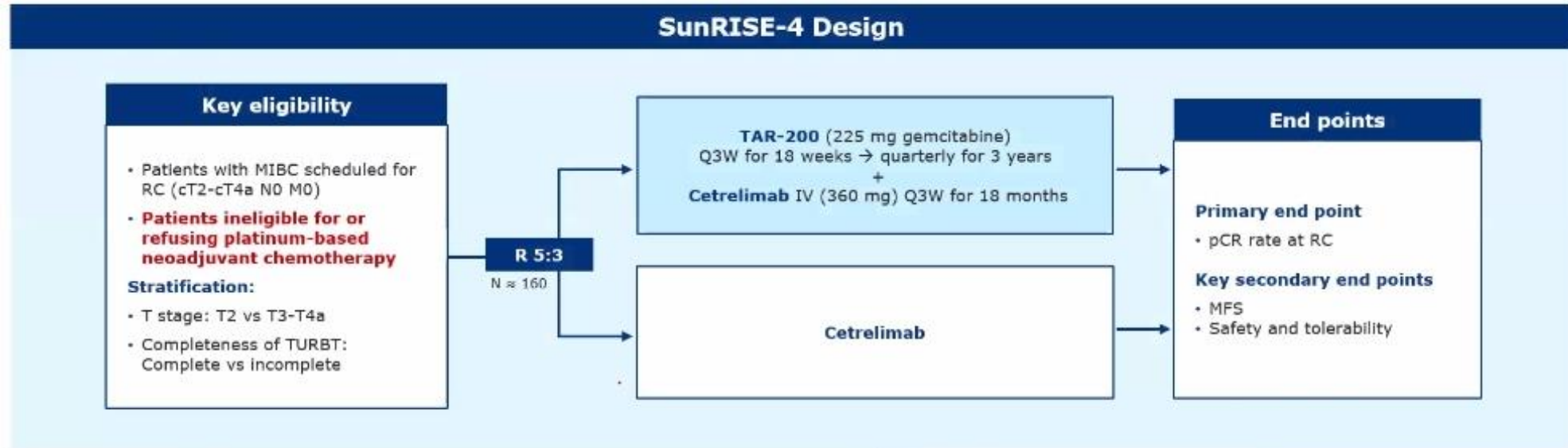
- Centres activés : 11
- Patients screenés: 23
- Patients randomisés: 9



TVIM : place de l'urologue dans le ttt plurimodal

SUNRISE 4 : inéligible à la chimio néoadjuvante, ok pour cystectomie

SunRISe-4 is a prospective, randomized, open-label, **phase 2**, window-of-opportunity study to demonstrate the activity of cetrelimab alone and cetrelimab in combination with TAR-200 with respect to pCR rates at RC and the potential subsequent correlation with postsurgical MFS



Statut de l'étude :

○ 54/160 pts recrutés

En France

- Centres activés : 14
- Patients screenés: 5
- Patients randomisés: **3**



En résumé

- Importance de la participation des urologues en recherche clinique :
 - TVNIM : **Prise en main de nouvelle thérapeutique intra-vésicale pour améliorer ou surplanter la BCG thérapie**
 - TVIM : Tendance très nette à la préservation vésicale et donc importance des ttt multimodaux
 - **Importance d'une RTUV complète pour l'envisager : Pierre angulaire à la réussite de la préservation**
 - Evolution de l'imagerie (IRM vésicale) et de la radiothérapie
 - Bénéfice des avancées systémiques réalisées dans les stades avancés : immunothérapie et ADC (comme Padcev®)

