To innovate the future of cancer care to cure patients and preserve organ function

October 17, 2024

aura

Legal disclosure

This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could', "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words. These forward-looking statements include statements about the initiation, timing, progress, results and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; statements regarding our expectations for an improved quality of life of patients after treatment with bel-sar and changes to the treatment paradigm for patients; statements regarding our beliefs and expectations for the high unmet medical need for an effective local treatment in urologic oncology to preserve organ function; and the size and growth potential of the markets for our product candidates and our ability to serve those markets.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and we undertake no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the SEC, which are available on the SEC's website at www.sec.gov. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We caution you not to place undue reliance on the forward-looking statements contained in this presentation.

This presentation discusses product candidates that are under preclinical or clinical evaluation and that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority. Until finalized in a clinical study report, clinical trial data presented herein remain subject to adjustment as a result of clinical site audits and other review processes. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied.

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Urologic oncology key opinion leaders participating on today's call

Max Kates, MD
Johns Hopkins

Joe Jacob, MD, MCR
Syracuse University

Neal Shore, MD, FACS
Carolina Urologic Research Center

Gary Steinberg, MD, FACS
RUSH University

Aura leadership participating on today's call

Sabine Brookman-May, MD
SVP, Therapeutic Area Head Urologic Oncology

Elisabet de los Pinos, PhD
Founder and CEO

Jill Hopkins, MD
Chief Medical Officer And President of R&D

Joseph McQuaid, MD
Director, Clinical Development Urologic Oncology

Cancer cases are predicted to increase by 77% by 2050 as our population ages and grows[1]

Large increase in the number of early-stage cancers requiring treatment options with improved benefit-risk profile

Growing need for function-preserving, organ-sparing, local therapies that can intercept the course of disease

1. World Health Organization. Global cancer burden growing, amidst mounting need for services. 2024. Available at: Global cancer burden growing, amidst mounting need for services (who.int) [Accessed October 1, 2024].

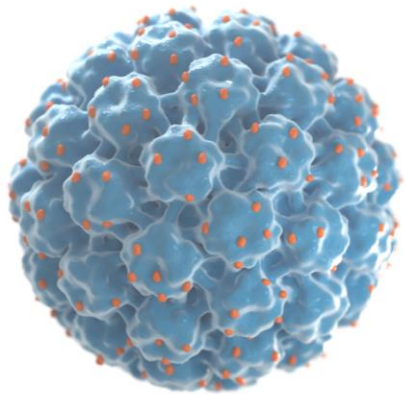
Virus-like drug conjugates have the potential to transform early cancer treatment

Unique tumor selectivity

Targets a key receptor molecule expressed in the early stages of malignant tumor transformation

Dual MOA

Targeted cytotoxicity and immune activation; potential to generate lasting anti-tumor T-cell memory



Tumor and mutation-agnostic

>100 cell lines
>15 animal tumor models

High potency

~200 cytotoxic molecules per VLP; demonstrated picomolar efficacy in multiple animal tumor models

Positive clinical data in multiple early-stage local cancers

- **Choroidal melanoma:** Positive phase 2 data; phase 3 ongoing
- **NMIBC:** Positive early phase 1 data; phase 1 ongoing

Favorable safety profile

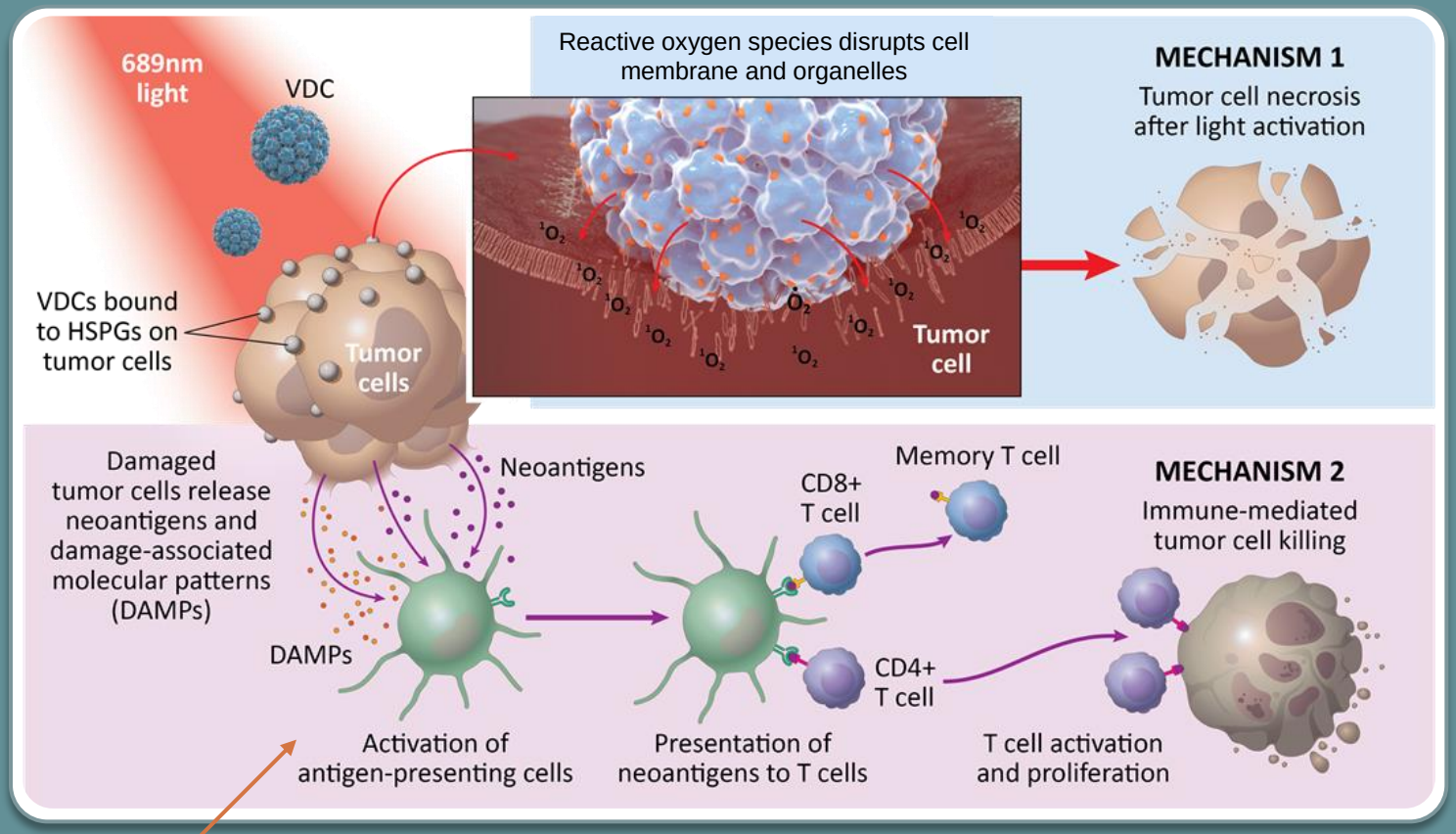
No treatment-related SAEs and no DLTs reported in bel-sar Phase 2 choroidal melanoma trial

DLT, dose-limiting toxicity; **MOA**, mechanism of action; **NMIBC**, non-muscle-invasive bladder cancer; **SAE**, serious adverse event; **VLP**, virus-like particle.

AU-011 has a novel dual mechanism of action

Disruption of the tumor cell membrane and pro-immunogenic cell death by necrosis leads to T cell activation and immune-mediated tumor cell killing

VLPs bind to macrophages, B cells, dendritic cells and neutrophils and are capable of **stimulating antigen-presenting cells** through TLR-4 engagement and NFk-β production



Release of **DAMPs** induces **anti-tumor immunity**

AU-011 treatment is designed to be cytopathic to resident suppressor cells, reducing the immune-suppressive microenvironment and contributing to **anti-tumor immunity**

Kines RC, et al. *Int J Cancer*. 2016;138(4):901–11. Kines RC, et al. *Mol Cancer Ther*. 2018;17(2):565–74. Kines RC, et al. *Cancer Immunol Res*. 2021;9:693–706.
DAMPs, damage-associated molecular patterns; **HSPG**, heparan sulfate proteoglycan; **VDC**, virus-like drug conjugate; **VLP**, virus-like particle.

Bladder cancer: High unmet medical need for function-preserving organ-sparing therapies

9th most common cancer worldwide[1]

>600,000 cases/year globally[1]

614,298 diagnosed in 2022[1]
(>7% increase from 2020)[1,2]

Ranked 13th for mortality[1]

One of the highest lifetime treatment costs of all cancers

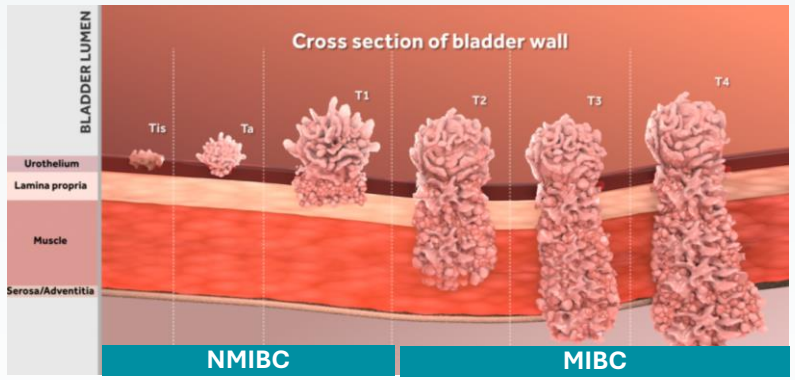
>$6 billion
Annual cost of treatment in US[5]

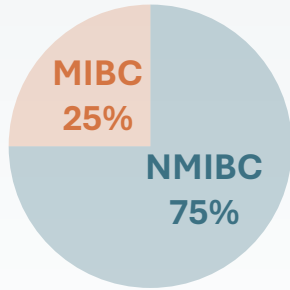
Conventional bladder cancer treatments are suboptimal

- *Short- and long-term side effects*
- *Considerable impact on QoL*
- *Inadequate efficacy*
- *Multiple TURBT surgeries*
- *Disease progression/metastasis*
- *Loss of bladder/cystectomy*

84% of patients do not complete a full course of BCG treatment[6]

Patients are receiving fewer courses of BCG due to global shortage[7]



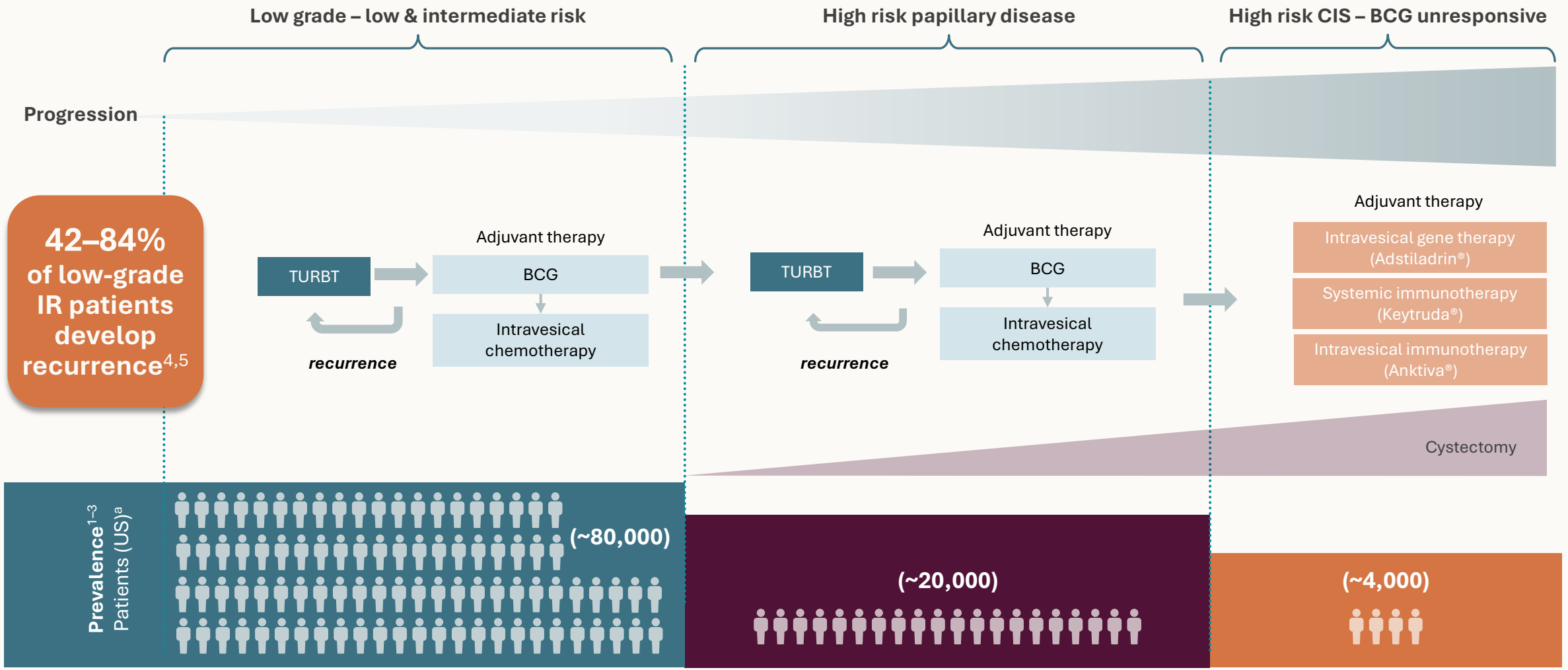


The majority of bladder cancer patients present with NMIBC[3]

~70-80% of patients with NMIBC develop recurrence after treatment[8]

1. GLOBOCAN 2022. Bladder. Available at: https://gco.iarc.who.int/media/globocan/factsheets/cancers/30-bladder-fact-sheet.pdf. [Accessed October 1, 2024]. **2.** Sung H, et al. *CA Cancer J Clin*. 2021;71(3):209–49. **3.** Burger M, et al. *Eur Urol*. 2013;63(2):234–41. **4.** Flaig TW, et al. *J Natl Compr Canc Netw*. 2018;16(9):1041–53. **5.** Clark O, et al. *Pharmacoecon Open*. 2024 Aug 18. doi: 10.1007/s41669-024-00512-8. [Online ahead of print]. **6.** Lamm DL, et al. *J Urol*. 2000;163(4):1124-9. **7.** Shore ND, et al. *Urol Oncol*. 39(10):642–63. **8.** Shalata AT, et al. *Cancers (Basel)*. 2022;14(20):5019. **BCG**, Bacillus Calmette-Guerin; **MIBC**, muscle-invasive bladder cancer. **QoL**, quality of life; **TURBT,** transurethral resection of bladder tumor.

High risk of recurrence and progression with current treatments for NMIBC



[a]Each figure represents 1000 persons.

1. Holzbeierlein JM et al. *J Urol.* 2024;212(1):3–10. **2.** Holzbeierlein JM et al. *J Urol.* 2024 Apr;211(4):533-538. **3.** Internal Aura epidemiology of market size; data on file. **4.** Shalata AT, et al. *Cancers (Basel).* 2022;14(20):5019. **5.** van Rhijn BWG, et al. *Eur Urol.* 2009;56(3):430–42.

BCG, Bacillus Calmette-Guérin; **CIS**, carcinoma in situ; **IR,** intermediate risk; **NMIBC**, non-muscle-invasive bladder cancer; **TURBT**, transurethral resection of bladder tumor.

AU-011 as a potential front-line immune ablative therapy in NMIBC

AU-011 has a dual mechanism of action and can potentially reduce the treatment burden

Treatment goals

- Focal treatment with direct tumor cell killing
- Stimulate broad anti-tumor T cell response
- Front-line early intervention for local disease
- Decreased treatment burden with favorable safety profile
- Reduce risk of recurrence and progression
- Avoid TURBT/operating room

NMIBC, non–muscle-invasive bladder cancer; **TURBT,** transurethral resection of bladder tumor.

AU-011 administration and activation may be optimized for the urology clinic

Local administration of AU-011 is aligned with current practice in urology offices

In-office procedure

Local cystoscopic administration of drug with standard cystoscopy needle

<5 minutes

Laser light activation

<10 minutes total laser time

<15 minutes total procedure time

Familiar procedures for urologists
Bladder injections (e.g. botox) and laser application are commonly used

No general anesthesia
AU-011 treatment may be feasible for patients with contraindications for general anesthesia/TURBT (e.g., comorbidities)

No requirement for additional safety precautions in drug handling
No viral replication or shedding

TURBT, transurethral resection of bladder tumor.

Phase 1 trial of AU-011 in bladder cancer

Review of early data from non-light activated and light-activated NMIBC cohorts

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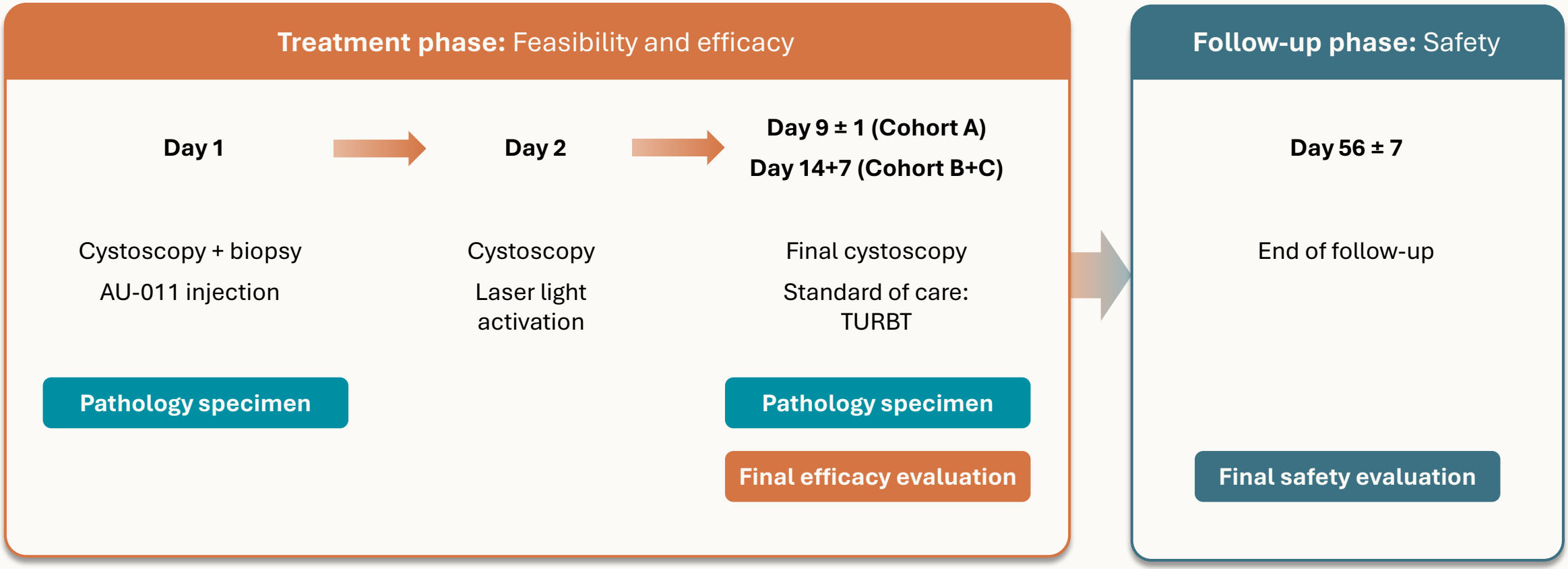
Window of opportunity study: AU-011 administered between scheduled biopsy and standard TURBT

Clinical response data up to 21 days; safety data up to 56 days



TURBT, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Phase 1 trial of AU-011 for bladder cancer designed to evaluate safety, feasibility, and mechanism of action

Single dose window of opportunity study in NMIBC all-comers

Histopathological assessment completed at time of standard of care TURBT

Part 1 (n=5)

AU-011 alone

Drug only (No light)

Total 100 µg

NMIBC (N=5)

50 µg at tumor base
50 µg within lamina propria

Part 2 (n=~10)

AU-011 + focal light activation

Cohort A: Drug + light

Total 100 µg

NMIBC (N=4)

50 µg at tumor base
50 µg within lamina propria

Cohort B: Drug + light

Total 100 µg

NMIBC (N=3)

100 µg at tumor base

Cohort C: Drug + light

Total 200 µg

NMIBC (N~3)

200 µg at tumor base

1 patient evaluable to date

Completed

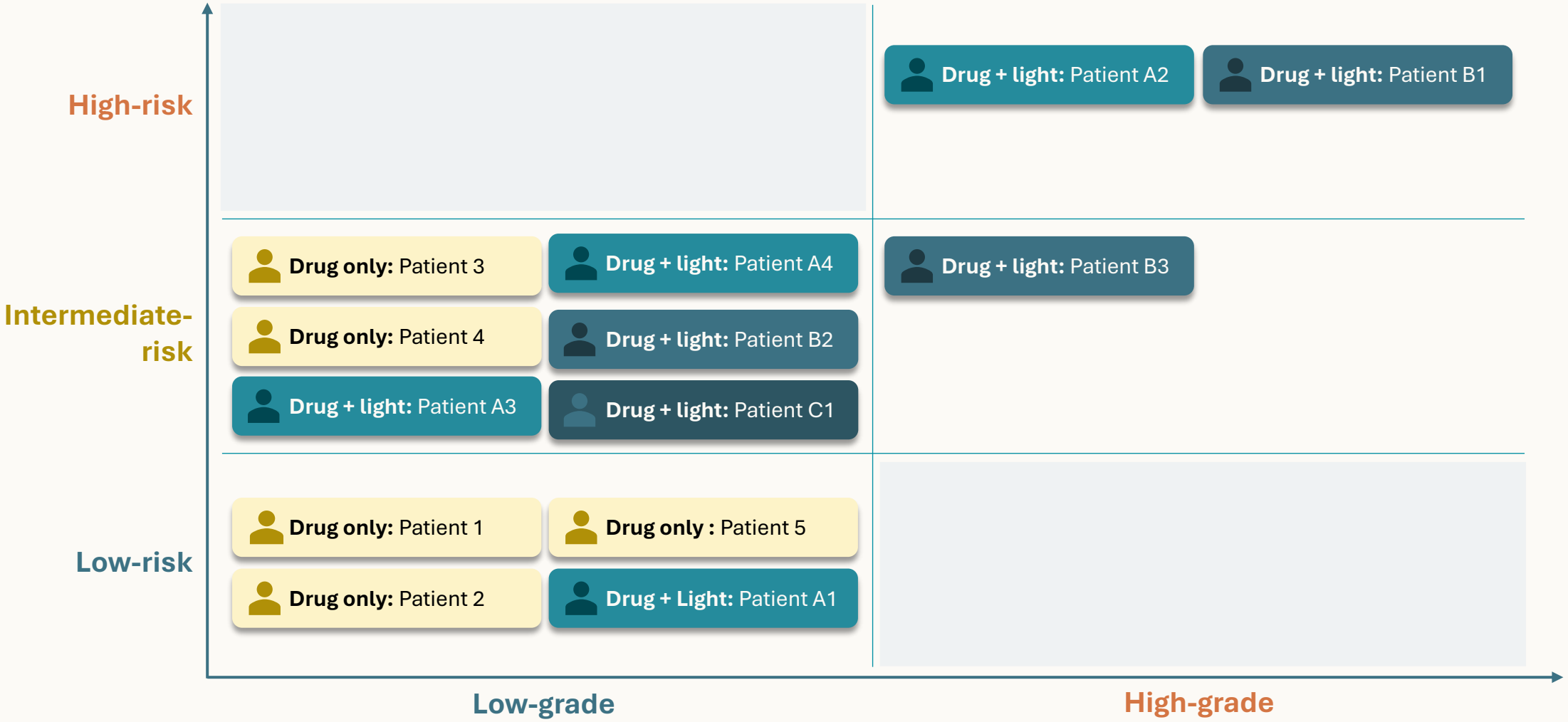
Open for enrollment

Safety Review Board completed after each cohort. Patients followed for safety after TURBT to 56 days.

Study objectives	Safety & dose-limiting toxicity	Feasibility of technique	Focal distribution of AU-011	Focal necrosis	Markers of immune activation

NMIBC, non-muscle-invasive bladder cancer; **MoA**, mechanism of action; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient population: AUA risk classification and grade at screening



AUA, American Urological Association.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Phase 1 trial of AU-011 for bladder cancer designed to evaluate safety, feasibility, and mechanism of action

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50 µg within lamina propria

Part 2 (n~10)

AU-011 + focal light activation

Cohort A: Drug + light

Total 100 µg

NMIBC (N=4)

50 µg at tumor base
50 µg within lamina propria

Cohort B: Drug + light

Total 100 µg

NMIBC (N=3)

100 µg at tumor base

Cohort C: Drug + light

Total 200 µg

NMIBC (N~3)

200 µg at tumor base

1 patient evaluable

Completed

Open for enrollment

Safety Review Board completed after each cohort. Patients followed for safety after TURBT to 56 days.

Study objectives	Safety & dose-limiting toxicity	Feasibility of technique	Focal distribution of AU-011	Focal necrosis	Markers of immune activation

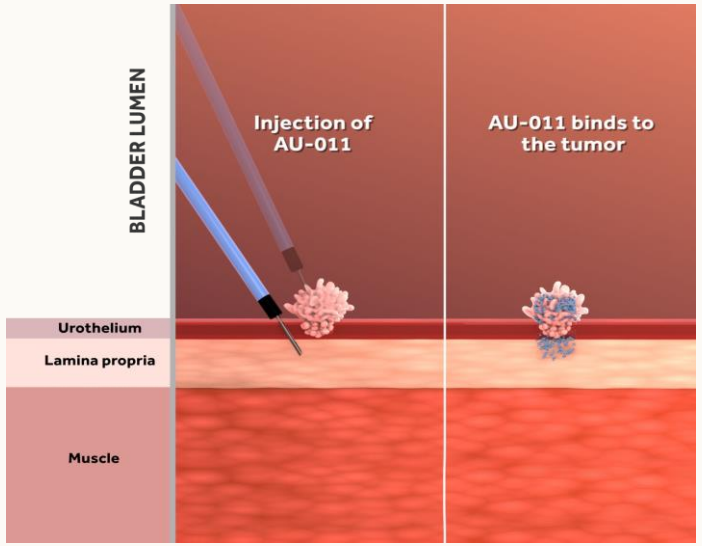
NMIBC, non-muscle-invasive bladder cancer; **MoA**, mechanism of action; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Drug only:
Treatment schedule

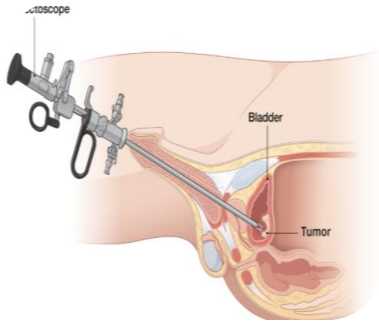
Total dose: 100 µg

- 50 µg into base of tumor
- 50 µg into lamina propria

Drug only without light activation (n=5)



TURBT



Pathology

Day 1

- Evidence of non-invasive urothelial carcinoma
- Injection of AU-011 performed within tumor (50 µg) and below tumor (lamina propria; 50 µg)

Day 2

- Urologist performs TURBT to include injected lesion
- Sample sent to central pathology for H&E and AU-011 staining

H&E, hematoxylin and eosin; TURBT, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Drug only:
Safety data

- First in human in bladder – safety cohort as required by FDA

Drug only without light activation (n=5)

Safety Data

Event	Grade	Number of patients
Adverse events (related to study drug)		
None	None	0/5
Adverse events (related to injection or laser procedure)		
Hematuria	1	1/5

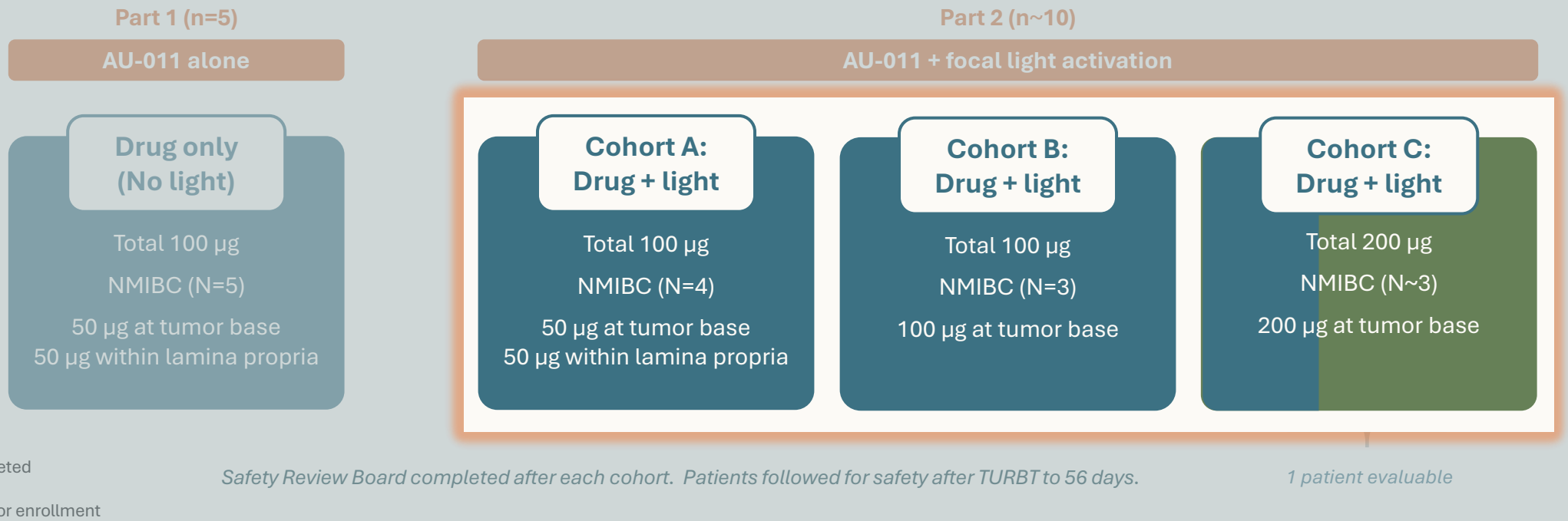
- No treatment emergent adverse events related to study drug
- No serious adverse events
- No dose limiting toxicities

ClinicalTrials.gov Identifier: NCT06007690; AU-011-301. **FDA,** Food and Drug Administration

Phase 1 trial of AU-011 for bladder cancer designed to evaluate safety, feasibility, and mechanism of action

Single dose window of opportunity study in NMIBC all-comers

Histopathological assessment completed at time of standard of care TURBT



Study objectives	Safety & dose-limiting toxicity	Feasibility of technique	Focal distribution of AU-011	Focal necrosis	Markers of immune activation

NMIBC, non-muscle-invasive bladder cancer; **MoA**, mechanism of action; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Cohorts A–C: Single-dose drug with light activation

Treatment schedule

Cohort A:

- 50 µg into base of tumor
- 50 µg into lamina propria

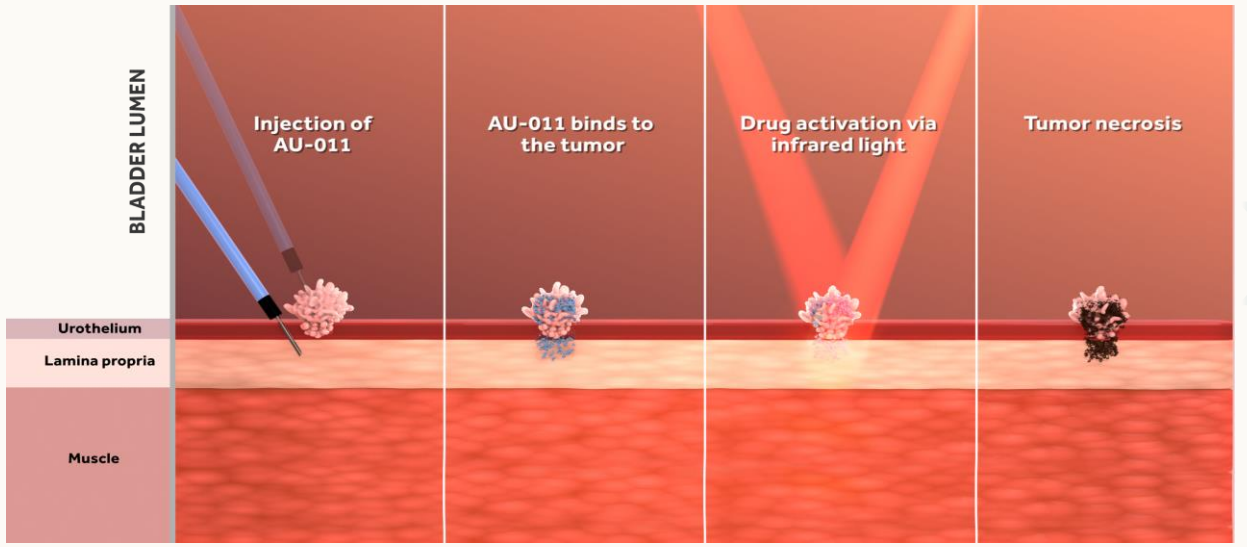
Cohort B:

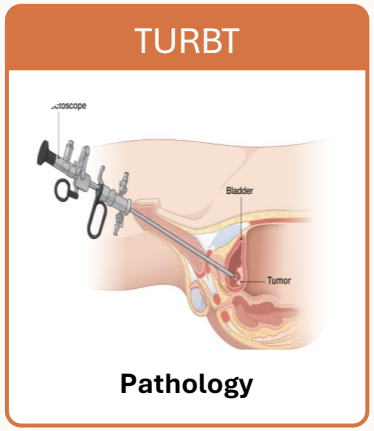
- 100 µg into base of tumor

Cohort C:

- 200 µg into base of tumor

Cohort A–C: Single-dose drug with light activation (n=~10)





Day 1

- Evidence of non-invasive urothelial carcinoma
- Injection of AU-011 performed within and below tumor (Cohort A) and within tumor (Cohort B/C)

Day 2

- Urologist performs light activation with 689 nm infrared light (75 J/cm^2)
- ~5 min duration

Day 3–7

Cohort A: Day 9 ± 1

Cohort B/C: Day 14+7

- Urologist performs TURBT in area where tumor used to be present
- Sample sent to central pathology for H&E and immune staining

H&E, hematoxylin and eosin; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Cohort A + B: Single-dose drug with light activation

Safety data

- No serious adverse events
- No dose limiting toxicities

Cohort A + B: Single-dose drug with light activation (n=7)[a]

Event	Grade	Number of patients
Adverse events (related to study drug)		
Nocturia	1	1/7
Urinary urgency	1	1/7
Adverse events (related to injection or laser procedure)		
Hematuria	1	1/7
Urinary blood clots	1	1/7
Nocturia	1	1/7
Urinary urgency	1	1/7

Favorable safety profile:
<10% of patients experienced Grade 1 TEAEs related to study drug; no Grade 2/3 adverse events related to study drug (n=12)

[A]Compiled safety data includes all completed light-activated cohorts (A and B). Data cutoff date of September 9, 2024.
TEAE, treatment-emergent adverse event.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Efficacy data: Ta low-grade

4/5 low-grade target tumors demonstrate complete response to AU-011

	Patient A1	Patient A3	Patient A4[c]	Patient B2	Patient C1[d]
Screening diagnosis	Single (Multiple at TURBT) Ta low-grade	Multiple Ta low-grade	Multiple Ta low-grade (2024) Ta high-grade (2023)	Multiple Ta low-grade	Multiple Ta low-grade
Screening AUA risk classification	Low	Intermediate	Intermediate	Intermediate	Intermediate
AU-011 dose/delivery	100 µg IT/IM	100 µg IT/IM	100 µg IT/IM	100 µg IT	200 µg IT
Clinical complete response: Target tumor[a]	✓	✓	✓	-	✓
Clinical complete response: Non-target tumor[a] (bladder urothelial field effect[b])	2/2	1/2	1/1	-	-
Immune response[e]: Target tumor	✓	✓	✓	✓	*pending*
Immune response[e]: Non-target tumor	✓	✓	✓	✓	*pending*
Necrosis	✓	✓	✓	-	*pending*
Visual changes on cystoscopy	✓	✓	-	✓	✓

Cohorts A–C:
Single-dose drug with light activation

[a]For purposes of this analysis, Clinical complete response defined as absence of tumor cells on histopathologic evaluation. [b]Bladder urothelial field effect: absence of tumor cells in non-target lesions. [c]Previously treated tumor demonstrated high-grade disease but pathology at time of treatment revealed low-grade disease in non-target tumor. [d]Complete response (target tumor) based upon local pathology with central review ongoing; immune response and necrosis evaluations pending central review. [e] Immune response is defined by immunocyte infiltration on post-treatment histopathology.
AUA, American Urological Association; **IM**, intramural; **IT**, intratumoral; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Light-activated cohorts (A + B):

Strong evidence of immune-mediated mechanism of action

- **100% (7/7)** of target tumors showed **infiltration of effector CD8+ T and CD4+ cells**, as early as 7 days after laser activation
- **100% (7/7)** of non-target tumors[a] (in the five patients with available immune staining) showed **T cell infiltration**, supportive of a **bladder urothelial field effect**
- **Focal eosinophilic infiltration** was observed in **57% (4/7)** target tumors and in **14% (1/7)** non-target tumors, supportive of a **local innate immune response** to tumor necrosis
- **Generation of lymphoid follicles**[b] was observed in **71% (5/7)** target tumors, supportive of a **local adaptive immune response**

AU-011 showed evidence of producing pro-immunogenic changes in situ that have the potential to bridge, activate, and enhance adaptive immunity, consistent with its expected MOA

[a]Patients for which biopsies were available. [b]Organized aggregates of immune cells.
MOA, mechanism of action
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A1

64-year-old Caucasian male

Screening diagnosis: (2023)
- Single
- **Ta low-grade <3 cm**
- No CIS

Screening AUA risk classification:
Low

Initial diagnosis: (2010)
- Single
- Ta low-grade <3 cm
- No CIS
- Low risk

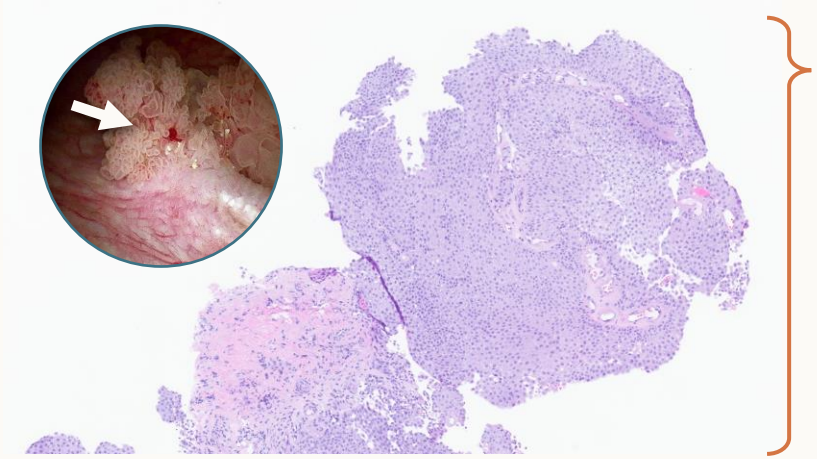
Prior TURBT:
2011; 2012; 2018

Prior adjuvant therapies:
- MMC (2011)
- Tamoxifen (2016)
- Gemcitabine (2018)

Complete clinical response visualized at time of TURBT confirmed with histopathologic evaluation

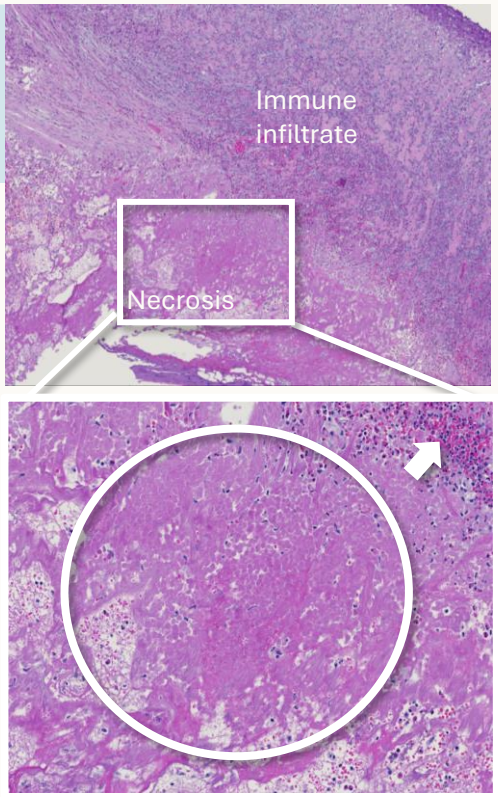
Evidence of clinical complete response by absence of tumor cells, as well as immune activation, after single dose treatment in first patient

Example of papillary carcinoma (Ta)



Papillary urothelial carcinoma

7 days after AU-011 treatment



Post-treatment TURBT demonstrating necrosis, inflammatory infiltrate, and no residual carcinoma. Circled region shows area of necrosis; arrow indicates edge of inflammatory infiltrate.

H&E stain

Pre-injection bladder biopsy demonstrating low-grade papillary urothelial carcinoma; non-invasive

Cohort A:
Single-dose drug with light activation

CIS, carcinoma in situ; **H&E**, hematoxylin and eosin; **MMC**, mitomycin C; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A1

64-year-old Caucasian male

Screening diagnosis: (2023)
- Single
- **Ta low-grade <3 cm**
- No CIS

Screening AUA risk classification:
Low

Initial diagnosis: (2010)
- Single
- Ta low-grade <3 cm
- No CIS
- Low risk

Prior TURBT:
2011; 2012; 2018

Prior adjuvant therapies:
- MMC (2011)
- Tamoxifen (2016)
- Gemcitabine (2018)

Summary of pre-and-post treatment pathology: Single low-grade target lesion and two non-target lesions

Pre-treatment pathology	Post-treatment pathology
Target lesion: Clinical complete response	
Local pathology: • Papillary urothelial carcinoma, non-invasive, low-grade • Muscularis propria not identified *Note – no central pathology*	Central pathology: • Negative for urothelial carcinoma • Chronic inflammation
Non-target lesion A & B: Absence of tumor cells (2/2 lesions)	
Not applicable: • No pre-treatment specimen obtained	Central pathology: • Negative for urothelial carcinoma • Chronic inflammation

Clinical complete response (target lesion)[a]

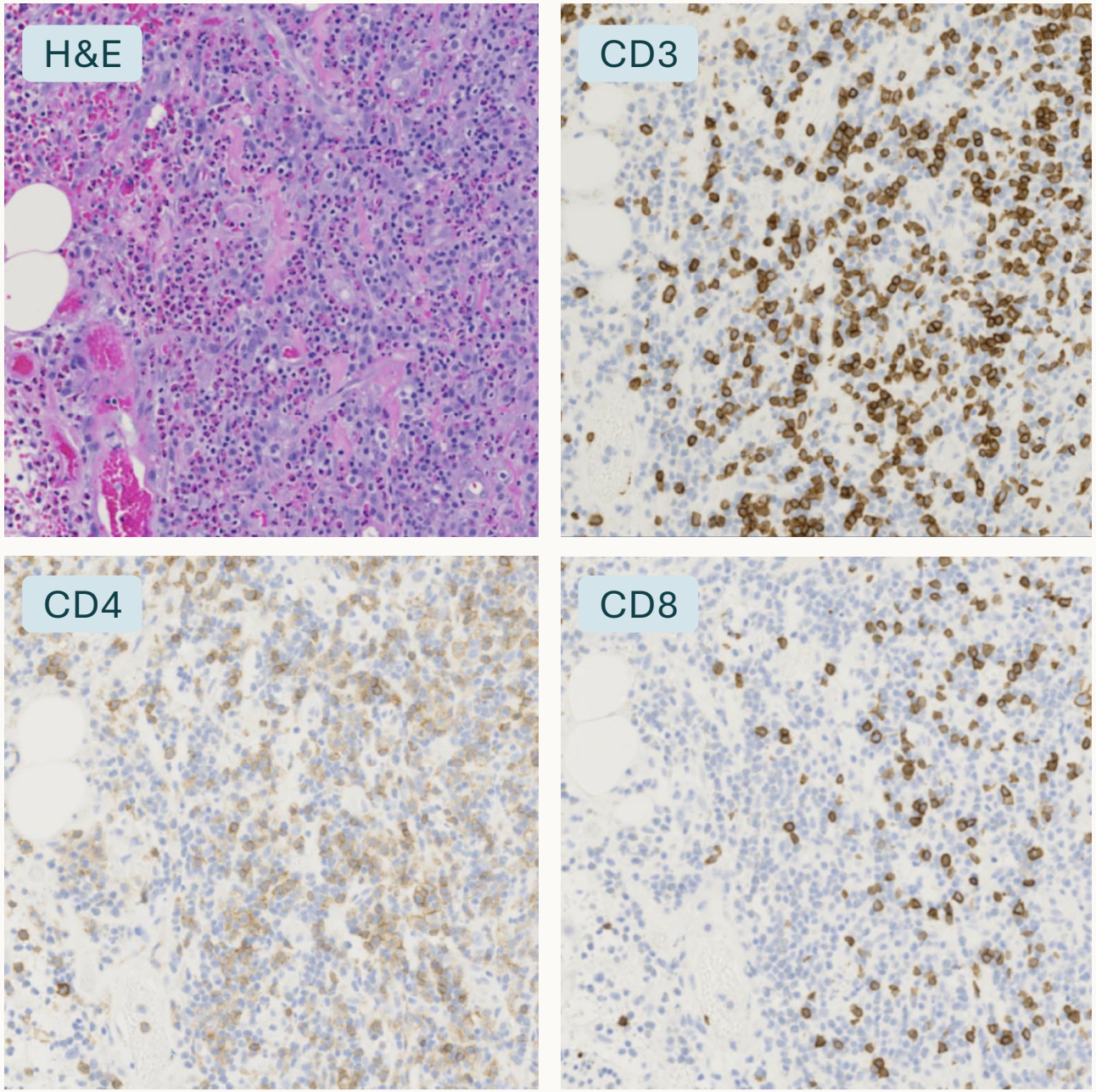
Bladder urothelial field effect[b]

[a]Clinical complete response identified on histopathologic evaluation. [b]Bladder urothelial field effect: absence of tumor in non-target lesions.
AUA, American Urological Association; **CIS,** carcinoma in situ; **MMC,** mitomycin C; **TURBT**, transurethral resection of bladder tumor.
ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

Cohort A:
Single-dose drug with light activation

Patient A1:
AU-011 focal distribution, necrosis, and positive immune staining (target lesion)

Post-treatment



No central pathology read available for pre-treatment; block lost at site.
H&E, hematoxylin and eosin.Clinicaltrials.gov identifier: NCT05483868; AU-011-102

Cohort A:
Single-dose drug with light activation

Patient A3

72-year-old Hispanic male

Screening diagnosis: (2024)

- Multiple
- **Ta low-grade (<3 cm)**
- No CIS

Screening AUA risk classification:
Intermediate

Initial diagnosis: (2019)

- Ta high-grade <3 cm
- No CIS
- Intermediate risk

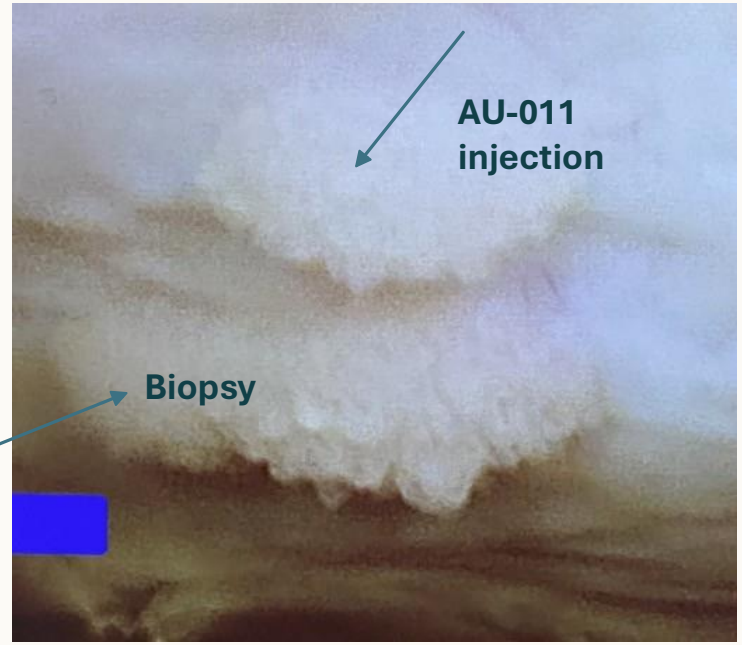
Prior TURBT:

- 2019, 2020 (x2), 2021 (x2), 2023

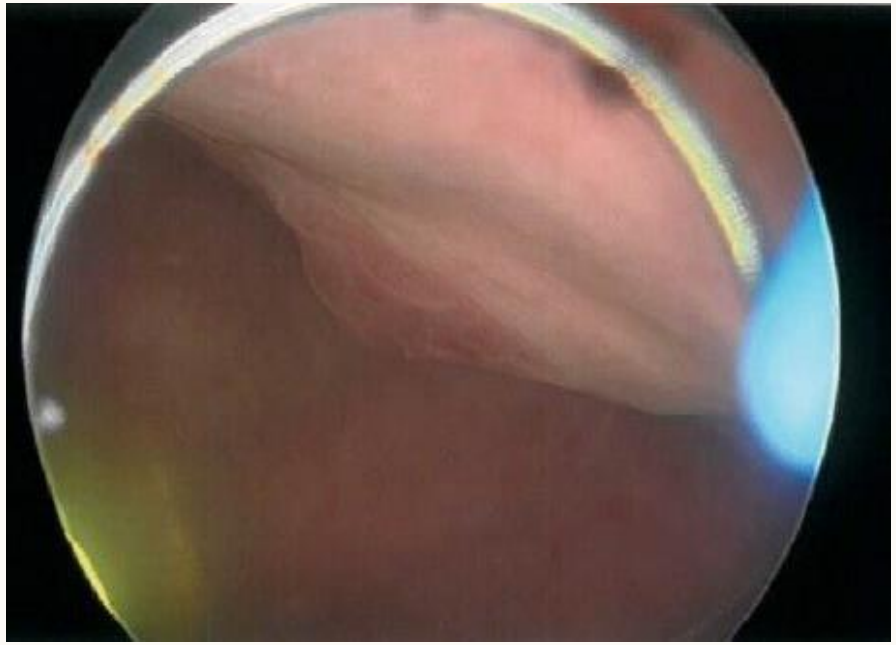
Prior adjuvant therapies:

- BCG induction and maintenance (2020-2021)

Complete clinical response visualized at time of TURBT confirmed with histopathologic evaluation



Pre-injection/pre-biopsy appearance of tumor on office cystoscopy



Post-injection edema and ecchymosis at injection site

Cohort A:
Single-dose drug with light activation

AUA, American Urological Association; **BCG**, Bacillus Calmette-Guerin; **CIS**, carcinoma in situ; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A3

72-year-old Hispanic male

Screening diagnosis: (2024)

- Multiple
- **Ta low-grade (<3 cm)**
- No CIS

Screening AUA risk classification:
Intermediate

Initial diagnosis: (2019)

- Ta high-grade <3 cm
- No CIS
- Intermediate risk

Prior TURBT:

- 2019, 2020 (x2), 2021 (x2), 2023

Prior adjuvant therapies:

- BCG induction and maintenance (2020-2021)

Summary of pre-and-post treatment pathology: Single low-grade target lesion and two non-target lesions

Pre-treatment pathology	Post-treatment pathology
Target lesion: Clinical complete response	
Central pathology: • Low-grade papillary urothelial carcinoma, non-invasive	Central pathology: • Negative for urothelial carcinoma • Acute and Chronic inflammation
Non-target lesion A and B: absence of tumor cells (A) / immune cell infiltration (B)	
LESION A Not applicable: Pre-treatment biopsy not completed	**LESION A** Central pathology: • Negative for urothelial carcinoma • Chronic inflammation
LESION B Not applicable: Pre-treatment biopsy not completed	**LESION B** Central pathology: • Papillary urothelial carcinoma; non-invasive • Low-grade • Additional findings: Cystitis cystica et glandularis

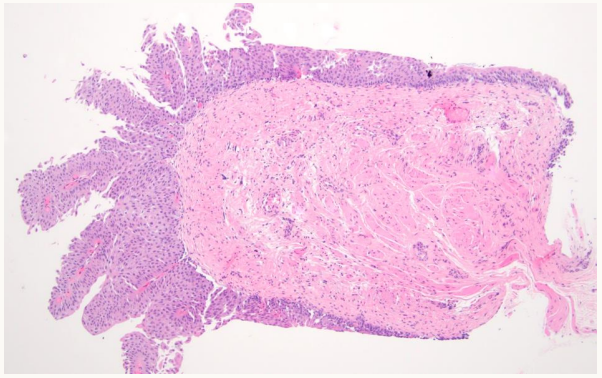
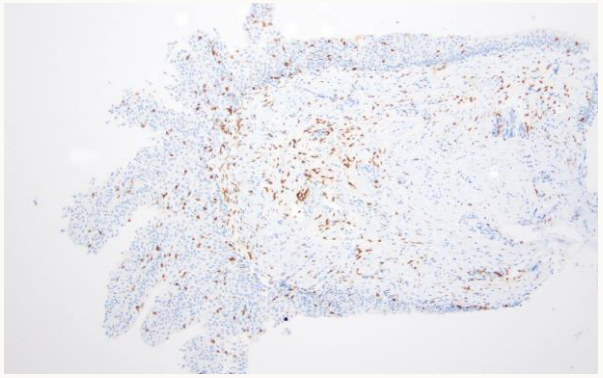
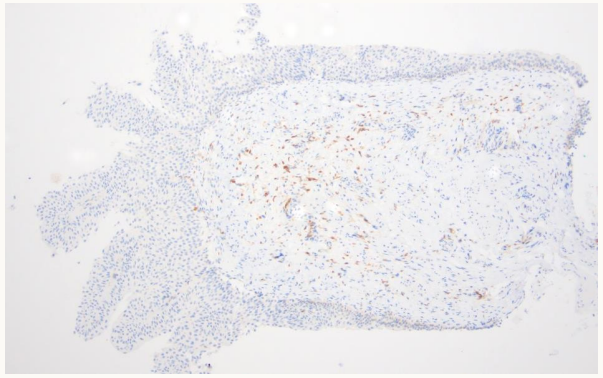
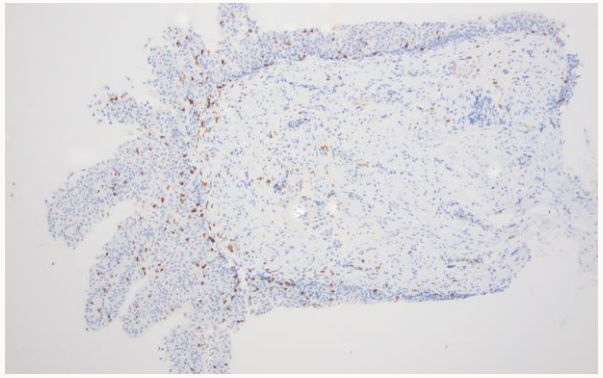
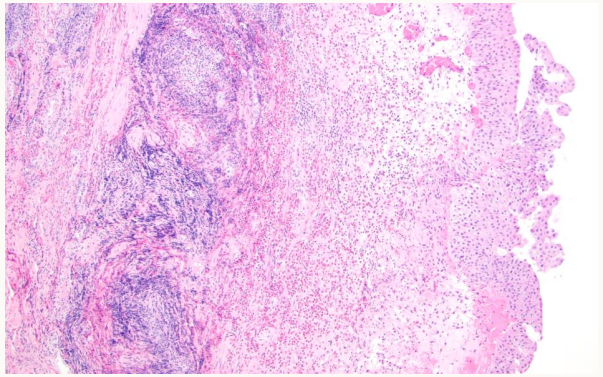
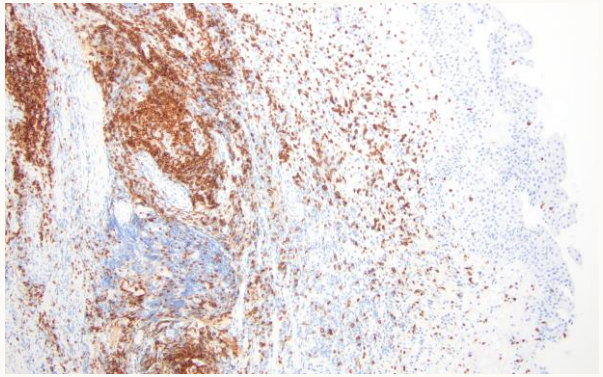
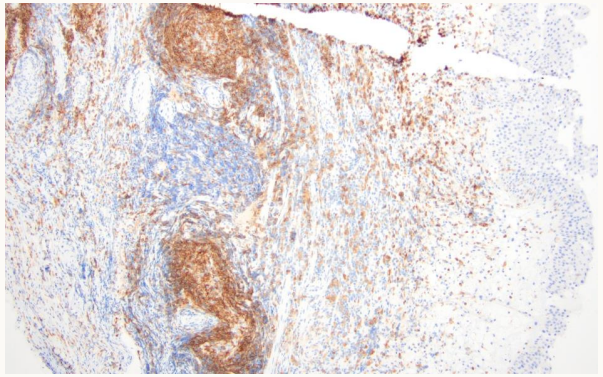
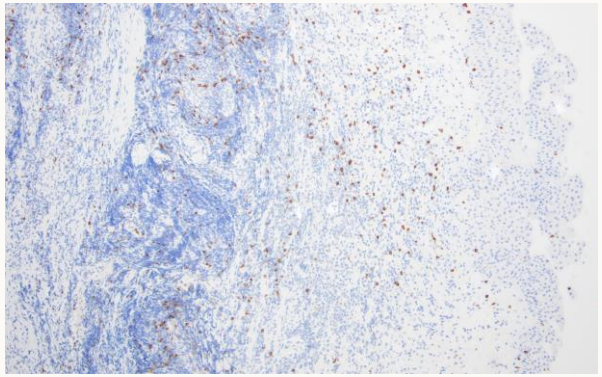
Clinical complete response (target lesion)[a]

Bladder urothelial field effect[b]

[a]Clinical complete response identified on histopathologic evaluation. [b]Bladder urothelial field effect: absence of tumor in non-target lesions. **AUA,** American Urological Association; **BCG**, Bacillus Calmette-Guerin; **CIS**, carcinoma in situ; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Cohort A:
Single-dose drug with light activation

Patient A3: AU-011 focal distribution, necrosis, and positive immune staining (target lesion)

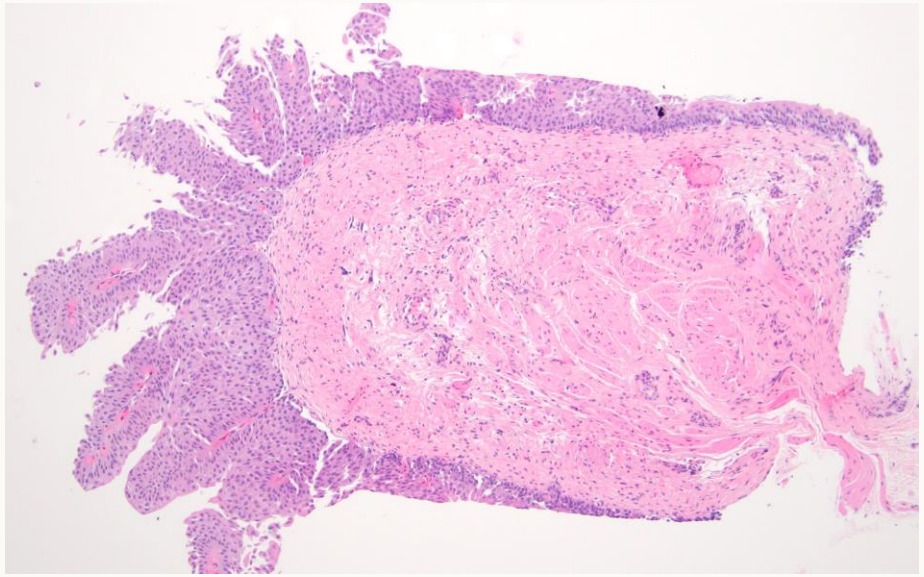
	H&E	CD3	CD4	CD8
Pre-treatment				
Post-treatment				

Cohort A:
Single-dose drug with light activation

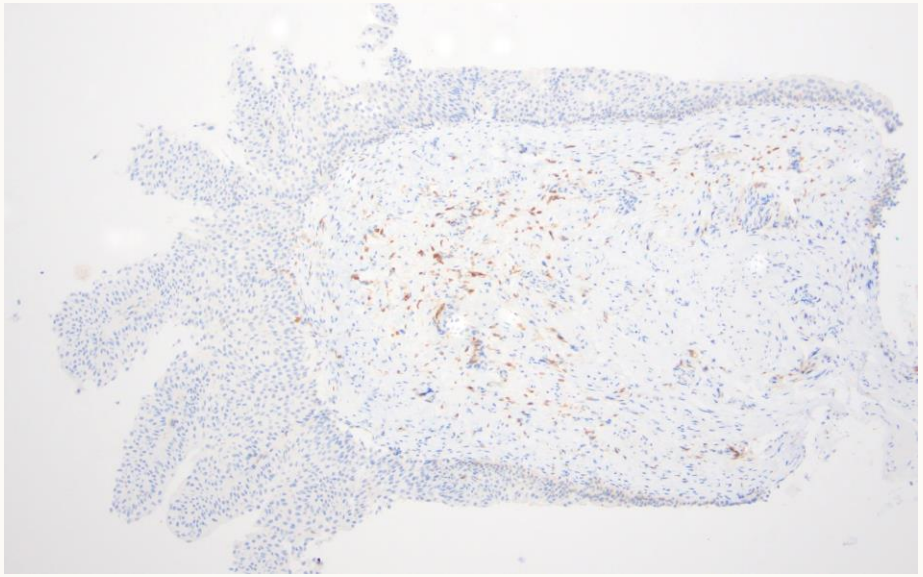
H&E, hematoxylin and eosin.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A3:
Post-treatment generation of secondary lymphoid follicles and increase in CD3, CD4, and CD8 infiltration

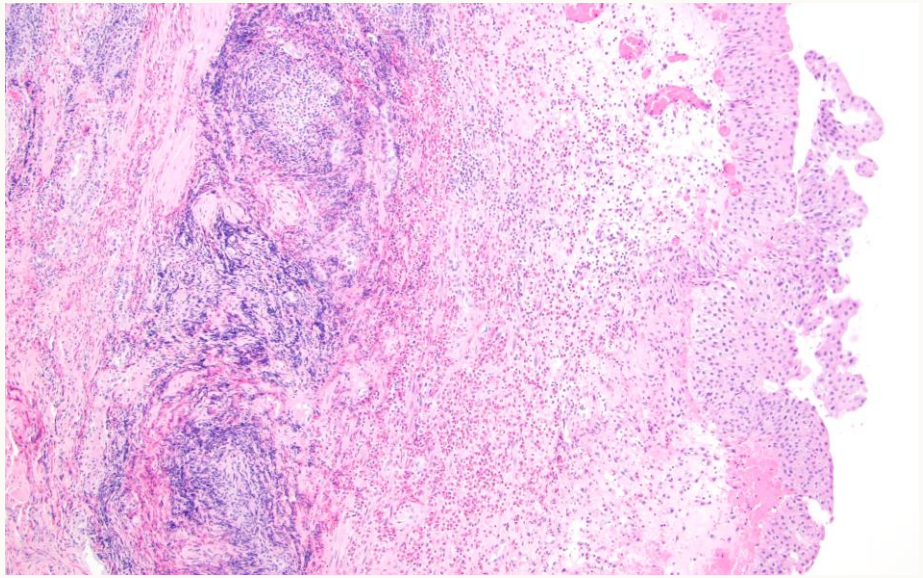
H&E: Pre-treatment



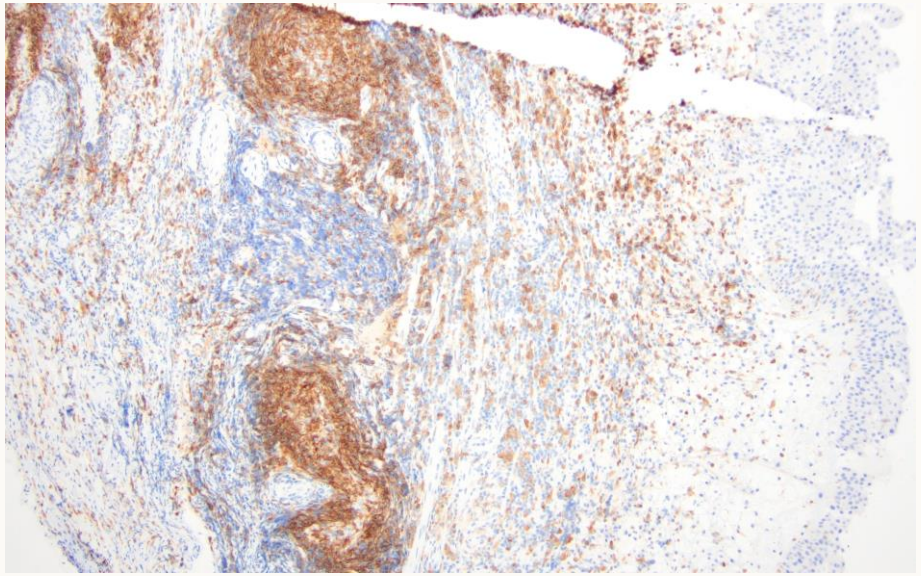
CD4: Pre-treatment



H&E: Post-treatment



CD4: Post-treatment



Cohort A:
Single-dose drug with light activation

H&E, hematoxylin and eosin.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Efficacy data: Ta high-grade

3/3 high-grade tumors demonstrated immune response to AU-011

	Patient A2	Patient B1	Patient B3
Screening diagnosis	Single Ta high-grade	Multiple Ta high-grade	Single Ta high-grade
Screening AUA risk classification	High	High	Intermediate
AU-011 dose/ delivery	100 µg IT/IM	100 µg IT	100 µg IT
Clinical complete response: Target tumor[a]	-	-	-
Clinical complete response: Non-target tumor[a] **(bladder urothelial field effect**[b]**)**	NA	-	NA
Immune response[c]**: Target tumor**	✓	✓	✓
Immune response[c]**: Non-target tumor**	NA	✓	NA
Necrosis	-	-	-
Visual changes on cystoscopy	Tumor Visually Smaller	Tumor Visually Smaller	-

Cohorts A + B:
Single-dose drug with light activation

[a]Clinical complete response defined as absence of tumor cells on histopathologic evaluation. [b]Bladder urothelial field effect: absence of tumor cells in non-target lesions.
[c]Immune response is defined by immunocyte infiltration on post-treatment histopathology
AUA, American Urological Association; **BCG**, Bacillus Calmette-Guerin; **CIS**, carcinoma in situ; **IM**, intramural; **IT**, intratumoral; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Summary

aura

AU-011 demonstrated a favorable safety profile with robust clinical and immunological response in early data readout of 'all-comers' NMIBC patients

Favorable safety profile

Only Grade 1 Drug-Related Adverse Events Reported in <10% of Patients

No drug-related grade 2 or higher AEs; no SAEs or DLTs

Focal treatment with no systemic adverse events observed as of data cutoff

Rapid Immune activation

100% of patients showed immune cell infiltration in target and non-target lesions

Immune-mediated MOA and bladder urothelial field effect

Tumor shrinkage and clinical response

Positive early data show 4/5 patients with low-grade disease had a complete clinical response

Single low-dose of AU-011 showed multiple clinical complete responses in target and non-target tumors

Development plan

Continued development of AU-011 with planned phase 1 trial expansion to test additional doses and treatment regimen

In parallel, prepare for a phase 2 trial to further evaluate bel-sar's clinical activity and durability of response

AE, adverse event; **DLT**, dose-limiting toxicity; **DOR**, duration of response; **MOA**, mechanism of action; **NMIBC**, non-muscle-invasive bladder cancer; **SAE**, serious adverse event.
ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

Appendix

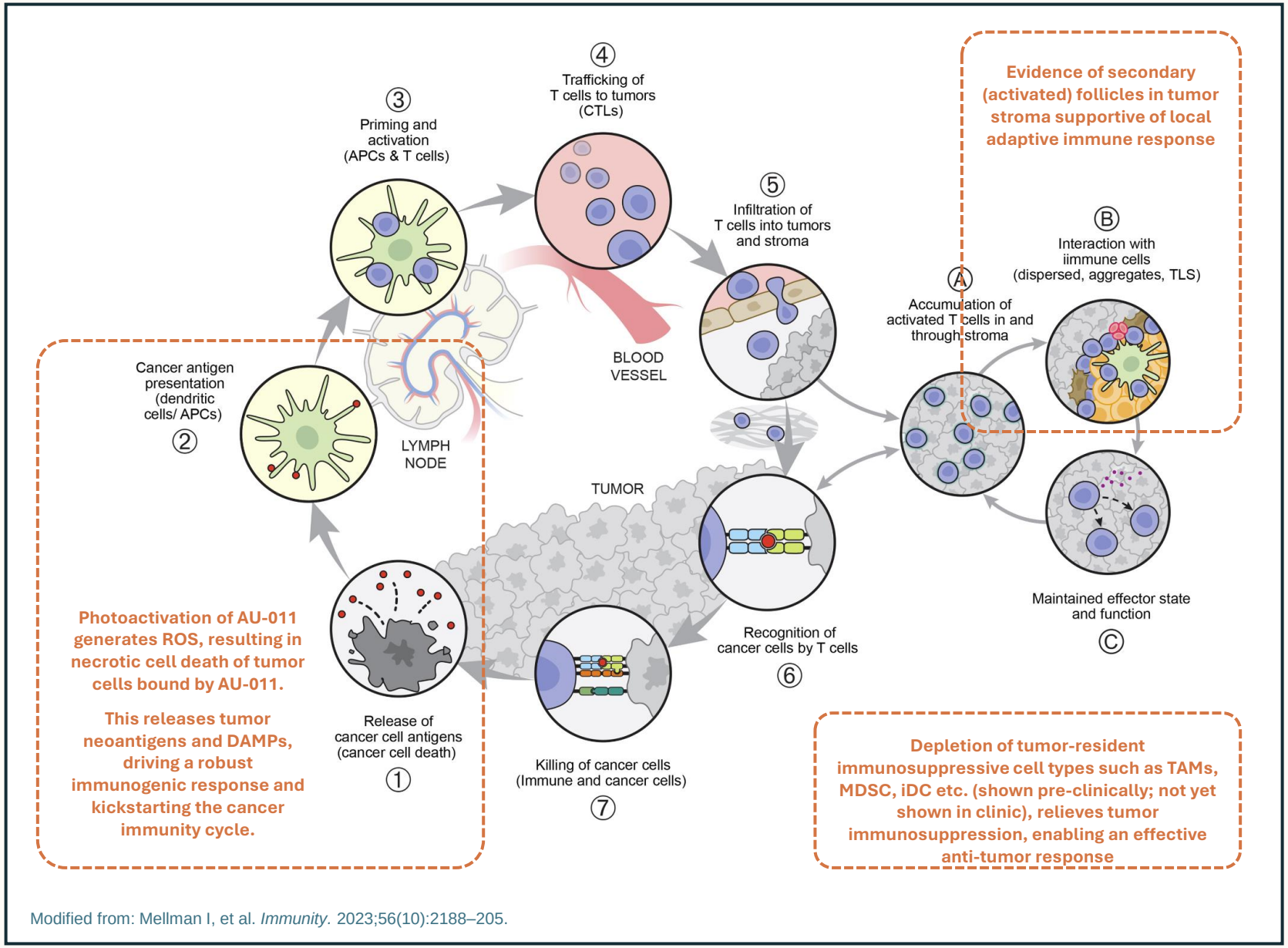
aura

Anti-tumor immunity: Treating beyond the target

Preclinical development

aura

Where does AU-011 fit in the cancer immunity cycle and the TME sub-cycle?

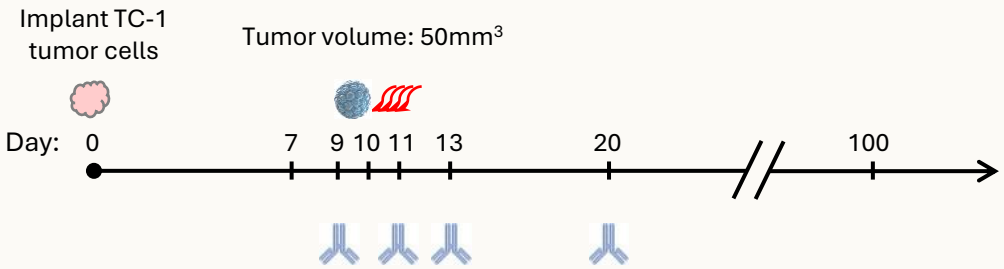


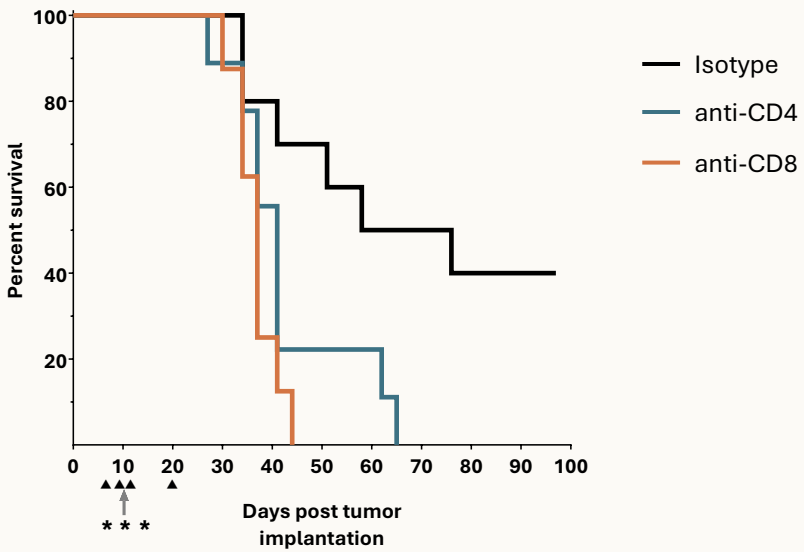
Modified from: Mellman I, et al. *Immunity*. 2023;56(10):2188–205.

APC, antigen-presenting cell; **CTL**, cytotoxic T lymphocyte; **DAMPs**, damage-associated molecular patterns; **iDC**, immature dendritic cell; **MDSC**, myeloid-derived suppressor cell; **ROS**, reactive oxygen species; **TAM**, tumor-associated macrophage; **TLS**, tertiary lymphoid structures; **TME**, tumor microenvironment.

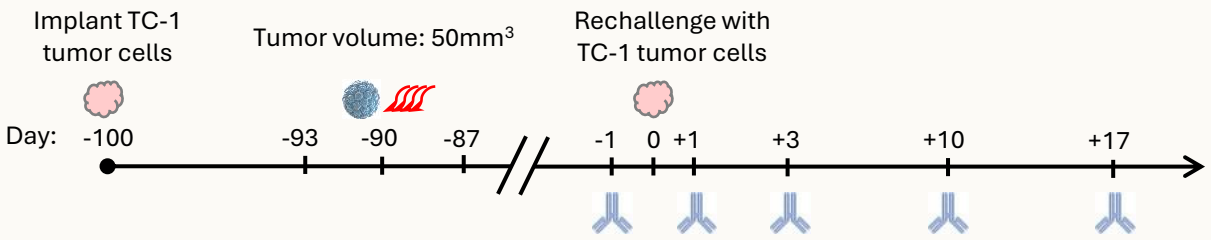
Role of CD4+ and CD8+ T-cells at time of treatment and time of tumor rechallenge in the TC-1 syngeneic murine tumor model

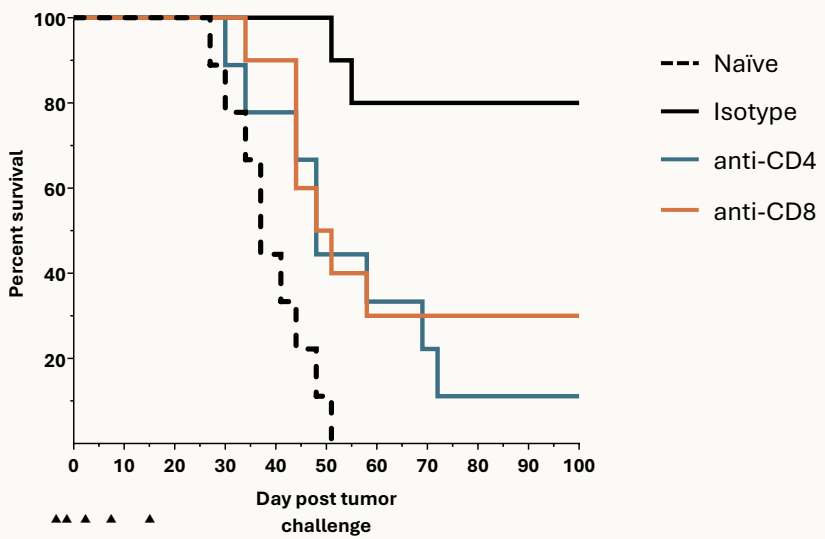
Depletion at the time of treatment





Depletion at the time of rechallenge





Intravenous AU-011 NIR treatment Depleting or matched isotype

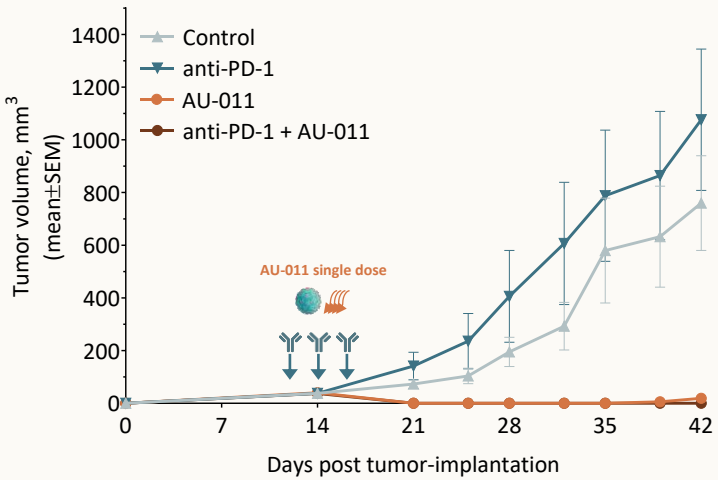
Kines RC, et al. *Cancer Immunol Res*. 2021;9(6):693–706. **NIR**, near-infrared.

Robust pre-clinical activity in bladder cancer both as a single agent and in combination with checkpoint inhibitors

AU-011 treatment impacts primary and distant tumors, overall survival, and induction of durable immunological memory

- Treatment resulted in complete response and prevented tumor growth after rechallenge
- Data supports potential prevention of metastatic disease

Tumor growth



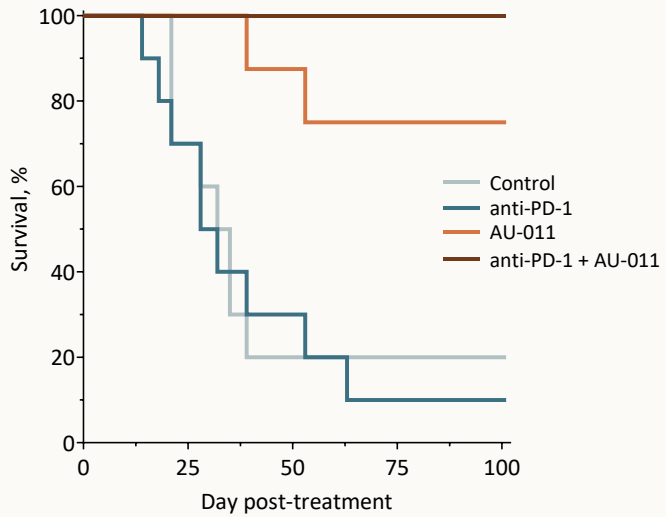
Syngeneic mouse tumor bladder model
- MB49 model in C57BL/6 mice
- N = 8–10/group

Anti-PD-1
- Mouse equivalent of pembrolizumab
- 100 µg administered 3 times every 3 days (IP)

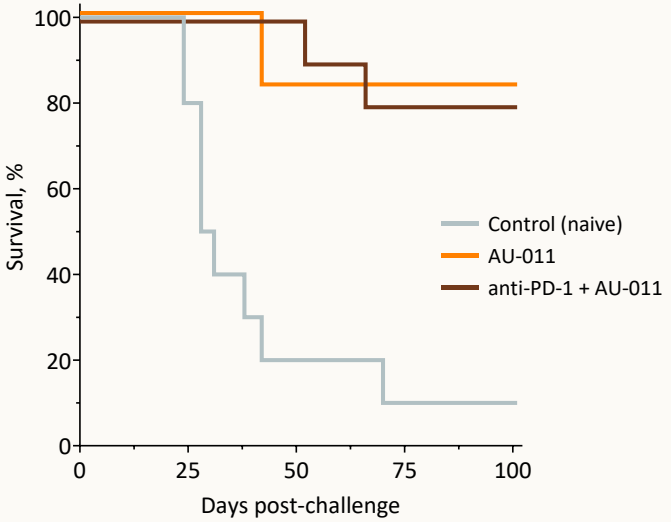
AU-011
- 100 µg as a single dose (IV)
- All groups treated with NIR (50 J/cm^2)

All animals that survived the first treatment were rechallenged and survival was evaluated up to 100 days after rechallenge

Survival



Survival after rechallenge



Kines RC, et al. *Cancer Immunol Res*. 2021;9:693–706.
IP, intraperitoneal; **IV**, intravenous; **NIR**, near-infrared.

Patient A1: Single-dose drug with light activation Immunohistochemistry

		Target lesion		Non-target lesion A		Non-target lesion B	
Stain		**Pre-treatment**	**Post-treatment**	**Pre-treatment**	**Post-treatment**	**Pre-treatment**	**Post-treatment**
AU-011		NA	Absent	NA	Absent	NA	Absent
Necrosis		NA	**Present**	NA	Absent	NA	Absent
CD3	Intratumoral	NA	NA	NA	NA	NA	NA
	Stromal	NA	**Moderate**	NA	**Moderate**	NA	**Moderate**
	Benign urothelial	NA	NA	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	**Marked**
CD4	Intratumoral	NA	NA	NA	NA	NA	NA
	Stromal	NA	**Moderate**	NA	**Moderate**	NA	**Moderate**
	Benign urothelial	NA	NA	NA	Absent	NA	Absent
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	**Marked**
CD8	Intratumoral	NA	NA	NA	NA	NA	NA
	Stromal	NA	**Mild**	NA	**Mild**	NA	**Mild**
	Benign urothelial	NA	NA	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Moderate**	NA	**Moderate**	NA	**Moderate**
CD45	Intratumoral	NA	NA	NA	NA	NA	NA
	Stromal	NA	**Marked**	NA	**Moderate**	NA	**Moderate**
	Benign urothelial	NA	NA	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	**Marked**

NA, not applicable.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A3: Single-dose drug with light activation Immunohistochemistry

		Target lesion (biopsy)		Target lesion (TURBT)		Non-target lesion A		Non-target lesion B	
Stain		**Pre-treatment**	**Post-treatment**	**Pre-treatment**	**Post-treatment**	**Pre-treatment**	**Post-treatment**	**Pre-treatment**	**Post-treatment**
AU-011		Absent	**Present**	Absent	Absent	NA	Absent	NA	Absent
Necrosis		Absent	Absent	Absent	**Present**	NA	Absent	NA	Absent
CD3	Intratumoral	Mild	NA	Mild	NA	NA	NA	NA	**Mild**
	Stromal	Mild	**Moderate**	Mild	**Moderate**	NA	**Mild**	NA	**Mild**
	Benign urothelial	Mild	Mild	Mild	Mild	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	NA	NA	NA
CD4	Intratumoral	Absent	NA	Absent	NA	NA	NA	NA	Absent
	Stromal	Mild	**Moderate**	Mild	**Moderate**	NA	**Mild**	NA	**Mild**
	Benign urothelial	Absent	**Mild**	Absent	**Mild**	NA	Absent	NA	**Mild**
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	NA	NA	NA
CD8	Intratumoral	Mild	NA	Mild	NA	NA	NA	NA	**Mild**
	Stromal	Mild	Mild	Mild	Mild	NA	**Mild**	NA	**Mild**
	Benign urothelial	Mild	Mild	Mild	Mild	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Mild**	NA	**Mild**	NA	NA	NA	NA
CD45	Intratumoral	Mild	NA	Mild	NA	NA	NA	NA	**Mild**
	Stromal	Mild	**Moderate**	Mild	**Moderate**	NA	**Moderate**	NA	**Moderate**
	Benign urothelial	Mild	Mild	Mild	Mild	NA	**Mild**	NA	**Mild**
	Lymphoid follicle	NA	**Marked**	NA	**Marked**	NA	NA	NA	NA

NA, not applicable; **TURBT**, transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Patient A3

72-year-old Hispanic male

Screening diagnosis: (2024)

- Multiple
- **Ta low-grade (<3 cm)**
- No CIS

Screening AUA risk classification:
Intermediate

Initial diagnosis: (2019)

- Ta high-grade <3 cm
- No CIS
- Intermediate risk

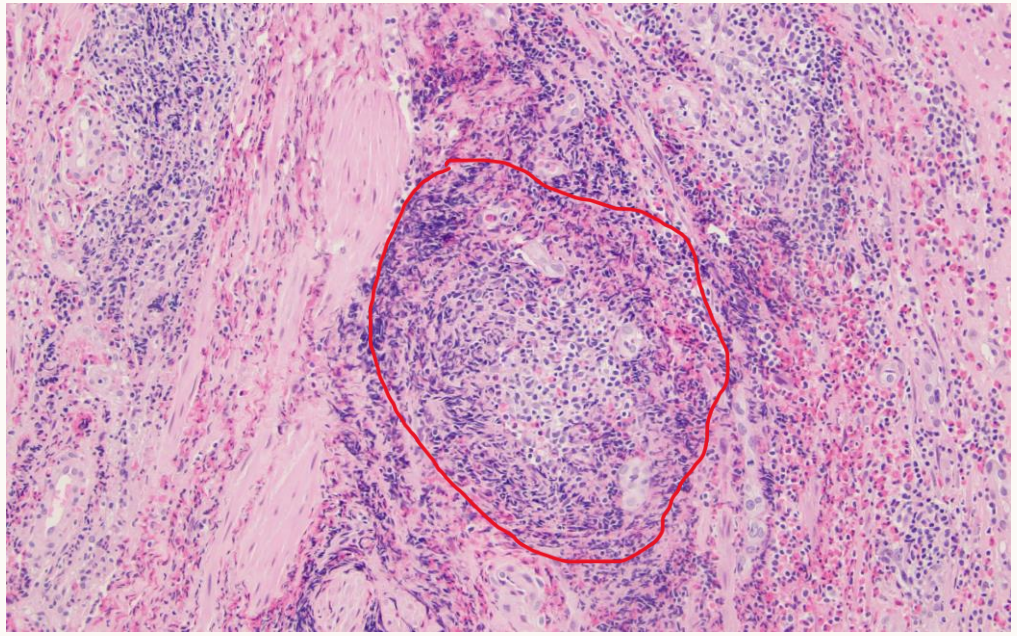
Prior TURBT:

- 2019, 2020 (x2), 2021 (x2), 2023

Prior adjuvant therapies:

- BCG induction and maintenance (2020-2021)

Secondary (activated) lymphoid follicle: Capable of generating tissue-specific, adaptive immune responses



- Secondary lymphoid follicles form ectopically at sites of chronic inflammation and antigenic stimulation
- Lymphoid follicles are widely reported in colorectal and ovarian carcinoma, suggestive of ongoing B-cell expansion and a favorable prognosis

Cohort A:
Single-dose drug with light activation

AUA, American Urological Association; **BCG**, Bacillus Calmette-Guerin; **CIS**, carcinoma in situ; **TURBT**, transurethral resection of bladder tumor.
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