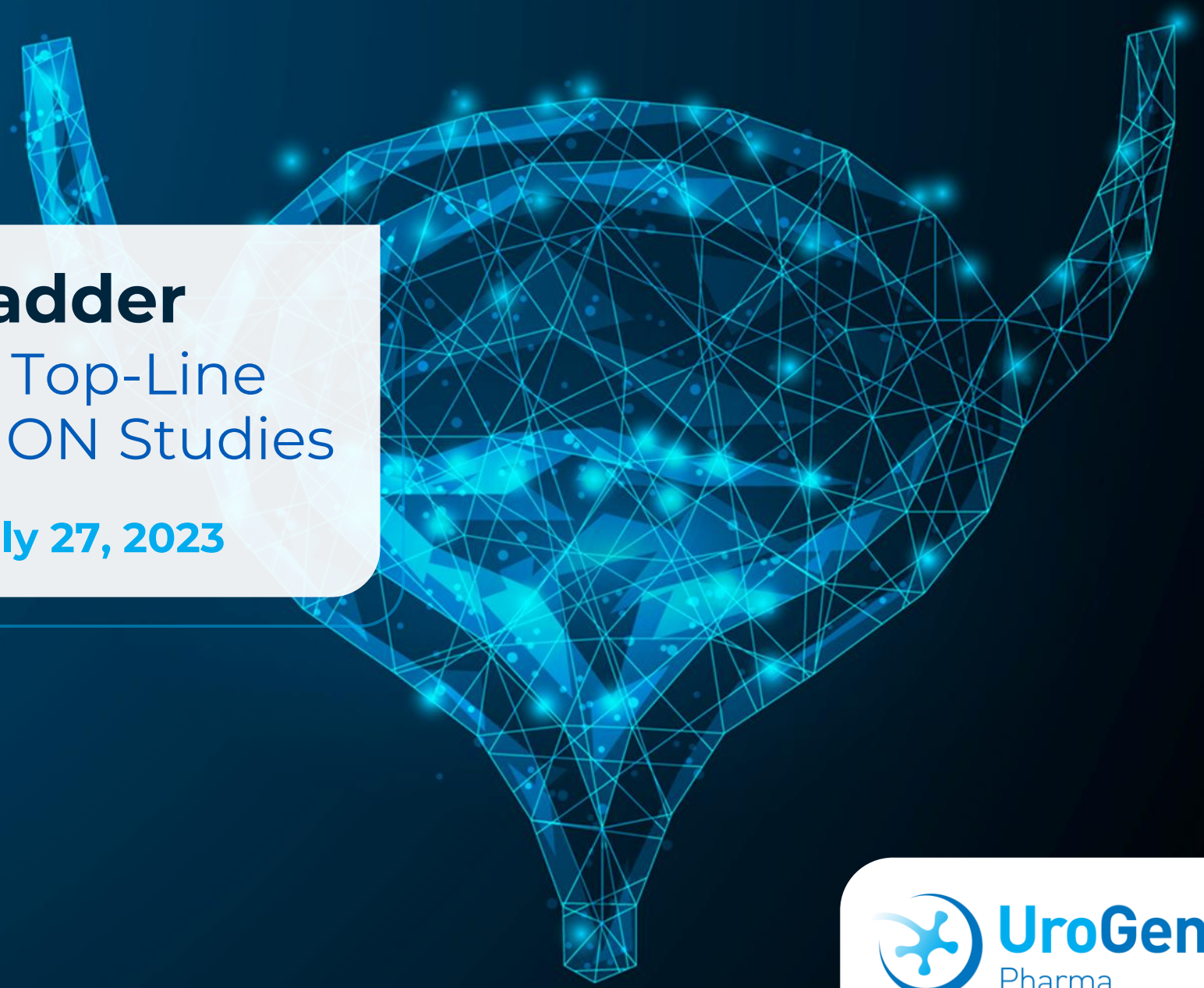
WELCOME

WE WILL BEGIN SHORTLY

New Horizons in Bladder Cancer: Insights from Top-Line Data of ATLAS & ENVISION Studies

July 27, 2023

NASDAQ: URGN



UroGen® Pharma

Forward-looking Statements

This investor presentation contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of JELMYTO® to change the treatment paradigm in LG-UTUC; the potential of UGN-102 to transform the treatment paradigm in LG-IR-NMIBC; the opportunity and potential benefits of UGN-102 for LG-IR-NMIBC and potential advantages over TURBT; the estimated patient population and market opportunity for UGN-102 in LG-IR-NMIBC; the potential of UGN-301 to expand to Immuno-Oncology for LG-IR and HG NMIBC and the estimated addressable patient population and market opportunity for UGN-301 in HG NMIBC; clinical results from ATLAS and ENVISION providing optimism for potential FDA approval of UGN-102; expected final data in the first half of 2024 and plans to submit an NDA for UGN-102 in 2024; potential prescriber behavior; the expectation that UGN-102 will be the primary driver of UroGen's future growth; and the potential of UroGen's proprietary RTGel® technology platform to improve therapeutic profiles of existing drugs to advance the treatment of specialty cancers and urologic disease. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential safety or other complications encountered therein; results from prior or ongoing clinical trials may not be indicative of results that may be observed in the future; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; potential prescriber behavior is based on preliminary feedback that may change as a result of new data, labeling limitations, or other factors; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with product development and commercialization activities; the labeling and packaging for any approved product; the scope, progress and expansion of developing and commercializing UroGen's product and product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; RTGel technology may not perform as expected and UroGen may not successfully develop and receive regulatory approval of any product candidate beyond JELMYTO that incorporates its RTGel technology; and UroGen's ability to attract or retain key management, members of the board of directors and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on May 11, 2023, and other filings that UroGen makes with the Securities and Exchange Commission (SEC) from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this presentation and are based on information available to UroGen as of the date of this presentation.

AGENDA

UroGen…Uniquely Positioned

Liz Barrett, *President and CEO, UroGen*

The Burden of LG-IR-NMIBC

Karim Chamie, *M.D., MSHS, Associate Professor of Urology, UCLA*

Top-Line Data Results: ATLAS and ENVISION

Sandip Prasad, *M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Hospital/Atlantic Health System, NJ*

Impact on Clinical Practice: Panel Discussion

Moderator, **Mark Schoenberg**, *M.D., Chief Medical Officer, UroGen*

Trinity Bivalacqua, *M.D., Ph.D., Director of Urologic Oncology and Co-Director Genitourinary Cancer Service Line, UPenn*

Karim Chamie, *M.D., MSHS, Associate Professor of Urology, UCLA*

Katie Murray, *D.O., Associate Professor of Urology, NYU*

Sandip Prasad, *M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Hospital/Atlantic Health System, NJ*

Q&A

UROGEN…UNIQUELY POSITIONED

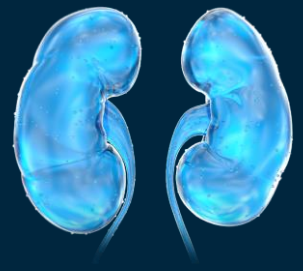
LIZ BARRETT

WE ASPIRE TO CHANGE THE TREATMENT PARADIGM

SURGICAL CARE

MINIMALLY INVASIVE, ORGAN-SPARING THERAPEUTIC OPTIONS

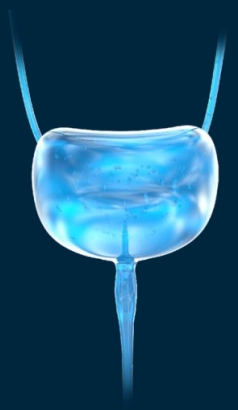
Because Patients Deserve Better



JELMYTO

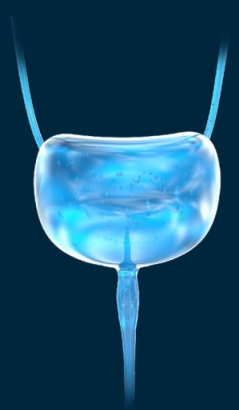
(UGN-101)

Changing the Treatment Paradigm for LG-UTUC



UGN-102

Potential to Transform the Treatment Paradigm in LG-IR-NMIBC Bladder Cancer

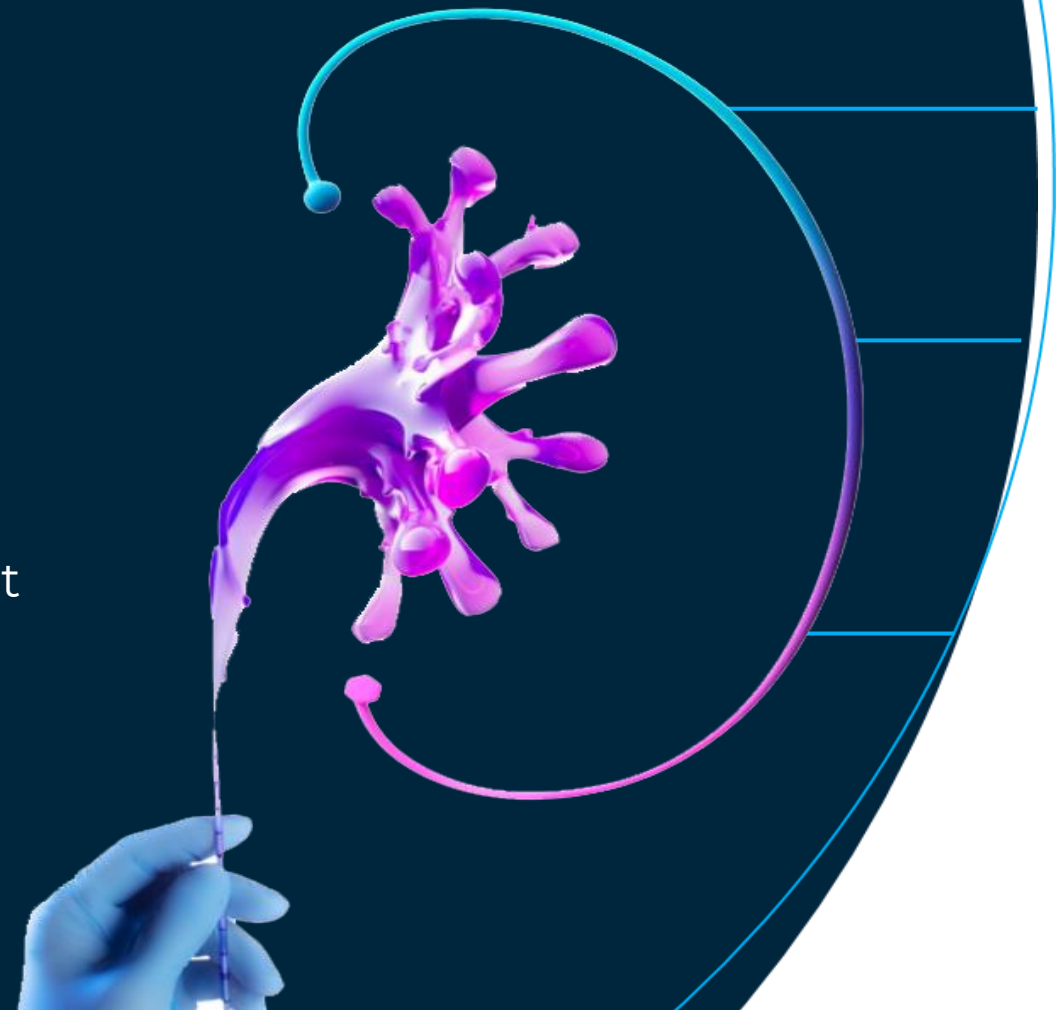


UGN-301

Expanding to Immuno-Oncology for LG-IR and HG-NMIBC

RTGel® Proprietary Reverse-Thermal Hydrogel Technology Uniquely Designed to Allow for Local Delivery of Medicines

RTGel® exists as a **liquid** at lower temperatures and converts to gel form at body temperature.



Increases dwell time and exposure of active drugs

Potentially **improves the therapeutic effects of existing products**

Leverages physiologic flow of urine to provide **natural exit from the body**

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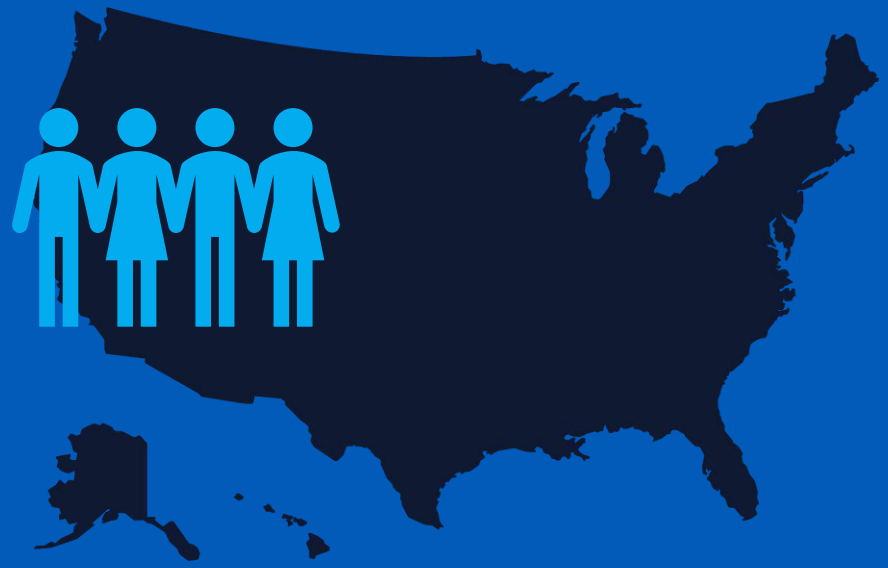
Bladder Cancer Affects Patients and Families Across the U.S.

~**726,000** people in the U.S. living with bladder cancer[1]



One of the

most recurrent

of **ALL** cancers[2]

1. Cancer Stat Facts: Bladder Cancer. National Cancer Institute: Surveillance, Epidemiology, and End Results Program. Accessed July 10, 2023. https://seer.cancer.go v/statfacts/html/urinb.html
2. MBA ASBP PhD. Cancer Recurrence Statistics. Cancer Therapy Advisor. Published November 30, 2018. https://www.cancertherapyadvisor.com/home/tools/fact-sheets/cancer-recurrence-statistics/#:~:text=Some%20cancers%20are%20difficult%20to

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NMIBC Patients Can Find Themselves in a Frustrating Cycle of Treatment

~68%

of recurrent patients **have 2 or more recurrences**[1]

~23%

of recurrent patients **have 5 or more recurrences**[1]

~82,000

addressable LG-IR-NMIBC patients[2-5]

1. Babjuk et al. European Urology (2019), Simon (2019), UroGen projections based on SEER (2016 2. Cancer Stat Facts: Bladder Cancer. National Cancer Institute Surveillance, Epidemiology, and End Results Program. Accessed July 10, 2023. https://seer.cancer.gov/statfacts/html/urinb.html 3. Chevli KK, Shore ND, Trainer A, Smith AB, Saltzstein D, Ehrlich Y, Raman JD, Friedman B, D'Anna R, Morris D, Hu B, Tyson M, Sankin A, Kates M, Linehan J, Scherr D, Kester S, Verni M, Chamie K, Karsh L, Cinman A, Meads A, Lahiri S, Malinowski M, Gabai N, Raju S, Schoenberg M, Seltzer E, Huang WC. Primary Chemoablation of Low-Grade Intermediate-Risk Nonmuscle-Invasive Bladder Cancer Using UGN-102, a Mitomycin-Containing Reverse Thermal Gel (Optima II): A Phase 2b, Open-Label, Single-Arm Trial. J Urol. 2022 Jan;207(1):61-69. doi: 10.1097/JU.0000000000002186. Epub 2021 Aug 26. PMID: 34433303; PMCID: PMC8667793. 4. Babjuk et al. European Urology (2019), Simon (2019), 5. Simon M, Bosset PO, Rouanne M, et al. Multiple recurrences and risk of disease progression in patients with primary low-grade (TaG1) non–muscle-invasive bladder cancer and with low and intermediate EORTC-risk score. Real FX, ed. PLOS ONE. 2019;14(2):e0211721. doi:https://doi.org/10.1371/journal.pone.0211721

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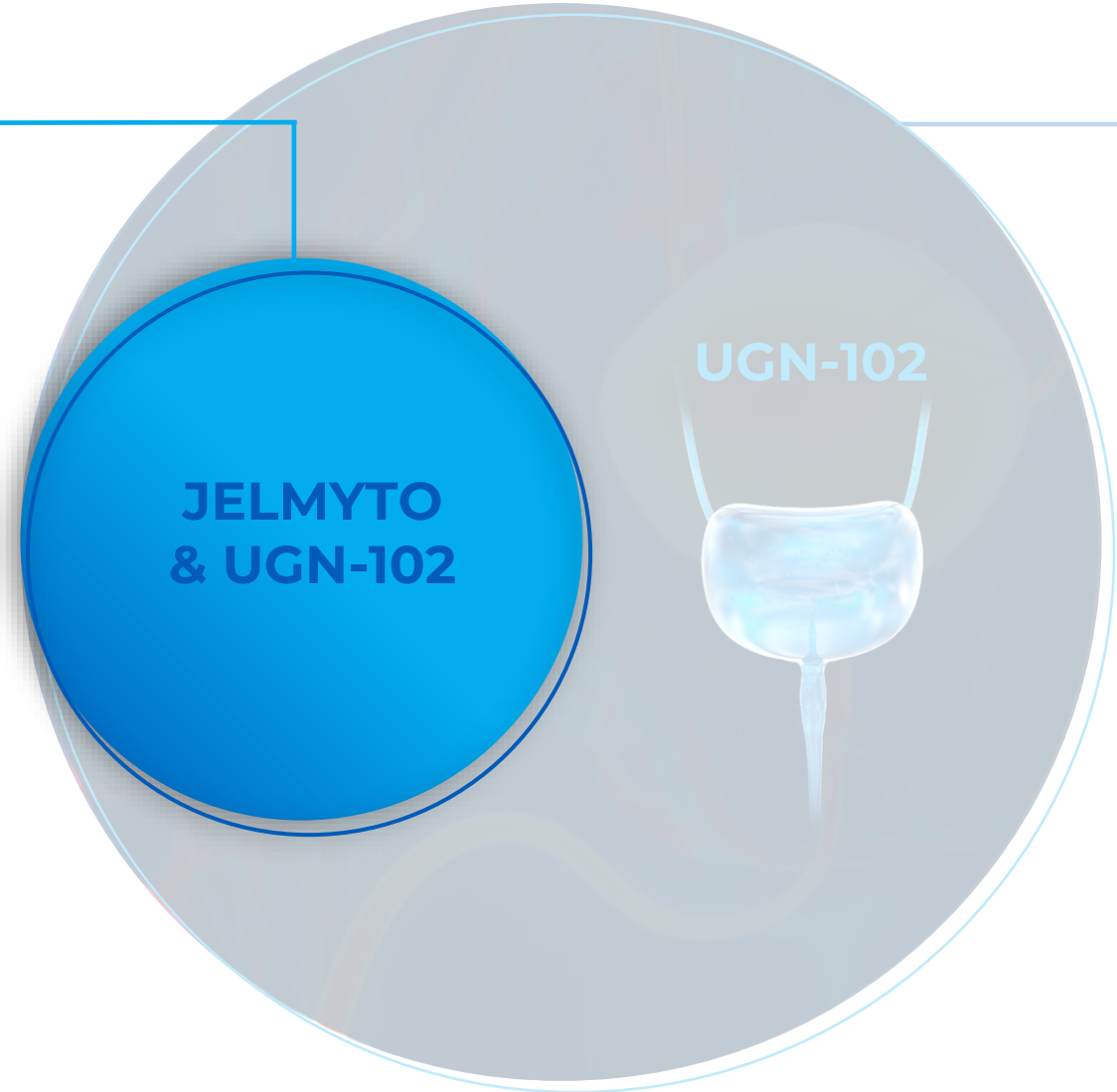
UGN-102: Leveraging Similarities

JELMYTO® & UGN-102

- **RTGel® method of delivery**
- **Mitomycin RTGel® combinations**
- Similar diseases at a **genetic & mutational** driver level
- **Share a 95% prescriber base**



UGN-102

- **10x larger** potential patient population
- **Simpler administration** to bladder than to upper tract
- **Routine procedure** in clinic that urology offices are very familiar with
- **No special equipment** like fluoroscopy

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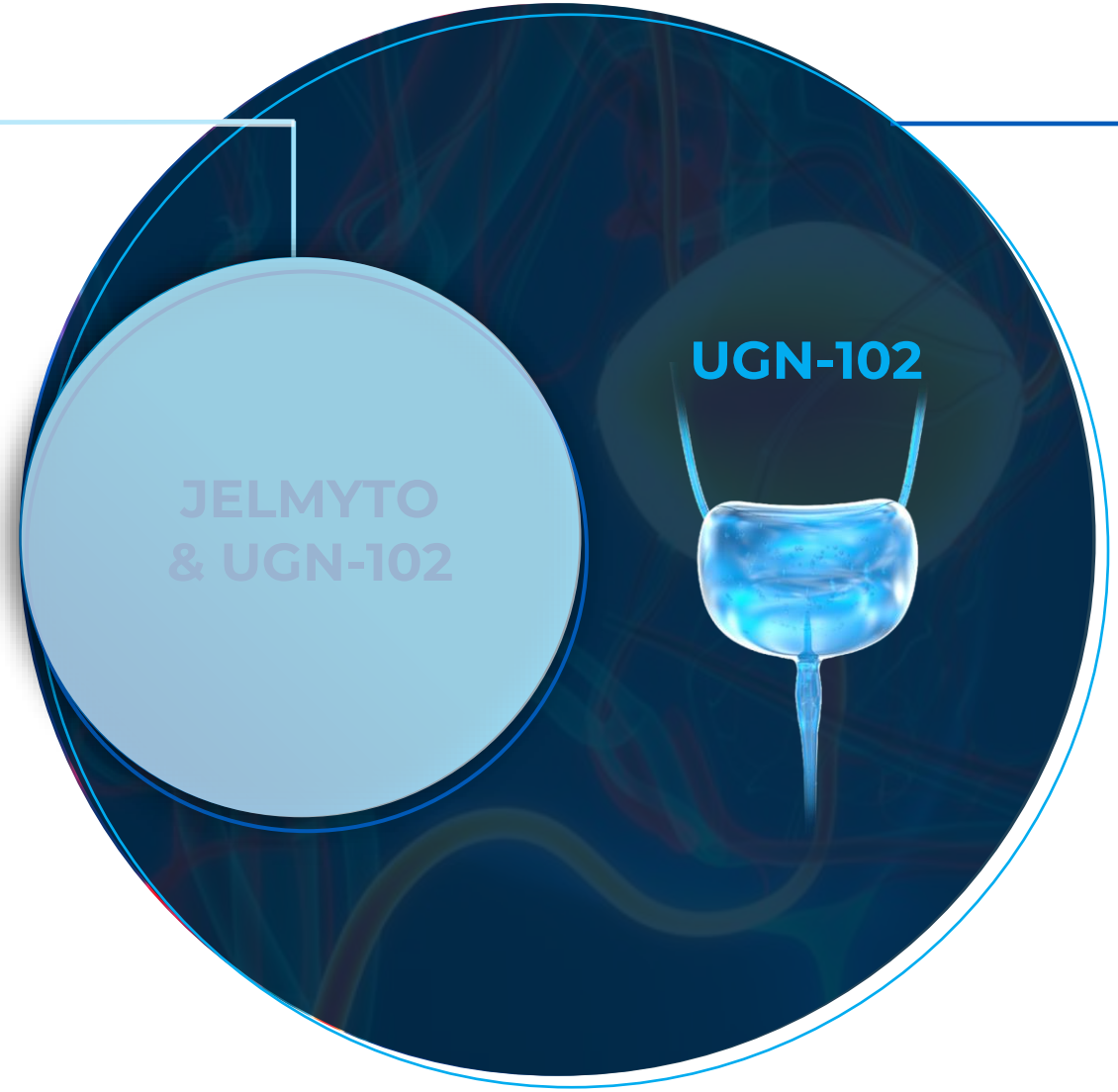
UGN-102: With Distinct Advantages

JELMYTO® & UGN-102

- **RTGel® method of delivery**
- **Mitomycin RTGel ® combinations**
- Similar diseases at a **genetic & mutational** driver level
- **Share a 95% prescriber base**



UGN-102

- **10x larger** potential patient population
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- **No special equipment** like fluoroscopy

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Potential to Unlock a Significant Market Opportunity in a Very Underserved Patient Population

UGN-102
Phase 3

~82,000
addressable U.S. population

$3B+ Market

Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

$5B+
combined TAM revenue opportunity in bladder cancer

UGN-301
Phase 1

~18,700
addressable U.S. population[1]

$2B+ Market

Immunotherapy Targeting High-Grade Non-Muscle Invasive Bladder Cancer (HG-NMIBC)

1. SEER*Stat Database (2019) Surveillance Research Program; Curr Urol Rep (2016) 17: 68; Ther Adv Urol. 2012 Feb; 4(1): 13–32; UroGen Market Research.

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UroGen is Poised to Transform the Way Bladder Cancer is Treated

#1

UGN-102 may become the **first medicine** to treat LG-IR-NMIBC

95%

shared prescriber base with JELMYTO®

$3B+TAM

LG-IR-NMIBC market ripe for **innovation**

$120M

private placement **with experienced biotech investors**

Compelling clinical data package from **3 trials** and **565 patients**

THE BURDEN OF LG-IR-NMIBC

KARIM CHAMIE, M.D.

Bladder Cancer is a HIGHLY Heterogeneous Condition

NMIBC | **MIBC**

Tis
non-invasive

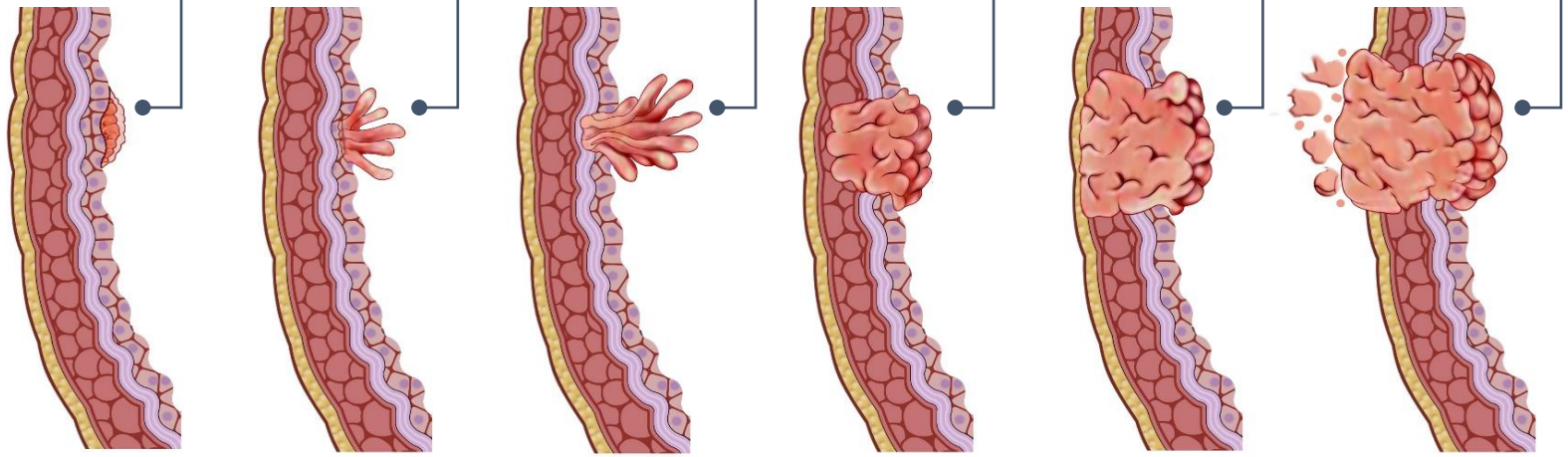
Ta
non-invasive

T1
tumor invades inner lining and connective tissue

T2
tumor invades muscle

T3
tumor invades perivesical fat

T4
tumor invades adjacent organs and structures



Higher spreading probability, worse prognosis

Risk

Low Risk

Intermediate Risk

High Risk

Grade and stage of disease
Tumor size and location
Multifocal or unifocal disease
Response to treatment
Age of patient
Comorbidities

While staging and grading of bladder cancer are based on objective measurements and are well understood, risk stratification is somewhat subjective

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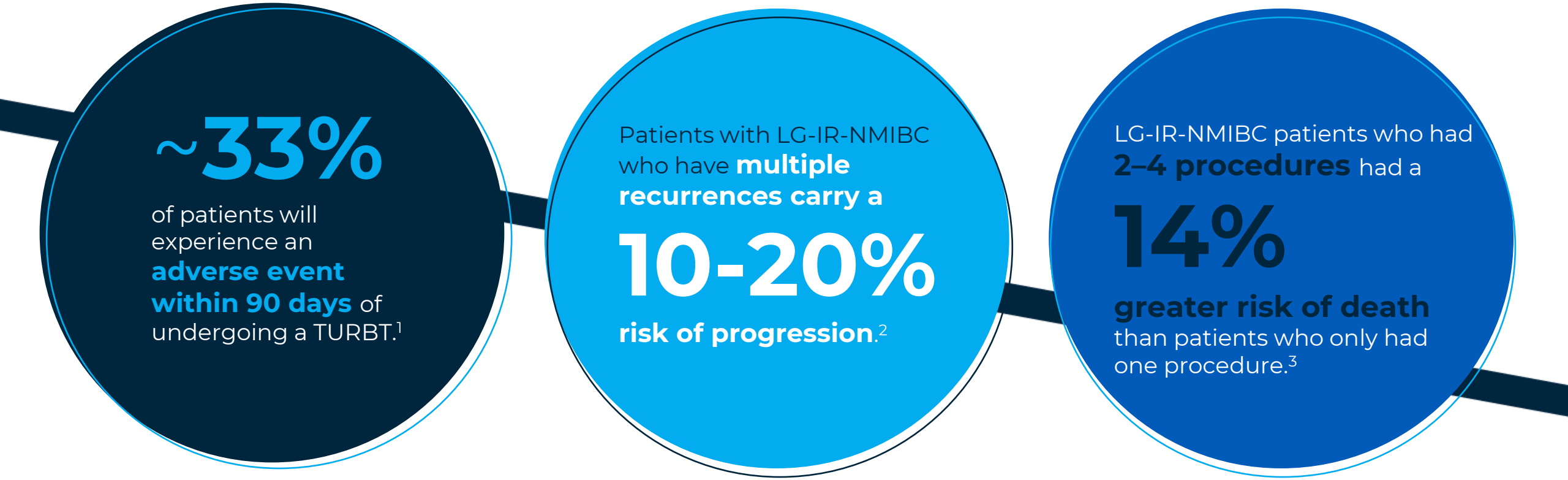
AUA Risk Stratification for Non-Muscle Invasive Bladder Cancer

Low Risk	Intermediate Risk	High Risk
LG [a] solitary Ta ≤ 3cm	Recurrence within 1 yr, LG Ta	HG T1
PUNLMP [b]	Solitary LG Ta > 3cm	Any recurrent, HG Ta
	LG Ta, multifocal	HG Ta, > 3 cm (or multifocal)
	HG [c] Ta, ≤ 3cm	Any CIS [d]
	LG T1	Any BCG failure in HG patient
		Any variant histology
		Any LVI [e]
		Any HG prostatic urethral involvement

[a]LG = low grade; [b]PUNLMP = papillary urothelial neoplasm of low malignant potential; [c]HG = high grade; [d]CIS = carcinoma *in situ*; [e]LVI = lymphovascular invasion

1. Chang SS, Boorjian SA, Chou R, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *J Urol*. 2016;196(4):1021-1029. doi:10.1016/j.juro.2016.06.049

Repeat Surgery Comes with Risks for this Patient Population



1. Sharma V, Aaronson DS, Fero KE, et al. Adverse events after transurethral resection of intermediate-risk non-muscle invasive bladder cancer. *J Urol*. 2021:206(suppl 3):e122. doi:10.1097/JU.0000000000001977.08 2. Sharma V, Chamie K, Schoenberg M, et al. Natural history of multiple recurrences in intermediate-risk non-muscle invasive bladder cancer: lessons from a prospective cohort. *Urology*. 2023;173:134-141. doi:10.1016/j.urology.2022.12.009 3. Erikson MS, Petersen AC, Andersen KK, Jacobsen FK, Mogensen K, Hermann GG. Do repeated transurethral procedures under general anesthesia influence mortality in patients with non-invasive urothelial bladder cancer? A Danish national cohort study. *Scand J Urol*. 2020;54(4):281-289. doi:10.1080/21681805.2020.1782978

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Challenging the Future Standard of Care for LG-IR-NMIBC

TURBT as the current standard of care

Requires **anesthesia**

Associated with **risk of complications**

Requires **lifelong surveillance** and **recurrent treatment**

Key **Unmet Needs** for Patients and HCPs

Additional treatment options

Reduction of recurrence

1. Erikson et al. Scan J Urol & Nephrol (2020)

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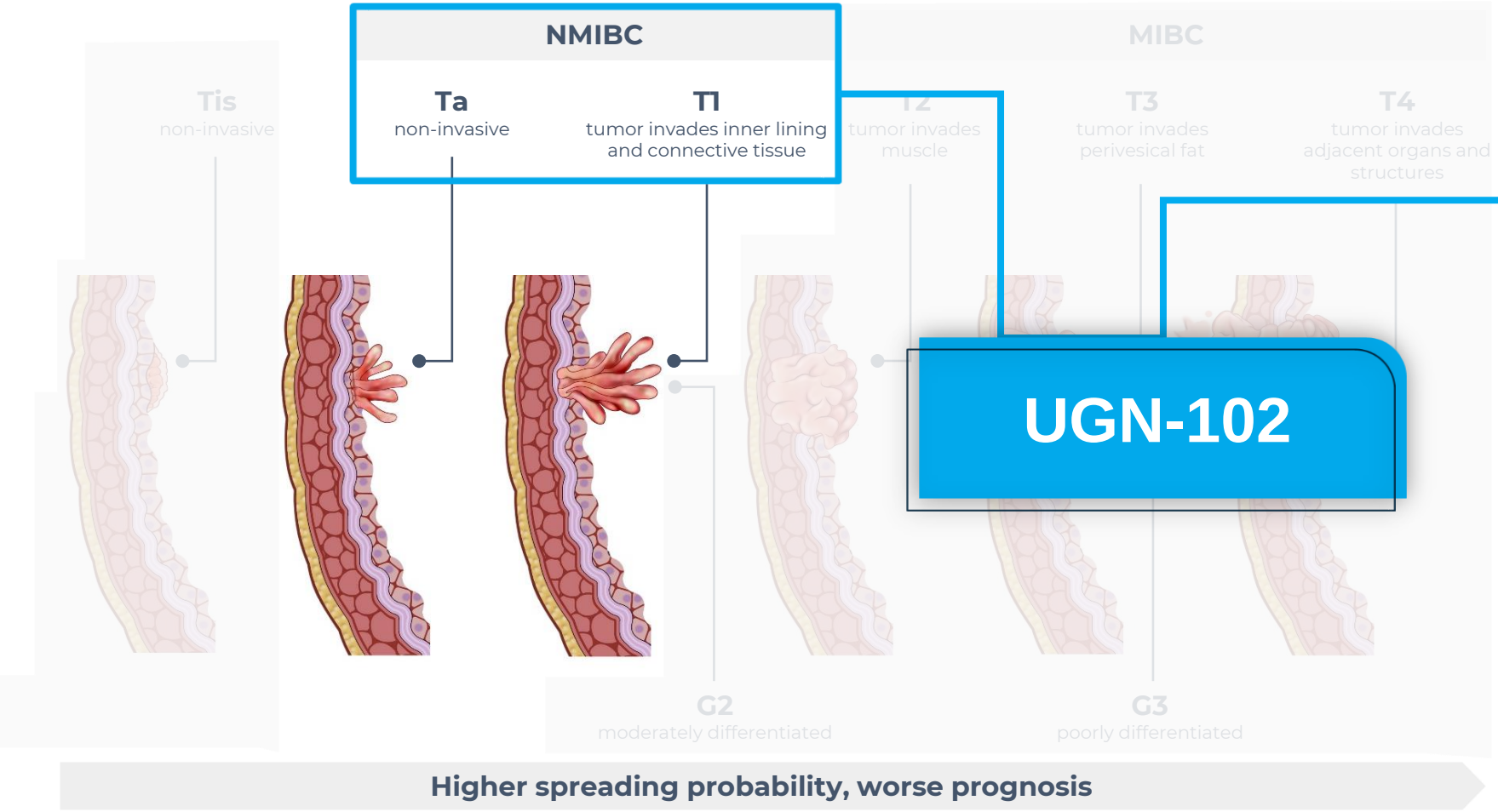
UGN-102 Could Become the First Approved Non-Surgical Treatment for LG-IR-NMIBC



Risk

Low Risk

Intermediate Risk

High Risk

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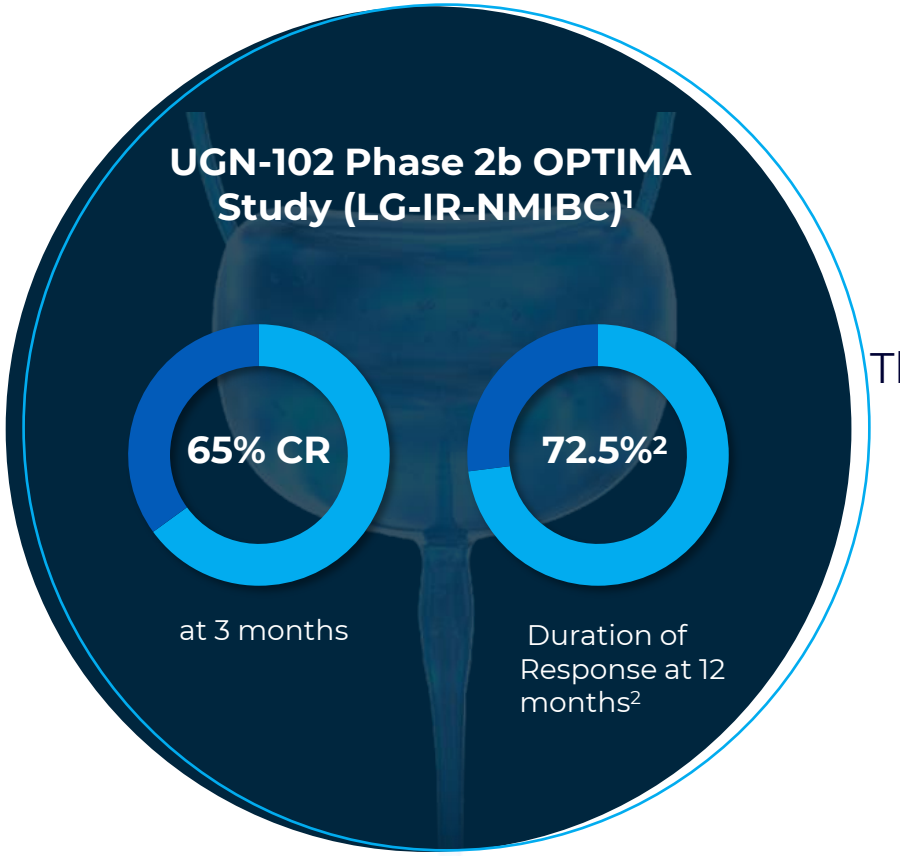
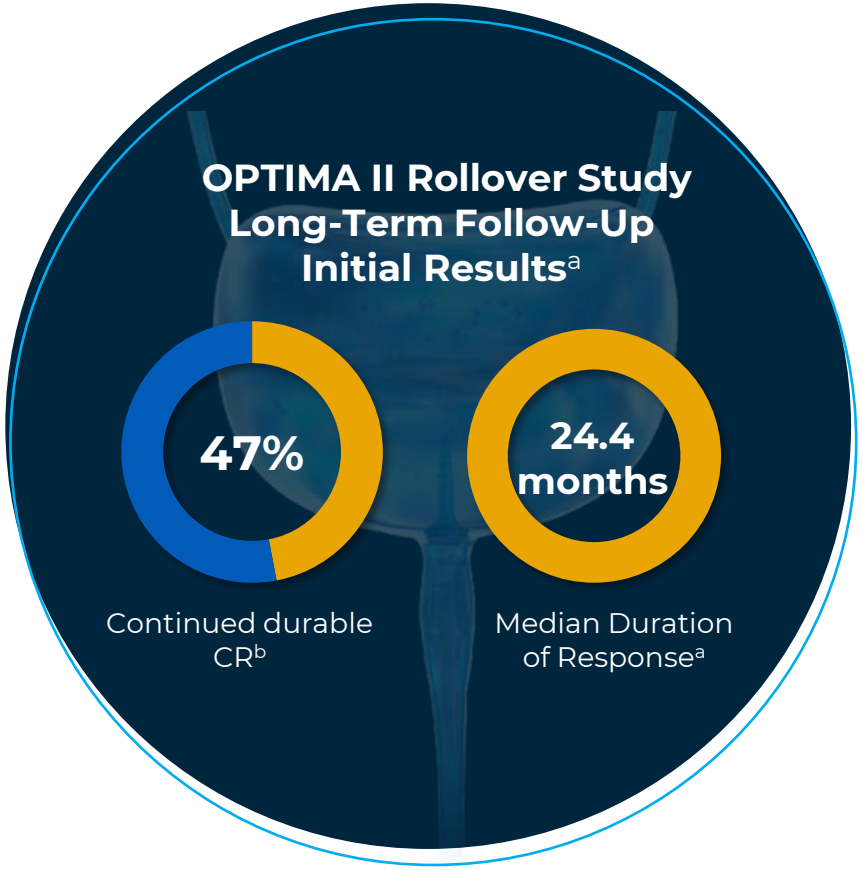
OPTIMA II Phase 2b Trial Showed Significant Tumor Response and Long-Term Treatment Benefit



These data suggest **continued durability** in patients who received **UGN-102**



1. Chevli KK, Shore ND, Trainer A, et al. Primary chemoablation of low-grade intermediate-risk nonmuscle-invasive bladder cancer using UGN-102, a mitomycin-containing reverse thermal gel (Optima II): a phase 2b, open-label, single-arm trial. *J Urol*. 2022;207(1):61-69. doi:10.1097/JU.0000000000002186
*Estimated probability by Kaplan-Meier analysis that a patient will remain in CR for 12 months after treatment initiation.
2.. Chevli KK, Shore ND, Trainer A, et al. Long-term outcomes of treatment with UGN-102 for primary chemoablation of low-grade intermediate risk non-muscle—invasive bladder cancer (LG IR NMIBC). Presented at: Society of Urologic Oncology 23rd Annual Meeting; November 30-December 2, 2022; San Diego, California. Poster 193. https://suo-abstracts.secure-platform.com/a/gallery/rounds/15/details/2419
* Continued durable CR beyond 12 months after treatment initiation observed in 7 of 15 evaluable patients who completed the OPTIMA II study and were eligible to participate in this rollover study.
a. Duration of complete response (10.1 – 30.7 months); median range among 15 evaluable patients
b. Continued durable CR beyond 12 months after treatment initiation observed in 7 of 15 evaluable patients who completed the OPTIMA II study and were eligible to participate in this rollover study.

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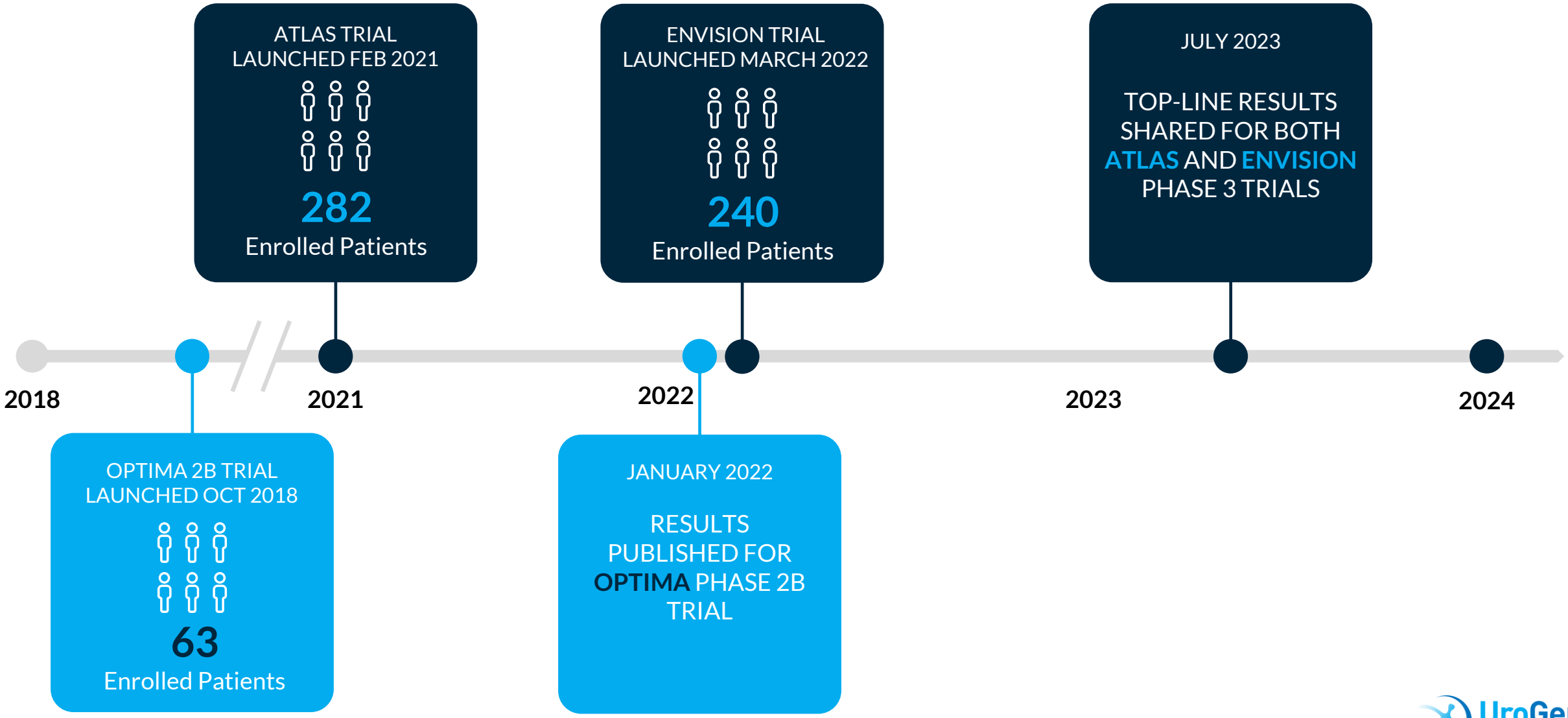
TOP-LINE DATA RESULTS: ATLAS AND ENVISION

SANDIP PRASAD, M.D., M.PHIL.

Overview of UGN-102 Program



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ATLAS

ATLAS Study Endpoints

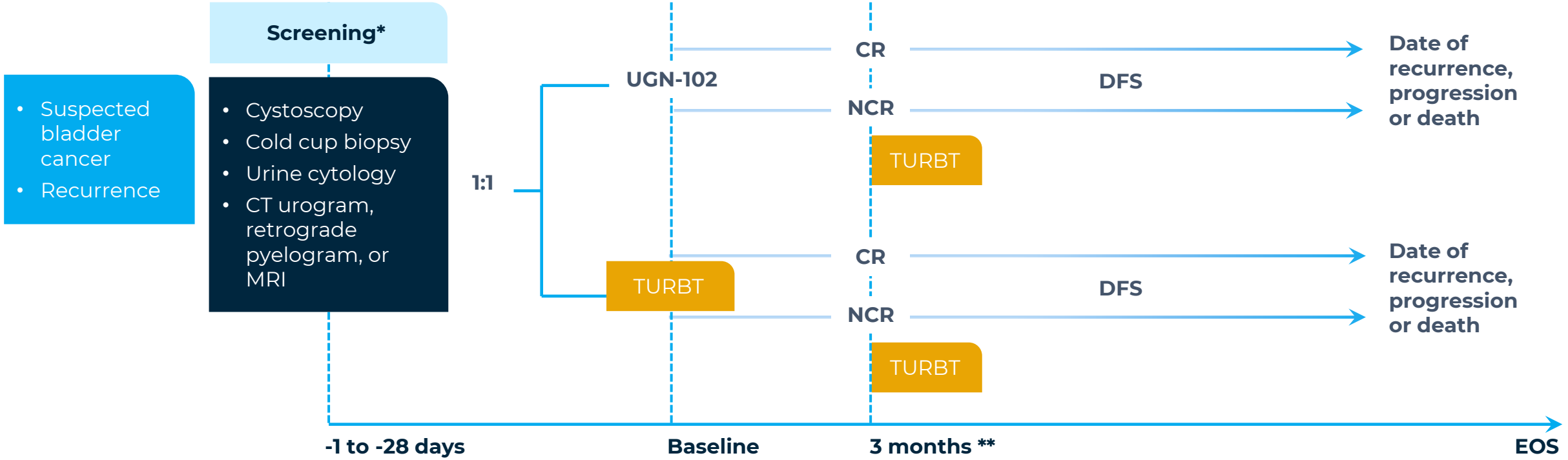
Primary Endpoint (ITT):

- **Disease-free survival (DFS)**, defined as the time from randomization until the earliest date of any of the following events:
  - ✓**Residual disease** at the 3-month assessment
  - ✓**Recurrence**
  - ✓**Progression**
  - ✓**Death**

Key Secondary Endpoints:

- **Complete response rate (CRR)** at 3-month visit
- **Duration of response (DOR)**, defined as the time from first documented CR until the earliest date of recurrence of low-grade disease, progression to high-grade disease, or death due to any cause (3-month CR analysis set)

ATLAS Trial Design



CR: Complete Response
NCR: Non-Complete Response
DFS: Disease-free Survival
EOS: End of Study

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ATLAS Demographics and Safety Profile

Demographics and baseline characteristics were **well balanced** between treatment arms

- Treatment-emergent AEs were generally **mild to moderate**
- **Similar safety profile** to other studies of UGN-102
- Any treatment or procedure related serious TEAEs were **comparable** across both arms
  - UGN-102 +/- TURBT: 1.4%
  - TURBT Alone: 0.8%

UroGen Data on File
Overall summary of Demographics and AE's can be referenced in the Appendix

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Summary of Disease-Free Survival: Significantly More Total Recurrence and Progression in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / **n** (%)	**TURBT Alone** (N = 140) / **n** (%)
Patients with Events, n (%)	**37 (26.1)**	**55 (39.3)**
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
Patients Censored, n (%)	**105 (73.9)**	**85 (60.7)**
Hazard Ratio (95% CI)	**0.45 (0.29, 0.68)**	

UroGen Data on File
Source: Table 14.2.1.1
Full table in Appendix

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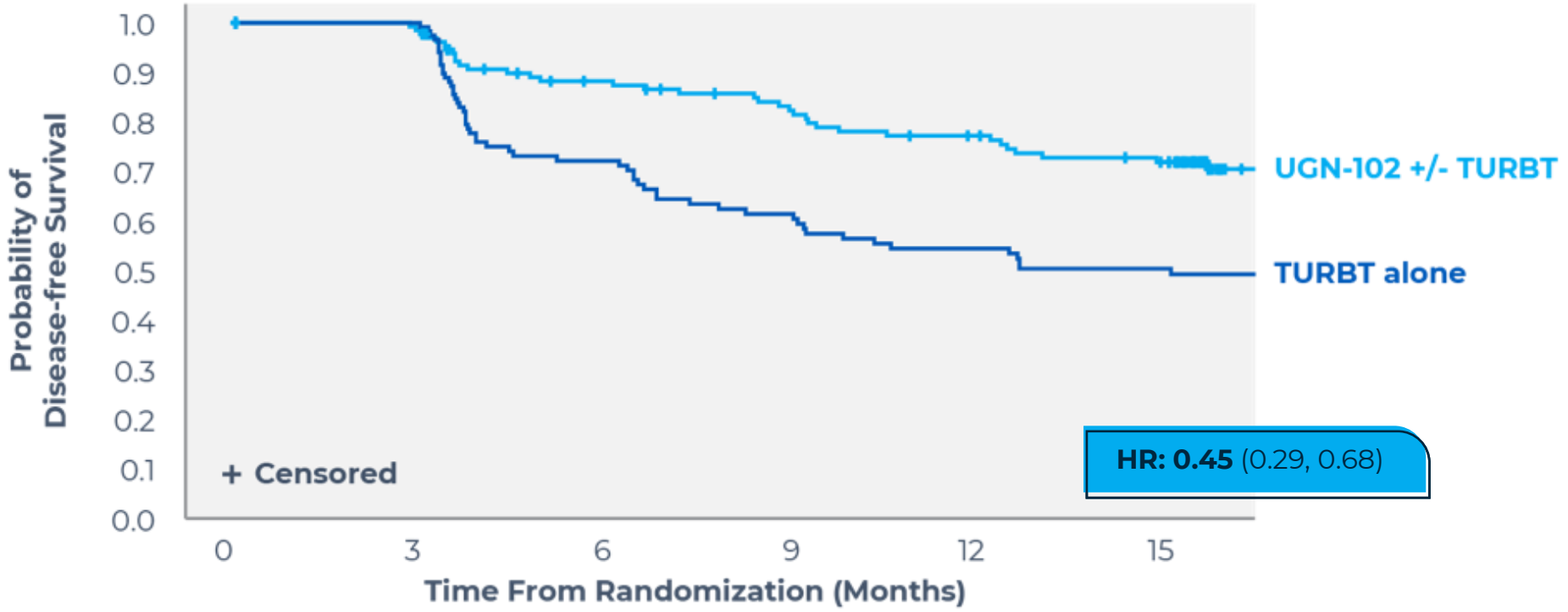
DFS - 55% Reduction of Risk for Recurrence, Progression, or Death in the Intent to Treat Population



Number at Risk						
UGN-102 +/- TURBT	142	128	108	96	87	73
TURBT Alone	140	119	76	60	54	42
Number Censored						
UGN-102 +/- TURBT	0	11	19	23	26	35
TURBT Alone	0	20	32	35	36	43

UroGen Data on File
Source: Table 14.2.1.1a
Kaplan-Meier Plot of Disease-Free Survival

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Three-Month Complete Response Rates Were Similar Between Treatment Arms

Response	UGN-102 Alone (N = 142) n (%)	UGN-102 Alone (N = 142) CRR (95%CI)	TURBT Alone (N = 140) n (%)	TURBT Alone (N = 140) CRR (95% CI)
Complete Response	92 (64.8)	**64.8% (56.3, 72.6)**	89 (63.6)	**63.6% (55.0, 71.5)**
Non-complete Response	50 (35.2)		51 (36.4)	
Residual Disease	26 (18.3)		22 (15.7)	
Progression to HG Disease	12 (8.5)		9 (6.4)	
Indeterminate	3 (2.1)		0	
Missing	9 (6.3)		20 (14.3)	

UroGen Data on File
Source: Table 14.2.2.2.1a

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Summary of Duration of Response in Complete Responders: Longer DOR with UGN-102 Alone

	UGN-102 Alone (N = 92) / **n** (%)	**TURBT Alone** (N = 89) / **n** (%)
Patients with Events, n (%)	**18 (19.6)**	**24 (27.0)**
Recurrence of LG Disease	15 (16.3)	17 (19.1)
Progression to HG Disease	3 (3.3)	6 (6.7)
Death	0	1 (1.1)
Patients Censored, n (%)	**74 (80.4)**	**65 (73.0)**
Hazard Ratio (95% CI)	**0.46 (0.24, 0.86)**	

UroGen Data on File
Source: Table 14.2.2.3.1a
Full table in Appendix

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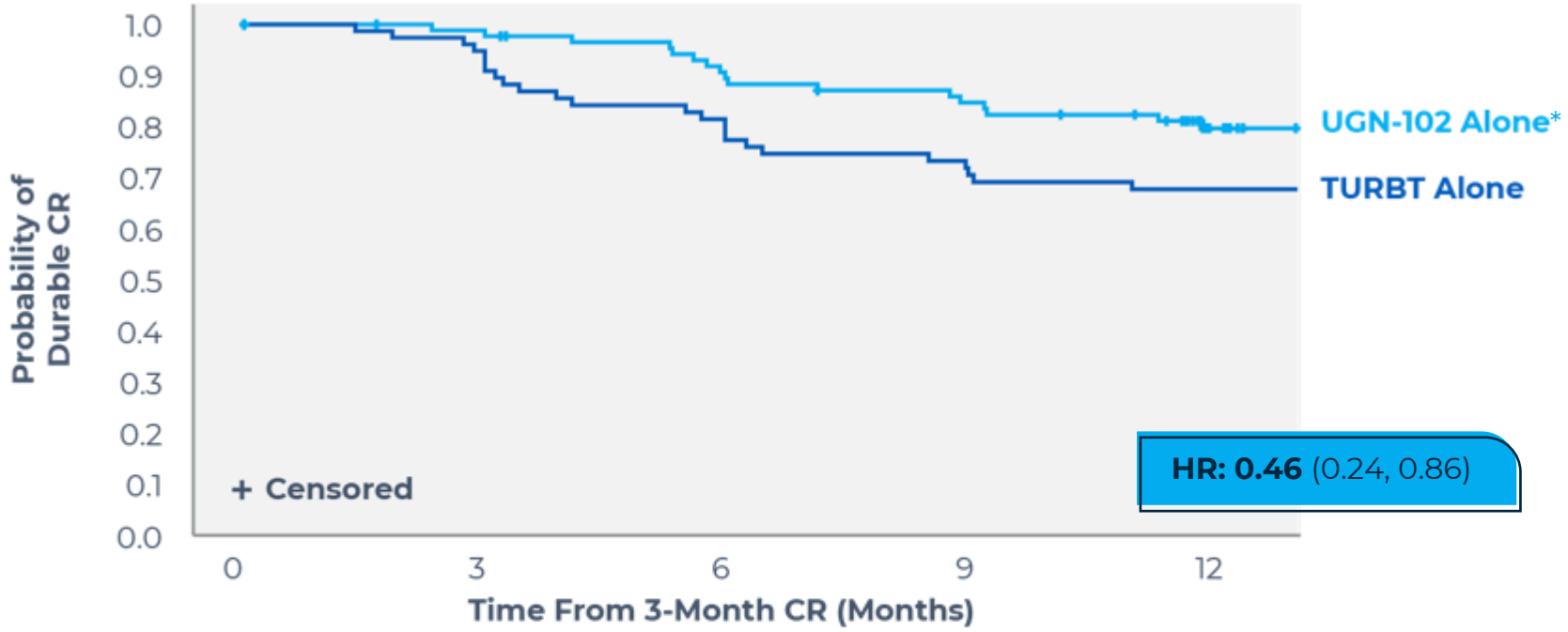
DOR - 54% Reduction of Risk for Recurrence, Progression, or Death in Patients Who had a 3-Month CR



Number at Risk					
UGN-102 Alone	92	86	77	71	49
TURBT Alone	89	73	60	53	34
Number Censored					
UGN-102 Alone	0	5	7	8	26
TURBT Alone	0	12	15	16	31

*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS
UroGen Data on File
Source: Table 14.2.1.1a
Kaplan-Meier Plot of Duration of Response in Complete Responders

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ENVISION

ENVISION Single-Arm Study Description

Primary endpoint:

- **Complete response rate (CRR)** at 3-month visit

Key Secondary endpoint:

- **Duration of Response (DOR)**, defined as time from first documented CR until the earliest date of:
  - ✓**Recurrence** of low-grade disease at the 3-month assessment
  - ✓**Progression**
  - ✓**Death**

Patient Population:

- **Previously diagnosed**

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ENVISION Demographics and Safety Profile

Demographics and baseline characteristics were **reflective of typical LG-IR-NMIBC patient population**

- Treatment-emergent AEs were generally **mild to moderate**
- **Similar safety profile** to other studies of UGN-102

UroGen Data on File
Overall summary of Demographics and AE's can be referenced in the Appendix

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Summary of Response Rate At 3-Month Disease Assessment: CRR of 79.2%

	UGN-102 (N = 240)	
	n (%)	**CRR** (95% CI)
Complete Response	**190 (79.2)**	**79.2 (73.5, 84.1)**
Non-Complete Response	**50 (20.8)**	
Residual Disease	35 (14.6)	
Progression to HG Disease	6 (2.5)	
Indeterminate	4 (1.7)	
Missing	5 (2.1)	

UroGen Data on File
Summary of Response Rate At 3-Month Disease Assessment

Next for ENVISION

DOR data expected in

1H, 2024

Planned NDA Submission

2024

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IMPACT ON CLINICAL PRACTICE

PANEL DISCUSSION

Dr. Mark Schoenberg

Moderator

M.D., Chief Medical Officer, UroGen

Dr. Trinity Bivalacqua

M.D., Ph.D., Director of Urologic Oncology and Co-Director Genitourinary Cancer Service Line with the Abramson Cancer Center, Hospital of the University of Pennsylvania, PA

Dr. Karim Chamie

M.D., MSHS, Associate Professor of Urology at UCLA, CA

Dr. Katie Murray

DO, Associate Professor of Urology, New York University Langone and Chief of Urology, Bellevue Hospital, NYC

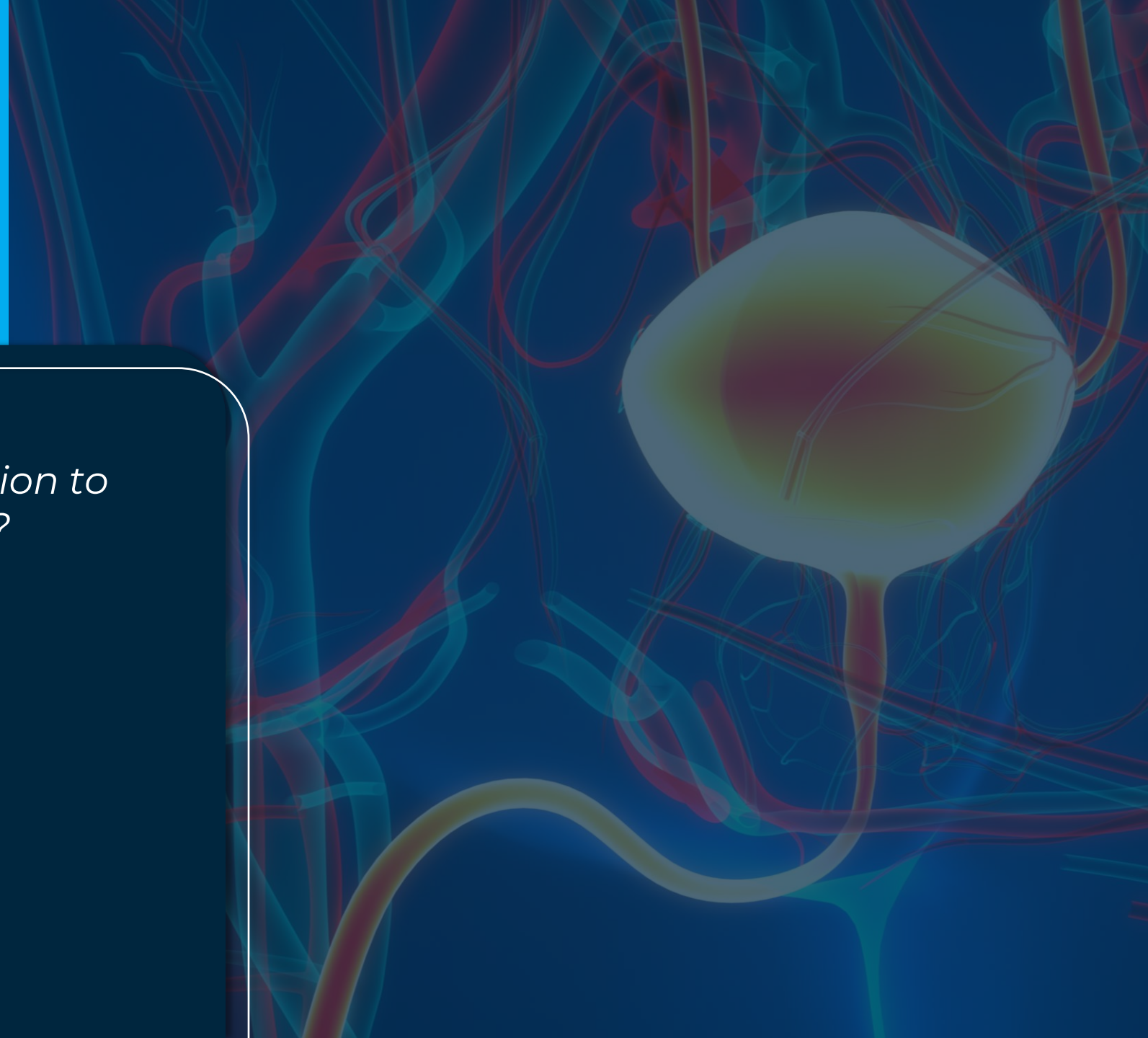
Dr. Sandip Prasad

M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Medical Center/Atlantic Health System, NJ

The views expressed by the healthcare professionals on this panel are their own and do not necessarily represent the views of their employers or affiliated institutions. Additionally, these healthcare professionals are consultants for UroGen and are being compensated for their participation in today's event.

TOPIC 1

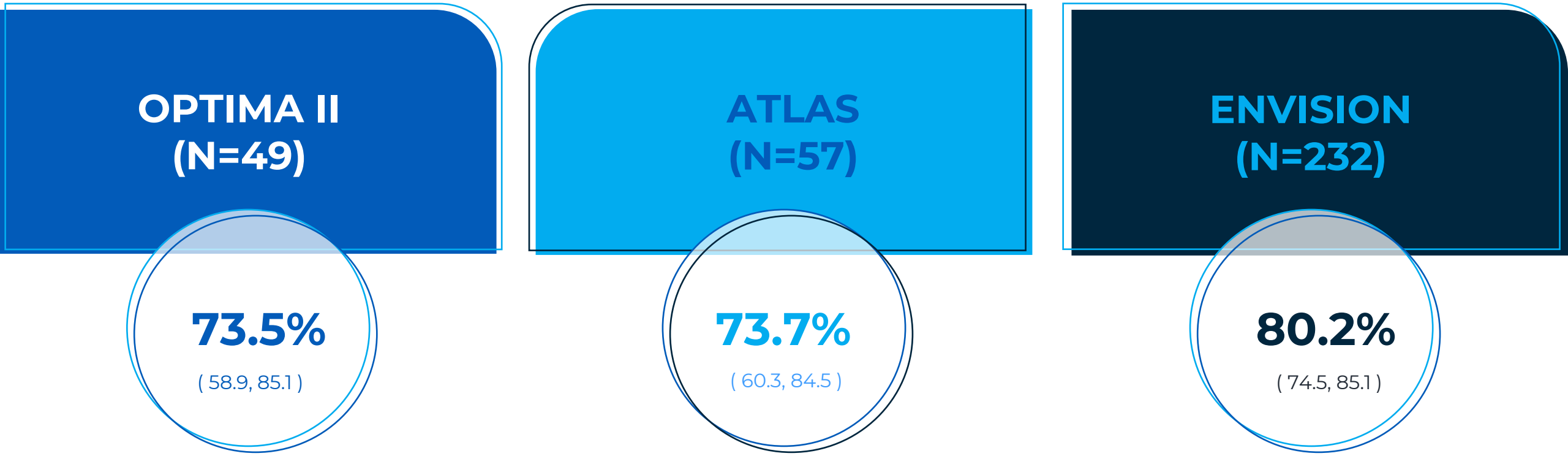
What 's your initial reaction to the data presented?



TOPIC **2**

Discussing the CR rate across the OPTIMA II, ATLAS and ENVISION trials.

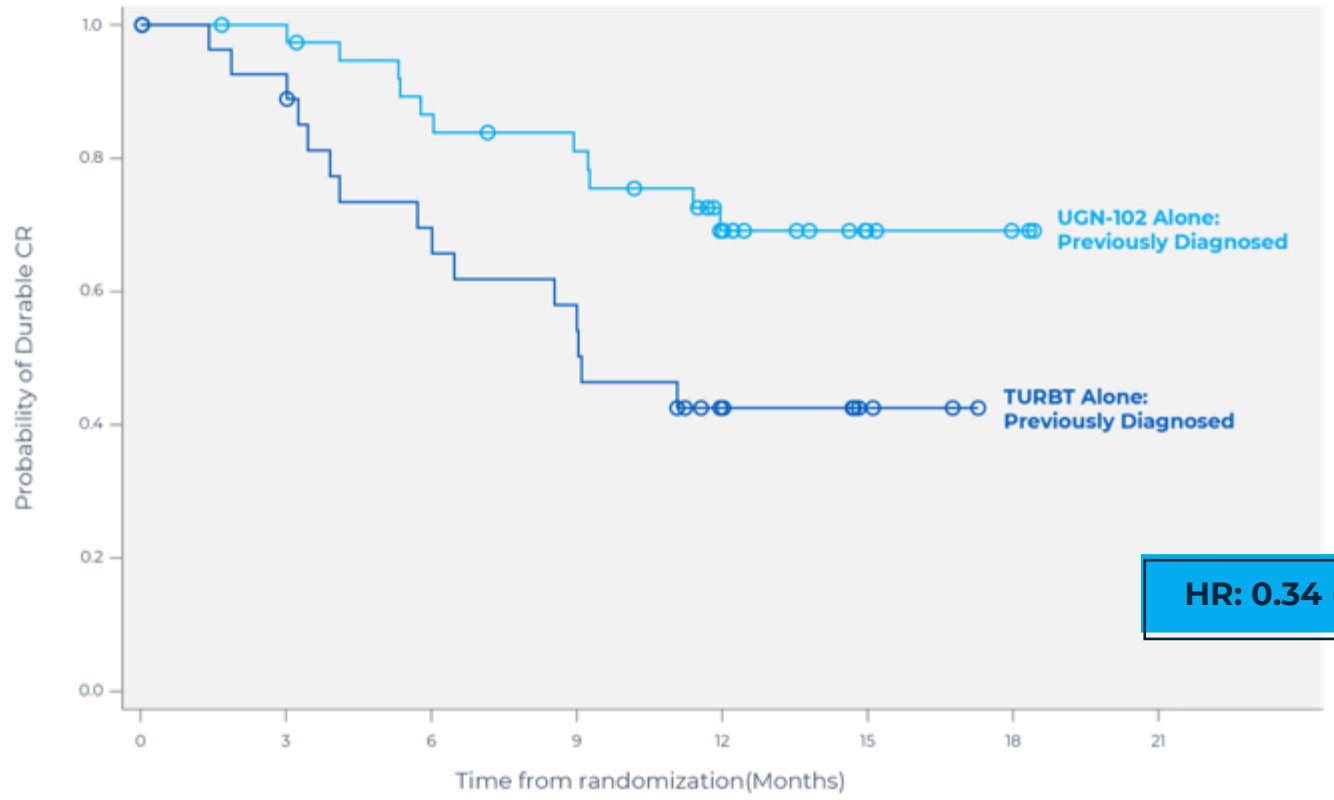
Complete Response Rate for Recurrent Patients Within the UGN-102 Trials



UroGen Data on File
Total OPTIMA II population n=63, recurrent population n=49
Total ATLAS population n=282, recurrent population n=57
Total ENVISION population n=240, recurrent population n=232

UroGen Pharma

DOR - 66% Reduction of Risk for Recurrence, Progression, or Death in Recurrent Patients Who Received UGN-102 Alone in the ATLAS Trial



UGN-102 Alone: Previously Diagnosed	42	38	32	29	16	4	2	0
TURBT Alone: Previously Diagnosed	35	25	18	15	7	3	0	0

*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS
UroGen Data on File
Kaplan-Meier Plot of DOR in Complete Responders in the Recurrent Subgroup (ATLAS)

UroGen Pharma

UGN-102 Shows Substantial **Reduction of Risk** of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

ITT – All Patients DFS	**0.45** (0.29, 0.68)
CR Duration – UGN-102 Alone DOR	**0.46** (0.24, 0.86)
Recurrent – UGN-102 Alone DOR	**0.34** (0.15, 0.75)

UroGen Data on File
Various ATLAS 3-Month CR Rate Cohorts

UroGen Pharma

TOPIC 3

How does the fact that UGN-102, if approved, can be given by an APP in the office impact how you might view adoption?

TOPIC 4

Given that urologists are familiar with neoadjuvant chemotherapy use in the context of treating MIBC, do you think it will be a big leap for them to adopt neoadjuvant therapy for NMIBC?

CLOSING THOUGHTS

UGN-102 Shows Substantial **Reduction of Risk** of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

ITT – All Patients DFS	**0.45** (0.29, 0.68)
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UroGen Data on File
Various ATLAS 3-Month CR Rate Cohorts

UroGen Pharma

Q&A

Moderated by LIZ BARRETT

UroGen is Poised to Transform the Way Bladder Cancer is Treated

UGN-102 **shows substantial risk reduction** across patient populations

Compelling clinical data package from **3 trials** and **565 patients**

#1

UGN-102 may become the **first medicine** to treat LG-IR-NMIBC

$3B+TAM

LG-IR-NMIBC market ripe for **innovation**

$120M

private placement **with experienced biotech investors**

THANK YOU

NASDAQ: URGN

APPENDIX

Demographics and Baseline Characteristics Were Well Balanced Between Treatment Arms

Characteristic	UGN-102 +/- TURBT (N = 142) / **n** (%)	TURBT Alone (N = 140) / **n** (%)
Median age (range), years	**68.0** (23, 85)	**67.0** (29, 88)
Age ≥ 65 years, n (%)	**91** (64.1)	**77** (55.0)
Sex, n (%)		
Male	**105** (73.9)	**93** (66.4)
Female	**37** (26.1)	**47** (33.6)
Any prior NMIBC episode, n (%)	**57** (40.1)	**66** (47.1)
Prior TURBT, n (%)	**55** (38.7)	**63** (45.0)

UroGen Data on File
Source: Tables 14.1.6.1 and 14.1.8.2

UroGen Pharma

Overall Summary of Adverse Events in ATLAS: Safety Profile Similar to Other Studies of UGN-102

	UGN-102 ± TURBT (N = 138)		TURBT Alone (N = 132)	
	Events	**n** (%)	**Events**	**n** (%)
Any Adverse Events	442	108 (78.3)	249	81 (61.4)
Any Serious Adverse Events	13	12 (8.7)	11	7 (5.3)
Any TEAEs	402	104 (75.4)	166	63 (47.7)
Any Treatment or Procedure Related TEAEs	211	65 (47.1)	21	15 (11.4)
Any Treatment Related TEAEs	186	54 (39.1)	19	15 (11.4)
Any Procedure Related TEAEs	65	31 (22.5)	2	2 (1.5)
Any TEAEs Leading to Treatment Discontinuation	19	5 (3.6)	NA	NA
Any TEAEs Leading to Study Discontinuation	7	4 (2.9)	2	2 (1.5)
Any Serious TEAEs	13	12 (8.7)	11	7 (5.3)
Any Treatment or Procedure Related Serious TEAEs	2	2 (1.4)	1	1 (0.8)
Any Treatment Related Serious TEAEs	0	0	1	1 (0.8)
Any Procedure Related Serious TEAEs	2	2 (1.4)	0	0
Any TEAEs Leading to Death	0	0	1	1 (0.8)
Any TEAEs of Special Interest	213	78 (56.5)	59	36 (27.3)

UroGen Data on File
Source: Table 14.3.1.1

UroGen Pharma

Most Commonly Reported AEs and Serious TEAEs

Incidence of Treatment-Emergent Adverse Events (≥ 5% in Either Group)

	UGN-102 ± TURBT (N = 138) / **n** (%)	**TURBT Alone** (N = 132) / **n** (%)
Patients With Any TEAE	**104 (75.4)**	**63 (47.7)**
Dysuria	42 (30.4)	6 (4.5)
Micturition urgency	25 (18.1)	10 (7.6)
Nocturia	25 (18.1)	9 (6.8)
Pollakiuria	22 (15.9)	8 (6.1)
Flatulence	13 (9.4)	4 (3.0)
COVID-19	11 (8.0)	8 (6.1)
Erectile dysfunction	9 (6.5)	4 (3.0)
Haematuria	9 (6.5)	6 (4.5)
Malaise	8 (5.8)	2 (1.5)

Incidence of Serious TEAEs (≥ 1% in Either Group)

	UGN-102 ± TURBT (N = 138) / **n** (%)	**TURBT Alone** (N = 132) / **n** (%)
Patients With Any Serious TEAE	**12 (8.7)**	**7 (5.3)**
COVID-19	4 (2.9)	2 (1.5)
Sepsis	1 (0.7)	2 (1.5)
Haematuria	0	2 (1.5)

UroGen Data on File
Source: Table 14.3.1.3.1
Overall summary of AE's can be referenced in the Appendix

UroGen Pharma

Summary of Disease-Free Survival: Significantly More Total Progressions and Recurrences in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / **n** (%)	**TURBT Alone** (N = 140) / **n** (%)
Patients with Events, n (%)	**37 (26.1)**	**55 (39.3)**
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
Patients Censored, n (%)	**105 (73.9)**	**85 (60.7)**
No Post-baseline Disease Assessment	10 (7.0)	20 (14.3)
Received Non-protocol Therapy	7 (4.9)	4 (2.9)
Early Termination	6 (4.2)	12 (8.6)
Disease-free at End of Study	81 (57.0)	49 (35.0)
Extended Lost to Follow-up	1 (0.7)	0
Hazard Ratio (95% CI)	**0.45 (0.29, 0.68)**	

UroGen Data on File
Source: Table 14.2.1.1

UroGen Pharma

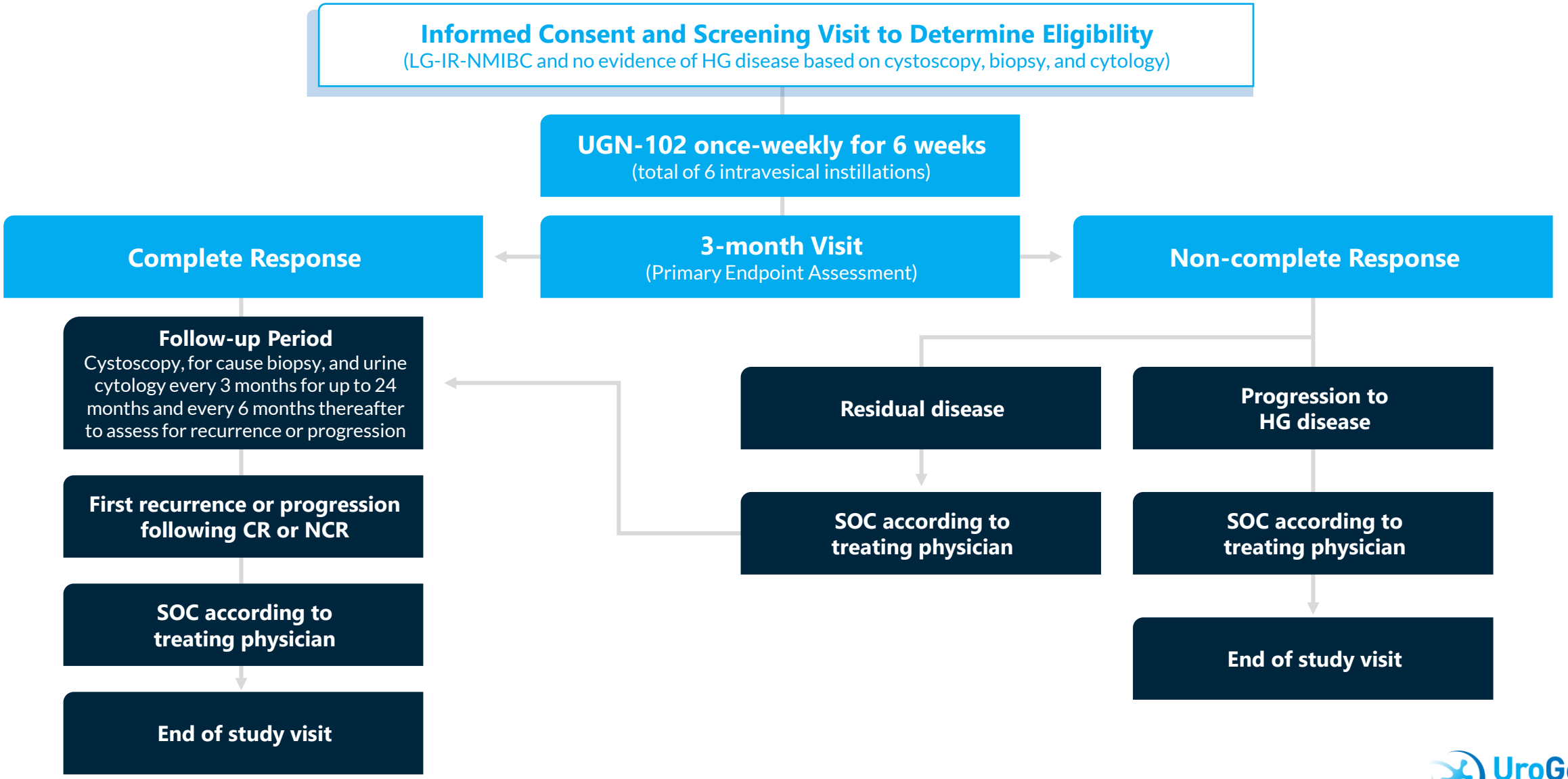
Summary of Duration of Response in Complete Responders: Longer DOR with UGN-102

	UGN-102 Alone (N = 92) / **n** (%)	**TURBT Alone** (N = 89) / **n** (%)
Patients with Events, n (%)	**18 (19.6)**	**24 (27.0)**
Recurrence of LG Disease	15 (16.3)	17 (19.1)
Progression to HG Disease	3 (3.3)	6 (6.7)
Death	0	1 (1.1)
Patients Censored, n (%)	**74 (80.4)**	**65 (73.0)**
No Follow-up	1 (1.1)	10 (11.2)
Received Non-protocol Therapy	5 (5.4)	4 (4.5)
Early Termination	1 (1.1)	2 (2.2)
Disease-free at End of Study	67 (72.8)	49 (55.1)
Extended Lost to Follow-up	0	0
Hazard Ratio (95% CI)	**0.46 (0.24, 0.86)**	

UroGen Data on File
Source: Table 14.2.2.3.1a

UroGen Pharma

ENVISION Trial Design



SOC: Standard of Care

Summary of Demographics and Baseline Characteristics

Characteristic Statistic	**UGN-102** (N = 240) / **n** (%)
Age	
Median Age (Min, Max)	70.0 (30, 92)
Age Group 2 (Years), n (%)	
>= 65	162 (67.5)
Sex, n (%)	
Male	147 (61.3)
Female	93 (38.8)
Prior TURBT, n (%)	
Yes	231 (96.3)
No	9 (3.8)
Previous LG NMIBC Episodes, n (%)	
Yes	224 (93.3)
No	16 (6.7)
Treatment Course, n (%)	
6 instillations	228 (95.0)
< 6 instillations	12 (5.0)

UroGen Data on File

UroGen Pharma

Overall Summary of Adverse Events in ENVISION: Safety Profile Similar to Other Studies of UGN-102

	UGN-102 (N = 240)	
	Events	**n** (%)
Any Adverse Events	**563**	**129 (53.8)**
Any Serious Adverse Events	26	19 (7.9)
Any TEAEs	**523**	**127 (52.9)**
Any Treatment or Procedure Related TEAEs	283	96 (40.0)
Any Treatment Related TEAEs	242	80 (33.3)
Any Procedure Related TEAEs	121	62 (25.8)
Any TEAEs Leading to Treatment Discontinuation	7	6 (2.5)
Any TEAEs Leading to Study Discontinuation	3	3 (1.3)
Any Serious TEAEs	**25**	**18 (7.5)**
Any Treatment or Procedure Related Serious TEAEs	4	4 (1.7)
Any Treatment Related Serious TEAEs	2	2 (0.8)
Any Procedure Related Serious TEAEs	3	3 (1.3)
Any TEAEs Leading to Death	2	2 (0.8)
Any TEAEs of Special Interest	241	96 (40.0)

UroGen Data on File

UroGen Pharma

Treatment-Emergent AEs were Generally Mild to Moderate and In Line with Expectations in the Field

Incidence of Treatment-emergent Adverse Events (≥ 5%)

UGN-102
(N = 240) / **n** (%)

	Mild	Moderate	Severe or Medically Significant	Life-threatening	Death	Total
Patients With Any TEAEs	**60 (25.0)**	**47 (19.6)**	**16 (6.7)**	**2 (0.8)**	**2 (0.8)**	**127 (52.9)**
Dysuria	43 (17.9)	9 (3.8)	1 (0.4)	0	0	53 (22.1)
Haematuria	15 (6.3)	5 (2.1)	0	0	0	20 (8.3)
Pollakiuria	13 (5.4)	2 (0.8)	0	0	0	15 (6.3)
Urinary tract infection	4 (1.7)	10 (4.2)	0	0	0	14 (5.8)
Fatigue	9 (3.8)	4 (1.7)	0	0	0	13 (5.4)

Incidence of Treatment Related Serious TEAEs

UGN-102
(N = 240) / **n** (%)

Patients With Any Treatment Related Serious TEAEs	**2 (0.8)**
Urethral stenosis	1 (0.4)
Urinary retention	1 (0.4)

UroGen Data on File
Summary of Overall AE's can be referenced in the Appendix

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Clinical Results Propel Us Towards FDA Submission

OPTIMA II	ATLAS	ENVISION
CR: 65.1%	CR: 64.8%	CR: 79.2%
12-month DOR: 72.5%	12-month DOR: 79.7%	
Safety: AEs mostly mild to moderate	Safety: AEs mostly mild to moderate	Safety: AEs mostly mild to moderate

Both DOR as estimated by Kaplan Meier Method.

UroGen Pharma

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