# New Horizons in Bladder Cancer: UGN-102 Duration of Response Results from the ENVISION Study

**NASDAQ: URGN** 

June 13, 2024



## 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 for UroGen to transform bladder cancer treatment; 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 potential of UGN-301 to expand to Immuno-Oncology for HG-NMIBC; the estimated patient population in bladder cancer and estimated addressable patient population for UGN-102 in LG-IR-NMIBC and UGN-301 in HG-NMIBC; the estimated total addressable market opportunity for UGN-102 in LG-IR-NMIBC; the potential for UGN-102 to become the first FDA-approved medicine for LG-IR-NMIBC; the opportunity and potential benefits of UGN-102 for LG-IR-NMIBC and potential advantages over TURBT; the potential NDA completion and review timeline for UGN-102, including the expected completion of the NDA submission to the FDA and the FDA's potential acceptance thereof and the FDA's potential approval timing; and the potential of UroGen's proprietary RTGel® technology platform to improve therapeutic profiles of existing drugs. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: ENVISION duration of response data may not be sufficient to support an NDA submission for UGN-102; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; 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; 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; competition in UroGen's industry; 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 for the guarter ended March 31, 2024, filed with the Securities and Exchange Commission (SEC) on May 13, 2024, and other filings that UroGen makes with the 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.



# UROGEN IS UNIQUELY POSITIONED TO TRANSFORM BLADDER CANCER TREATMENT

# LIZ BARRETT, PRESIDENT AND CEO

## Today's Agenda

UroGen Overview
 Liz Barrett
 President and CEO, UroGen

# •Mark P. Schoenberg, M.D.

Chief Medical Officer, UroGen

#### **UGN-102 Clinical Data**

•Sandip Prasad, M.D., M.Phil. Morristown Hospital/Atlantic Health System, NJ

#### **Patient Perspectives from ENVISION**

•Angela Stover, Ph.D. UNC Gillings School of Global Public Health

#### **Patient Interview**

•Julio Lago Patient

•Liz Barrett President and CEO, UroGen

#### **Panel Discussion**

•Moderator: Mark P. Schoenberg, M.D. Chief Medical Officer, UroGen

•Max Kates, M.D. Johns Hopkins School Of Medicine •Jennifer Linehan, M.D.

Saint John's Cancer Institute

•James McKiernan, M.D. Columbia University Irving Medical Center, New York Presbyterian

•Sandip Prasad, M.D., M.Phil. Morristown Hospital/Atlantic Health System, NJ

•Angela Stover, Ph.D. UNC Gillings School of Global Public Health

#### What is Next?

•Liz Barrett President and CEO, UroGen

Q&A



## WE ASPIRE TO CHANGE THE TREATMENT PARADIGM

SURGICAL CARE



#### MINIMALLY INVASIVE, ORGAN-SPARING THERAPEUTIC OPTIONS



JELMYTO

Changing the Treatment Paradigm for Low-Grade Upper Tract Urothelial Cancer (LG-UTUC)

## UGN-102

**Because Patients Deserve Better** 

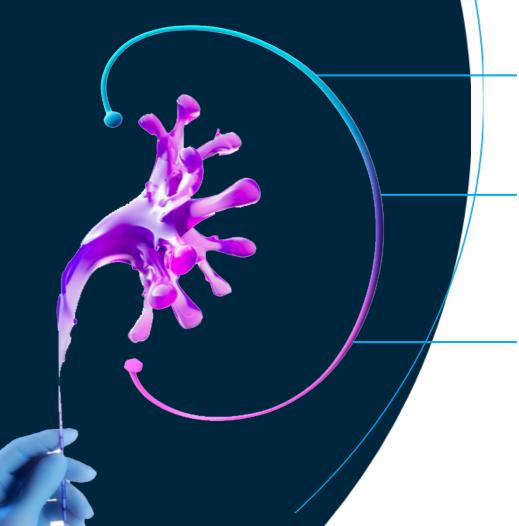
Potential to Transform the Treatment of Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

# UGN-301

Expanding to Immuno-Oncology for High-Grade Non-Muscle Invasive Bladder Cancer (HG-NMIBC) **RTGel®** Proprietary Reverse-Thermal Hydrogel Technology Uniquely Designed to Allow for Local Delivery of Medicines



RTGel<sup>®</sup> exists as a liquid at lower temperatures and converts to gel form at body temperature.



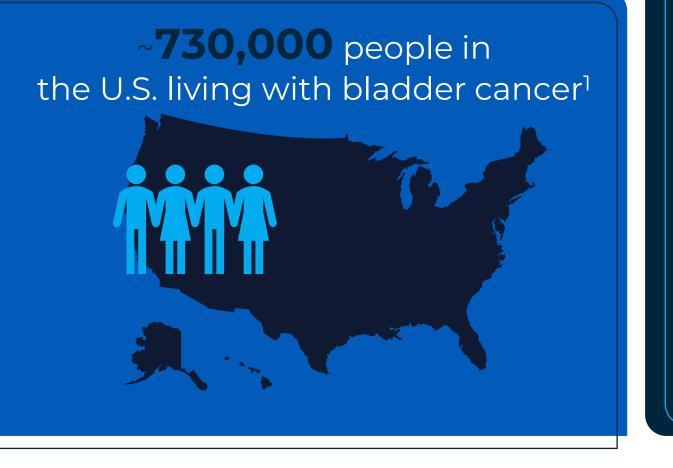
**Increases dwell time** and exposure to active drugs

Potentially improves the therapeutic effects of existing products

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



## Bladder Cancer Affects Patients and Families Across The U.S.

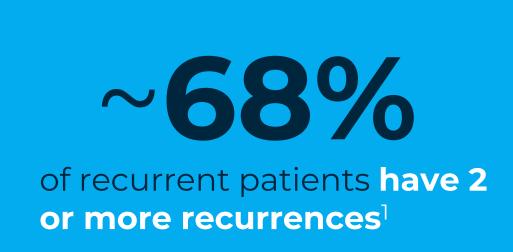


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- Cancer Stat Facts: Bladder Cancer. National Cancer Institute: Surveillance, Epidemiology, and End Results Program. Accessed June 5, 2024 (data as of 2021). https://seer.cancer.go v/statfacts/html/urinb.html
- 2. MBA ASBP PhD. Cancer Recurrence Statistics. Cancer Therapy Advisor. Published November 30, 2018. https://www.cancertherapyadvisor.com/home/tools/fact-sheets/cancer-recurrence-statistics/#:~:text=Some%20cancers%20are%20difficult%20to

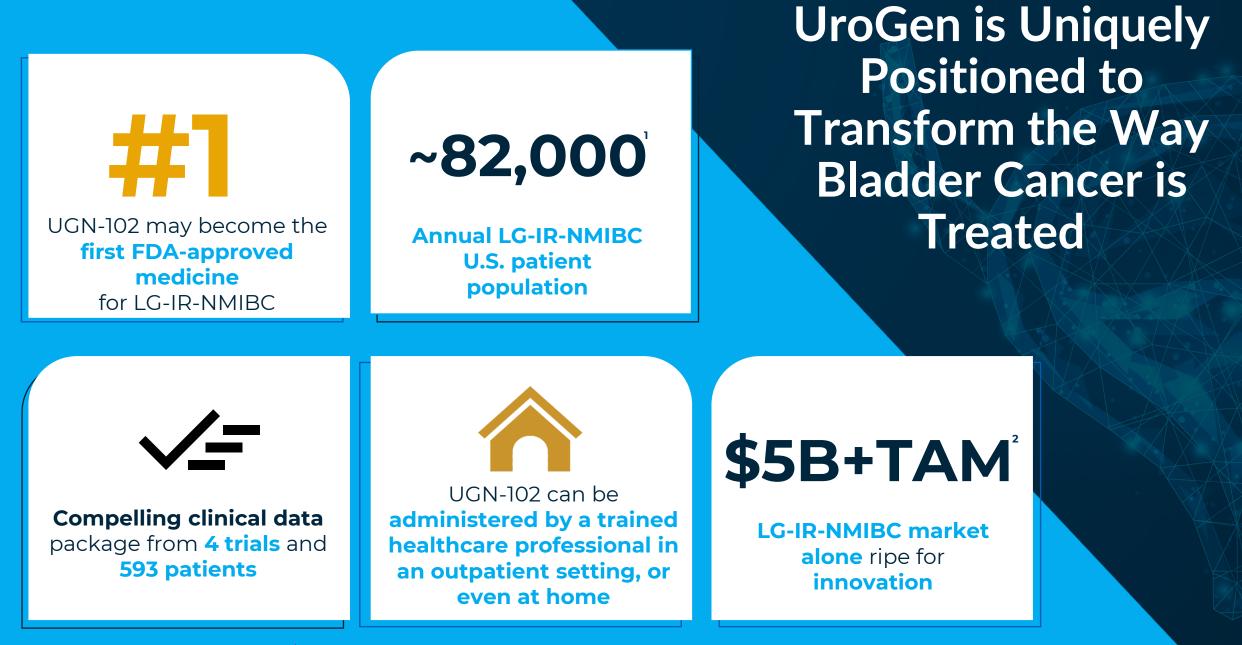


# High Recurrence Rate Leads to Frustrating Treatment Cycle









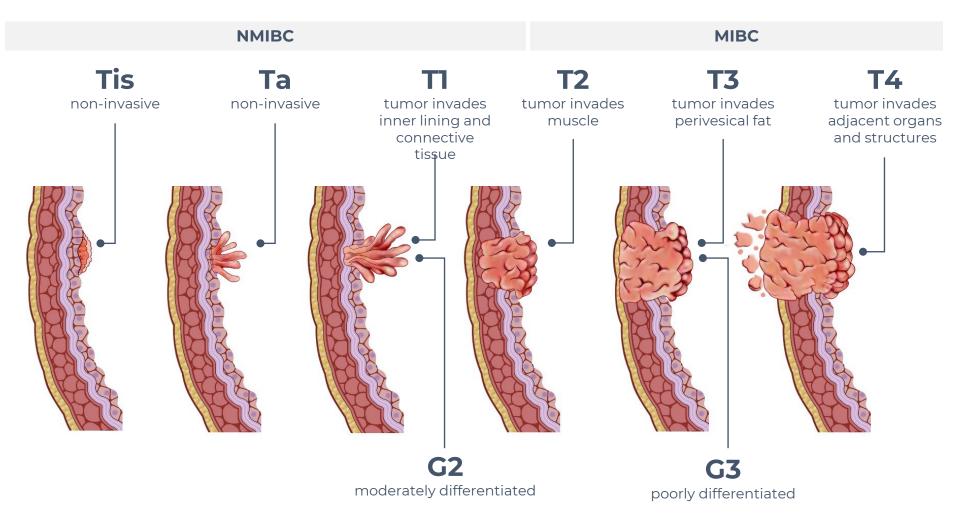
1. 🔰 ACS Cancer Facts & Figures 2023; SEER, AUA/SUO joint guideline; Babjuk et al. European Urology (2019), Simon et al (2019) PLoS ONE 14(2): e021172

2. UroGen estimates based on market research

# THE BURDEN OF LGR-NMIBC

# MARK SCHOENBERG, M.D., CHIEF MEDICAL OFFICER

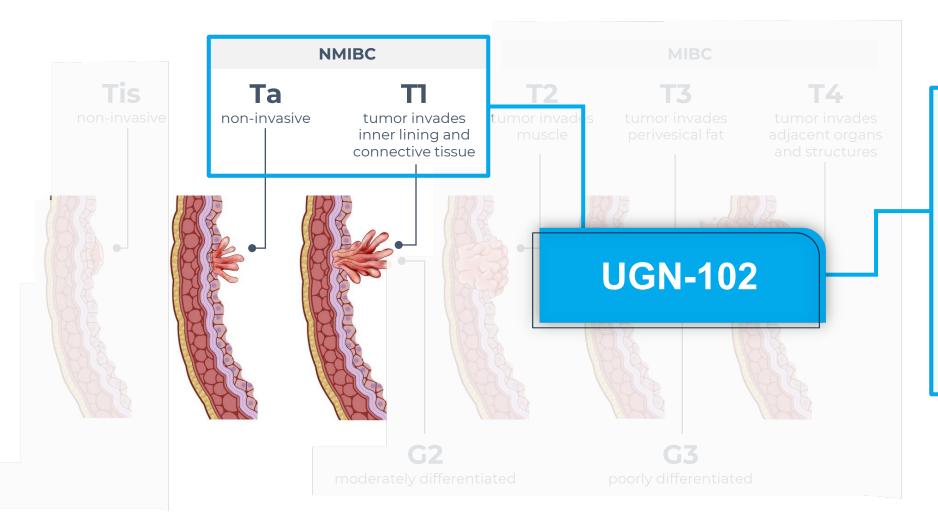
# NMIBC Has Multiple Stages Before Becoming Muscle Invasive





American Joint Committee on Cancer. AJCC Cancer Staging Manual. Urinary Bladder. 7th edn. New York, NY: Springer; 2010: 497-502.

# UGN-102's Proposed Indication: For Treatment of LG-IR-NMIBC



## Low Grade

- ~70% of all bladder cancers
- High risk of recurrence
- Low risk of progression

#### Intermediate Risk

- LG Ta Tumors that are large (> 3cm), multifocal, or recurrent
- LG TI Tumors
- SOC: Repeated Transurethral Resection of Bladder Tumor (TURBT)



# Repeat Surgery for LG-IR NMIBC Comes with Risks for Patients



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.000000000001977.08
 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.

 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

 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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# LG-IR-NMIBC Market: Key Differences Compared to HG-NMIBC Market

## Low-Grade IR-NMIBC

**Issues**: Chronic recurrence; rarely progresses to high-grade disease

**SOC**: Repetitive TURBT

VS

**Newly diagnosed**: ~23K/year<sup>1,2,3</sup> **Recurrent**: ~59K/year<sup>1,2,3</sup>

**Limited competition**: UGN-102 is furthest along in clinical development as a non-surgical chemoablative therapy

#### BCG is not widely used in low-grade disease

## **High-Grade NMIBC**

Issues: Progression, metastasis & death

**SOC**: TURBT, BCG, radical cystectomy, clinical trials

Incidence: ~25K/year<sup>4</sup> BCG-refractory: 18.7K/year<sup>4</sup>

**Clinical trials ongoing** in BCG-refractory populations

Significant unmet need given low response rates and durability

Goal is to avoid radical cystectomy



ACS Cancer Facts & Figures 2023

2. SEER, AUA/SUO joint guideline

3. Babjuk et al. European Urology (2019), Simon (2019),

. 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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## Positioning UGN-102 for Success

#### Low-Grade IR NMIBC

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- ACS Cancer Facts & Figures 2023
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4. 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.

# UGN-102: ROBUST AND CONSISTENT CLINICAL RESULTS

# About Dr. Sandip Prasad



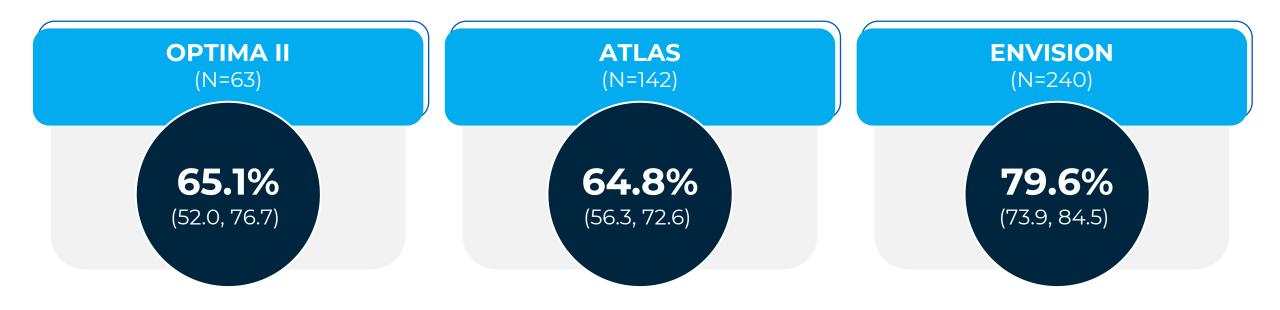
## Sandip Prasad, M.D., M.Phil.

- Garden State Urology
- Director of Genitourinary Surgical Oncology
- Vice-Chair of Urology at Morristown Medical Center/Atlantic Health System in New Jersey
- Clinical Associate Professor at Rutgers NJMS
- Clinical Assistant Professor at Thomas Jefferson University
- Completed residency at the Harvard Program in Urology and an SUO fellowship at the University of Chicago
- 60 peer-reviewed journal articles and book chapters
- Associate editor or editorial reviewer for nine specialty journals in Urology



**ENVISION** DURATION OF RESPONSE RESULTS

## Strong, Consistent Complete Response Rate At 3 Months



#### UroGen Data on File

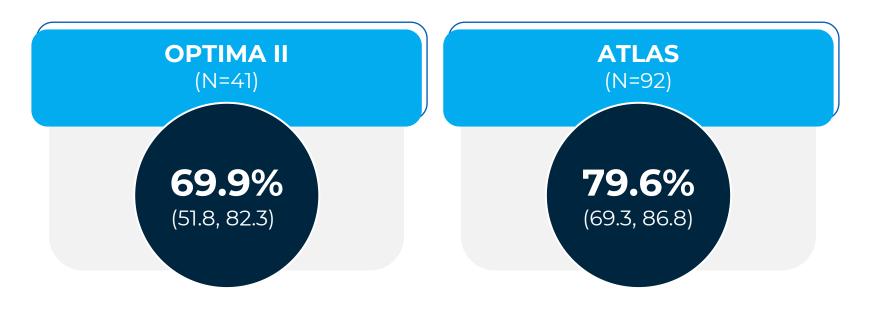
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19 ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.

# Robust Duration of Response (DOR) Observed in Multiple Trials



### 9-month DOR KM estimate 12-mo

## 12-month DOR KM estimate





# **ENVISION Single-Arm Pivotal Study Description**

## **Patient Population:**

- Demographics and baseline characteristics reflective of general LG-IR-NMIBC patient population
- All patients followed for a minimum of 15 months

## **Primary Endpoint:**

• **Complete response rate (CRR)** at 3-month visit, as defined by cystoscopy, for cause biopsy, and urine cytology

## **Key Secondary Endpoint:**

- Duration of response (DOR), defined as time from first documented CR until the earliest date of:
  - ✓ Recurrence
  - ✓ Progression
  - ✓ Death

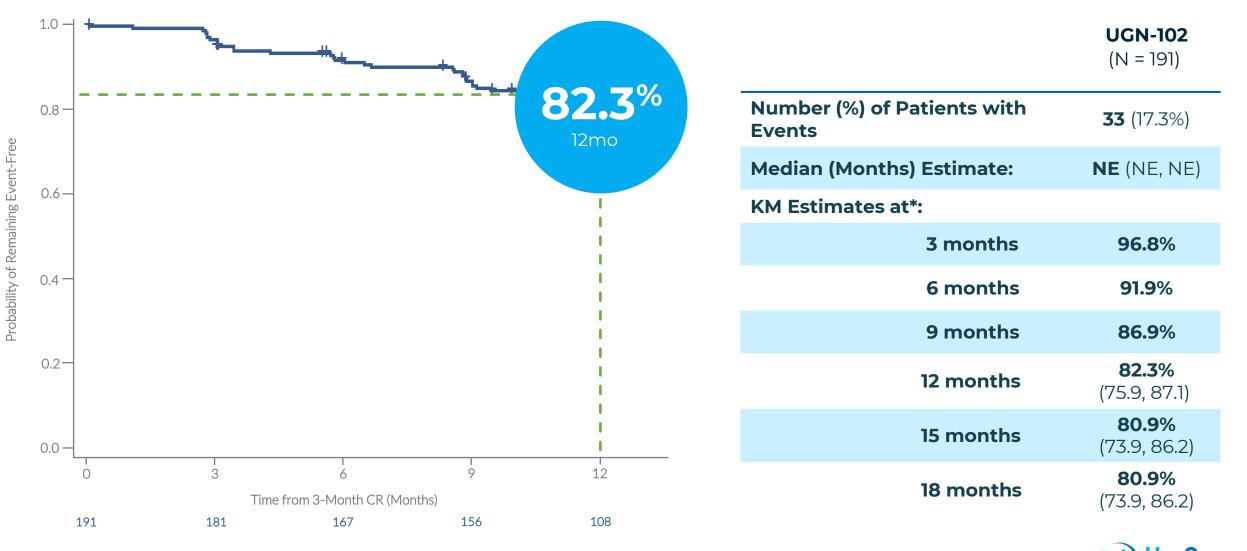


# Robust Complete Response Rate At 3 Months

|                           | <b>UGN-102</b><br>(N = 240) |   |                           |  |
|---------------------------|-----------------------------|---|---------------------------|--|
| Complete Response         | n (%)<br>191 (79.6)         | <b>CRR</b> (95% CI)<br><b>79.6 (73.9, 84.5)</b> | Complete<br>Response Rate |  |
| Non-Complete Response     | 49 (20.4)                   |   | 79.6%                     |  |
| Residual Disease          | 35 (14.6)                   |   |                           |  |
| Progression to HG Disease | 7 (2.9)                     |   |                           |  |
| Indeterminate             | 2 (0.8)                     |   |                           |  |
| Missing                   | 5 (2.1)                     |   |                           |  |
|                           |                             |   |                           |  |

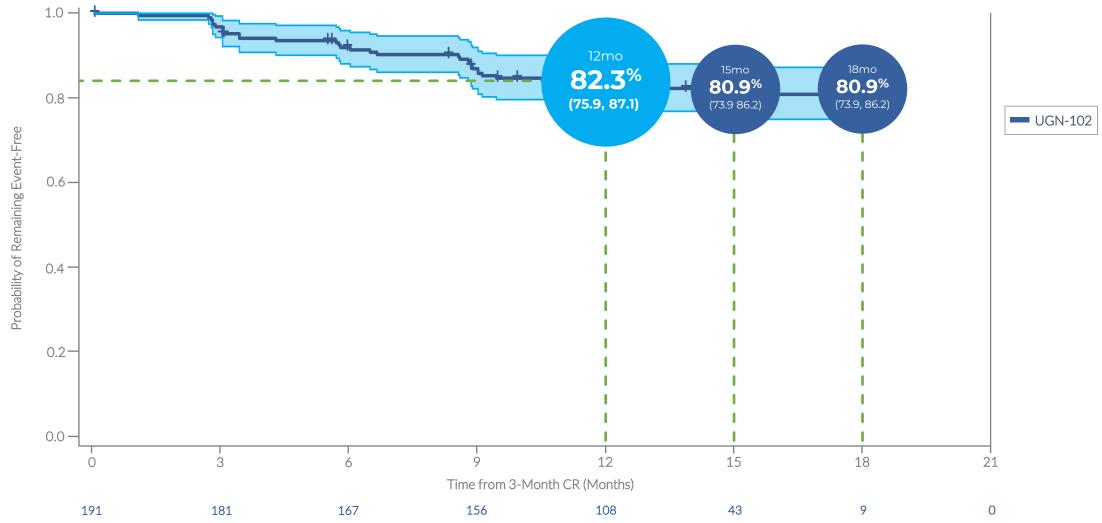


## DOR: 82.3% at 12 Months, Overwhelming Majority Remain Disease Free



\*Time from 3-Month CR 📄

## Large Sample Size Resulted In Tight DOR Confidence Intervals



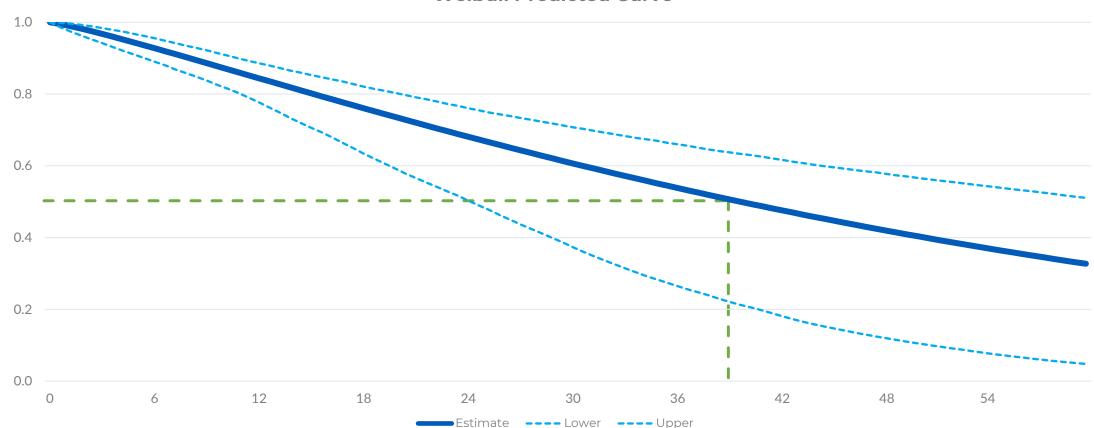


# Median DOR Not Estimable Due to Patients Remaining in CR

|   | <b>UGN-102</b><br>(N=191)            |
|---|--------------------------------------|
| Kaplan-Meier Estimates of Duration of Response (Months) |                                      |
| 1st Quartile (95% CI)                                   | Not Estimable (14.7, Not Estimable ) |
| Median (95% CI)   | Not Estimable                        |
| 3rd Quartile (95% CI)                                   | Not Estimable                        |
|   |                                      |
| Median Follow-Up Time, Months (95% Cl)                  | 13.8 ( 12.2, 14.5 )                  |



# Predicted Median Duration Of Response (DOR) is 40.0 Months



**Weibull Predicted Curve** 

Predicted Median (95% CI): 40.0 months (23.9, 63.9)



## AEs Generally Mild to Moderate in Severity

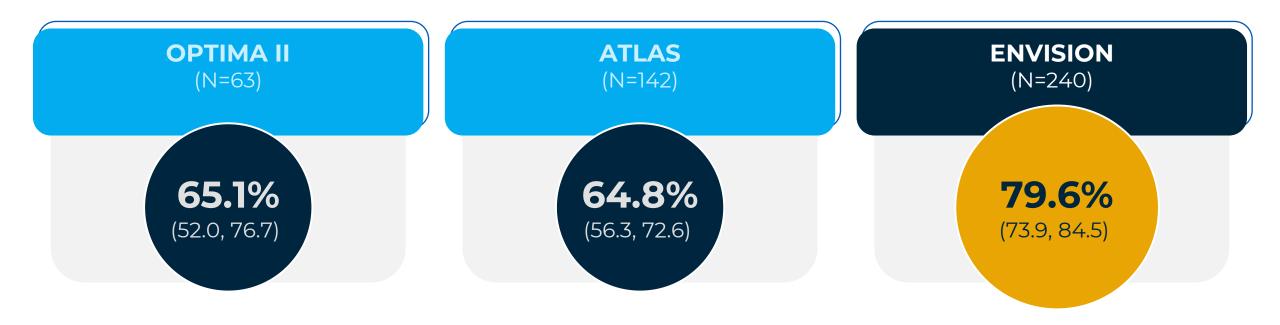
|  | <b>UGN-102</b><br>(N=240)<br>n (% incidence)              |
|--|---|
| Any Adverse Events   | 140 (58.3)  |
| Any Serious Adverse Events   | 30 (12.5)   |
| Any TEAEs  | 137 (57.1)  |
| Any Grade ≥3 TEAEs   | 33 (13.8)   |
| Any Treatment or Procedure Related TEAEs<br>Any Treatment Related TEAEs<br>Any Procedure Related TEAEs<br>Any TEAEs Leading to Treatment Discontinuation<br>Any TEAEs Leading to Study Discontinuation | 97 (40.4)<br>81 (33.8)<br>64 (26.7)<br>7 (2.9)<br>6 (2.5) |
| Any Serious TEAEs  | 29 (12.1)   |
| Any Treatment or Procedure Related Serious TEAEs   | 4 (1.7)   |
| Any Treatment Related Serious TEAEs  | 2 (0.8)   |
| Any Procedure Related Serious TEAEs  | 3 (1.3)   |
| Any TEAEs Leading to Death   | 3 (1.3)   |
| Any TEAEs of Special Interest  | 100 (41.7)  |

 AEs mainly related to lower urinary tract symptoms

- The 2 treatment-related SAEs were urethral stenosis and urinary retention (both resolved)
- The 3 deaths were unrelated to treatment: (cardiac event, pneumonia, and not reported)



# Consistently High Complete Response Rate At 3 Months



UroGen Data on File

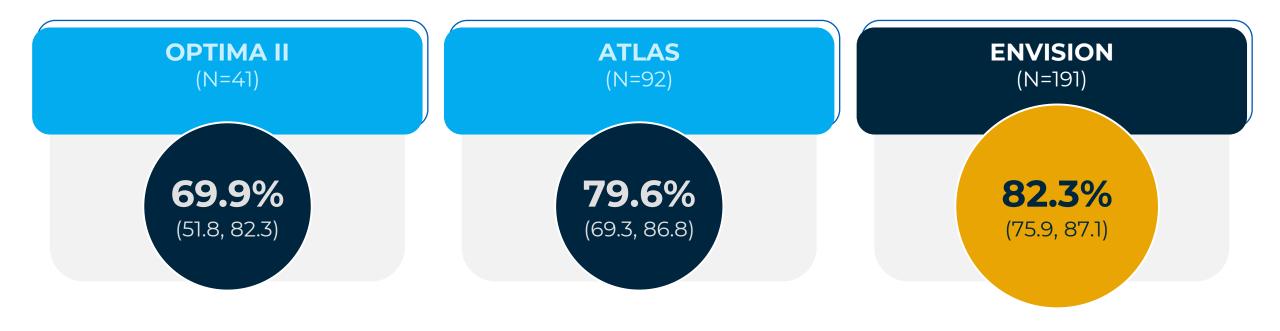
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ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.



# High CR Rates Maintained with Robust Duration of Response



9-month DOR KM estimate

12-month DOR KM estimate

### 12-month DOR KM estimate

UroGen Data on File ATLAS DOR estimates based on treatment with UGN-102 alone Based on Kaplan-Meier (KM) Estimates.

29



# 79.6%

(73.9, 84.5)

Complete Response Rate at 3 months

82.3%

(75.9, 87.1)

Estimated probability of maintaining Complete Response at 12 months UGN-102 Potentially Addresses the Unmet Need for a Non-Surgical Option



Safety profile characterized primarily by mild to moderate AEs



Non-surgical treatment with potential to reduce overall burden on patients

UroGen Data on File

# **PATIENT PERSPECTIVES FROM ENVISION**

ANGELA STOVER, PH.D. ASSOCIATE PROFESSOR DEPARTMENT OF HEALTH POLICY AND MANAGEMENT AT UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

# ABOUT DR. ANGELA STOVER



## Angela Stover, PhD

- Associate Professor, Department of Health Policy and Management at UNC Gillings School of Global Public Health
- A health services researcher with expertise in patient-reported outcomes (PRO) methods and implementation science
- Co-directs the NC TraCS' Implementation Science Methods Unit
- Associate member of Lineberger Comprehensive Cancer Center
- Research program quantifies the impact of treatment for chronic health conditions on symptom burden, identifies important gaps in implementing evidence-based practices in clinics, and determines how those gaps are related to poor patient and clinic outcomes
- Dr. Stover's research program is funded by NIH, PCORI, AHRQ, Pfizer Global, and foundations



# ENVISION PATIENT PERCEPTIONS OF UGN-102 AND TURBT: IMPACT ON DAILY ACTIVITIES



# ENVISION Interviews

- Patients with NMIBC commonly ask urologists how their daily activities/responsibilities will be affected by treatment(s)
- In ENVISION, we interviewed patients about the impact on their daily activities with UGN-102 and their recollection of standard of care (transurethral resection of bladder tumor [TURBT])

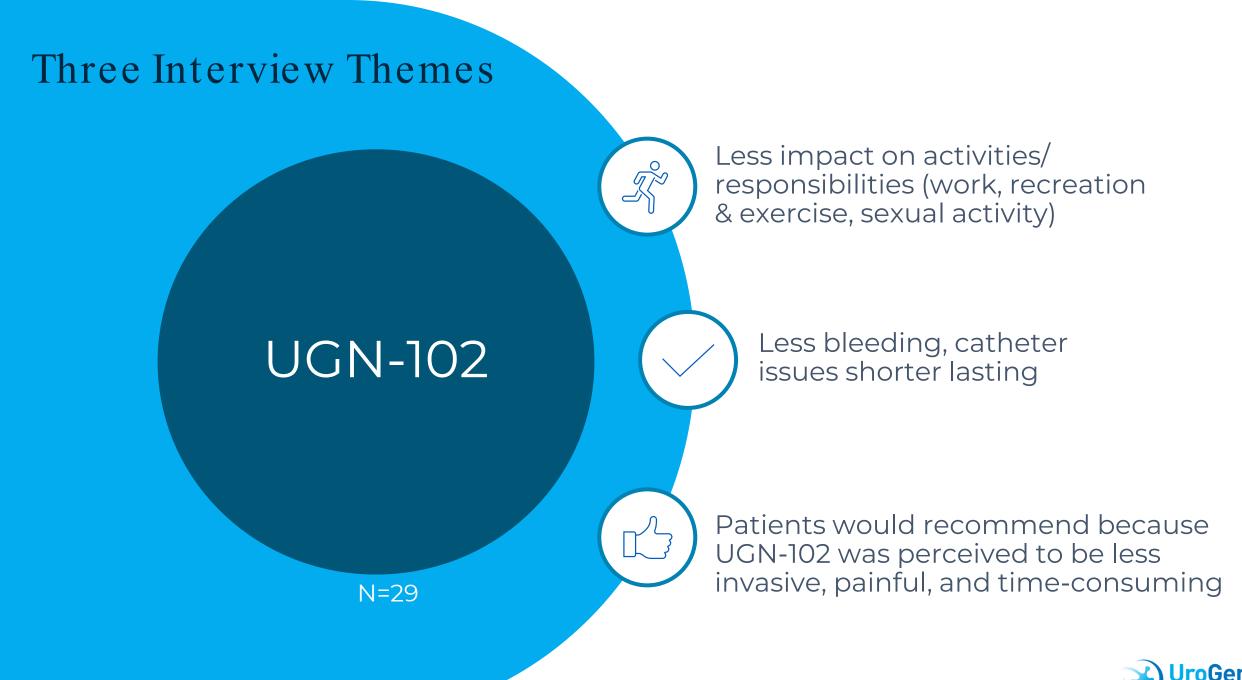
• N=29 U.S. patients (out of 39 eligible [74%])



## Methods

- Gold standard: content analysis
   Data are patient quotes
  - Data are patient quotes
- Semi-structured interview guides at enrollment and 3 months
- Transcripts coded by 3 experienced coders with detailed codebooks (software: Dedoose)
- Emerging themes and discrepancies were captured and reconciled through consensus





## Recovery Time

#### TURBT

"Well, first off, they're [TURBTs]
gettin' more and more painful, and it's taken longer and longer to recover from them.
It's just a little bit of—every time they do it [TURBT], it's just little bit more incontinence. It's gotten much worse with each procedure." (17)

## UGN-102

"Yes. I think it took me a longer time to recover from the bladder resection than the gel. [For TURBT], maybe at two weeks I felt better and things like that, and I start to exercise, but I do believe that I was not at my 100 percent until many weeks later." (27)



## No Impact on Daily Activities

## TURBT

#### [TURBT not discussed]

## UGN-102

"With the gel, the daily activity was a big difference, and I didn't worry at all. **Basically, I lived my normal life except the one day [instillation], which was well worth it."** (34)

"They [UGN-102] didn't have any impact on me. I went in, and I went back to my normal activity...I had no problems at all." (37)



## Impact on Work

#### TURBT

"It's [incontinence] mostly a big embarrassment and an absolute pain in the ass at work...some days are much worse than others and depending on what I'm doin'-but sometimes my pants get wet, and I have to go out to the car, get my clothes, change, and they're lookin' for me....Runnin' to the bathroom all the time, everybody'll, 'Well, you're always in the bathroom'." (17)

**UGN-102** 

"The TURBT, I was basically missing for seven, eight days, I could do no work. Here [with UGN-102], really, work has continued, I have not had an impact. Again, postponing travel, meetings, things like that, but I was present, mostly, I was present. I do think the outcome is better with the gel than with the **TURBT.**" (27)



<sup>39</sup> Stover and Smith, under review

## Treatment-Related Side Effects

#### TURBT

#### "I honestly have as much side effects **from the anesthesia**." (06)

#### "I'll tell you one thing. I do not look forward to spending the **rest of my life attached to a catheter**. That's a no-no for me." (08)

## UGN-102

"For six weeks, I was in stages of extreme to moderate to low level of pain/itching—extreme internal itching."(20)

"It was **very itchy, all my bladder and everything**. The second time, I knew what it was. Knowing what it was, the scary part went away. I wasn't worried anymore. It was just toughing it out that one or two days." (29)



<sup>40</sup> Stover and Smith, under review

Bleeding

#### TURBT

"That [TURBT] was a lot of bleeding." (45)

"They removed five polyps at that time...**Then I bled for two weeks.** Finally shut off. [My urologist] told me that there would be some bleeding. **I don't think he realized that it was gonna be that long of a bleeding...**He told me that I would be bleeding for 'a while' after the surgery." (43) "At least two occasions [for TURBT], one of which there was fair amounts of bleeding." (03)

**UGN-102** 

It [TURBT] was more painful, there was a lot of blood came out — not a little, a lot." (27)



<sup>41</sup> Stover and Smith, under review

## Impact on Sexual Activity

#### TURBT

"Basically, I would like to get away from having them [tumors] extracted from me 'cause my doctor told me the more surgeries they keep doin', my bladder—especially since I've been doing it so young-that it would mess up good things like erectile function, things like peeing..." (41)

## UGN-102

"I would say that I didn't have any difference in performance, but I took longer to have relationships with my wife with TURBT [than UGN-102]." (27)

"You have this medicine in you and you don't wanna be having sex with your partner...but once that was done, everything was back to normal." (15)



From the patient perspective, UGN-102 meets an unmet need in care delivery for a non-surgical treatment alternative for NMIBC



## PATIENT INTERVIEW: JULIO LAGO









## **THOUGHT LEADER PANEL**



**Max Kates, MD,** is an Associate Professor of Urology and Oncology in the Brady Urological Institute and directs the Division of Urologic Oncology for the Brady Urological Institute at Johns Hopkins School Of Medicine, where he works with the team at the Johns Hopkins Greenberg Bladder Cancer Institute to deliver a personalized approach to bladder cancer utilizing cutting edge precision medicine approaches.



**Jennifer Linehan, MD** is a board-certified urologist, and is an Associate Professor of Urology and Urologic Oncology at the Saint John's Cancer Institute. She also practices general urology, including both male and female voiding dysfunction and treatment for kidney stones.



**James McKiernan, MD,** the John K. Lattimer Professor of Urology, is the chair of the Department of Urology of the College of Physicians and Surgeons at Columbia University Irving Medical Center and urologist-in-chief at New York Presbyterian/Columbia. Dr. McKiernan is only the sixth physician to hold this title since the founding of the department in 1917.



**Sandip Prasad, MD,** is s a member of Garden State Urology and serves currently as the director of Genitourinary Surgical Oncology and Vice-Chair of Urology at Morristown Medical Center/Atlantic Health System in New Jersey. He is also a Clinical Associate Professor at Rutgers NJMS and a Clinical Assistant Professor at Thomas Jefferson University. He has published over 60 peer-reviewed journal articles and book chapters and serves as an associate editor or editorial reviewer for nine specialty journals in Urology.



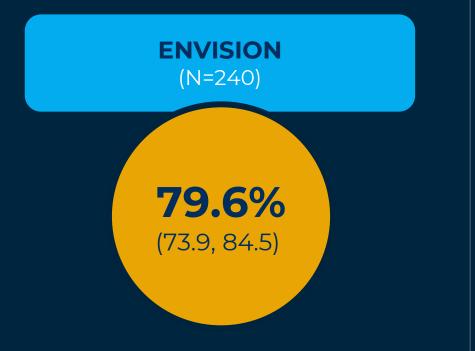
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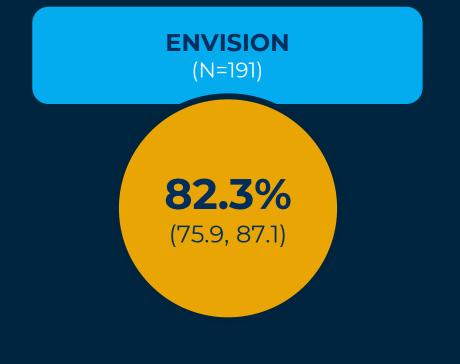
## WHAT IS NEXT?

# Unprecedented Clinical Results Further Support Completion of NDA Submission

Strong Complete Response Rate At 3 Months



Robust Duration of Response KM Estimate At 12 Months





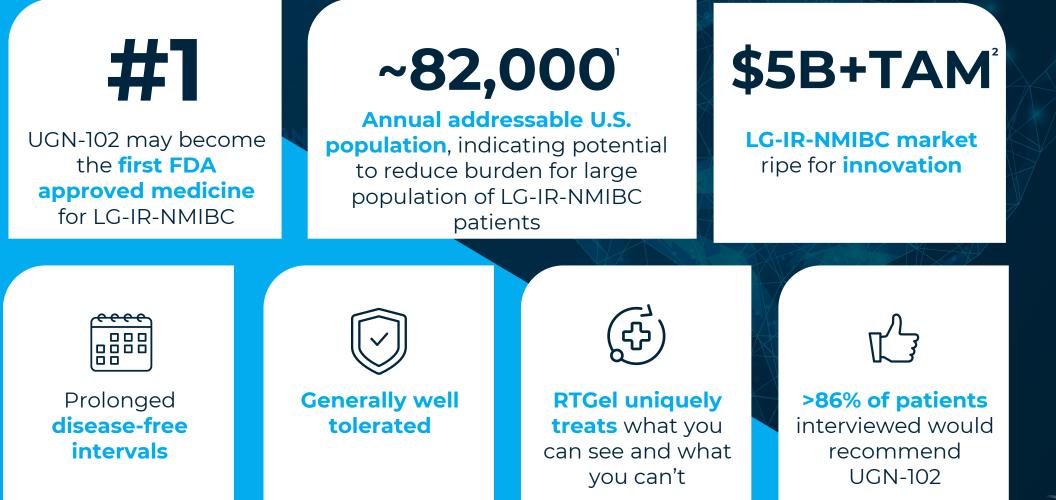
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## Potential to Launch UGN-102 in One Year If Approved





## UroGen is Uniquely Positioned to Transform the Way Bladder Cancer is Treated





ACS Cancer Facts & Figures 2023; SEER, AUA/SUO joint guideline; Babjuk et al. European Urology (2019), Simon et al (2019) PLoS ONE 14(2): e0211721

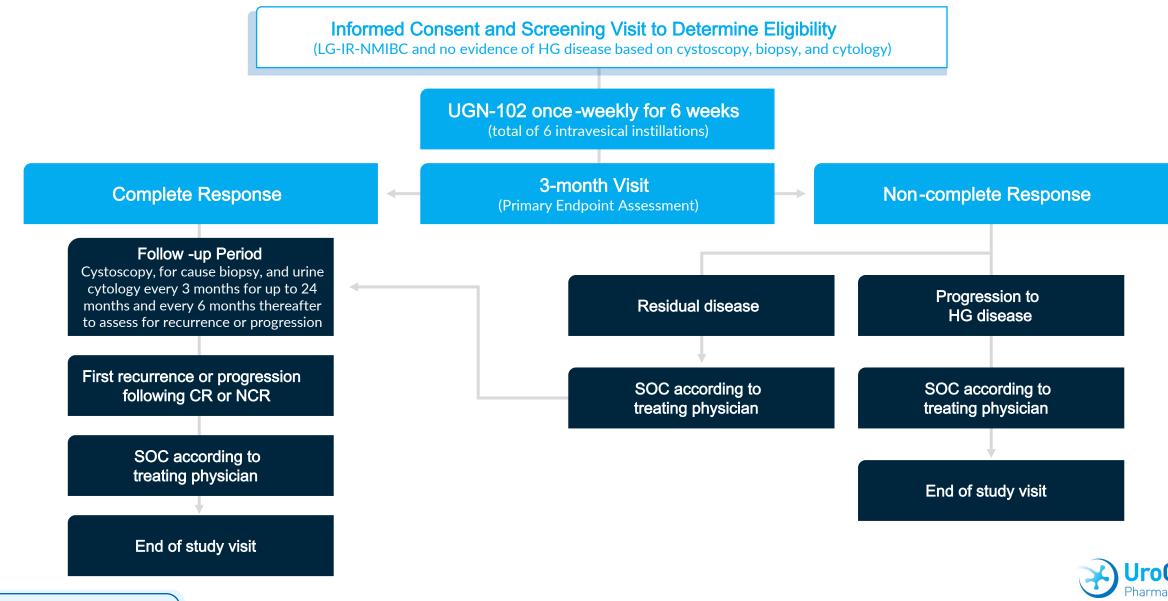
UroGen estimates based on market resear



## **THANK YOU!**

# APPENDIX

## ENVISION Trial Design



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## **Summary of Demographics and Baseline Characteristics**

| Characteristic Statistic          | <b>UGN-102</b><br>(N = 240) / <b>n</b> (%) |
|-----------------------------------|--|
| 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                               | 232 (96.7)                                 |
| No                                | 8(3.3)                                     |
| Previous LG NMIBC Episodes, n (%) |  |
| Yes                               | 229 (95.4)                                 |
| No                                | 11 (4.6)                                   |
| Treatment Course, n (%)           |  |
| 6 instillations                   | 228 (95.0)                                 |
| < 6 instillations                 | 12 (5.0)                                   |
|                                   |  |



## Summary of Adverse Events Occurring in $\geq 5.0\%$ of Participants

|                         | UGN-102<br>(N=240) |
|-------------------------|--------------------|
| Patients with Any TEAE  | 137 (57.1)         |
|                         |                    |
| Dysuria                 | 54 (22.5)          |
| Haematuria              | 20 (8.3)           |
| Urinary tract infection | 17 (7.1)           |
| Pollakiuria             | 16 (6.7)           |
| Fatigue                 | 13 (5.4)           |
| Urinary retention       | 12 (5.0)           |

