

UROGEN CORPORATE PRESENTATION

JEFFERIES HEALTHCARE CONFERENCE
June 2, 2020



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 market opportunity of Jelmyto in LG-UTUC; commercial plans for favorable market access and physician uptake following the Jelmyto launch; plans for the successful launch of Jelmyto; the timing for completion of commercial and medical activities and infrastructure build-out in anticipation of the planned commercial launch of Jelmyto; the expected readiness of UroGen for the launch Jelmyto; plans for distribution and product packaging for Jelmyto; the potential of UroGen's proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the opportunity and potential of UGN-102 for LG-NMIBC; plans to commence a pivotal trial for UGN-102 in LG NMIBC in 2020; plans to publish durability and CR data for UGN-102 for its Phase 2B Study; the market opportunity for UGN-102; plans to initiate a Phase 1 study with UGN-201; plans to investigate UGN-201 in combination with AGEN1884 in HG-NMIBC; plans to build a sustainable growth company; projections of revenue opportunities in markets of interest; plans to develop a global footprint; and the anticipated completion of a Phase 2 trial of RTGel with Botox. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the risks associated with Covid-19 and other pandemic risks, as more fully described in the accompanying pandemic disclosure; the timing and success of clinical trials, including the OLYMPUS Phase 3 trial and the OPTIMA II Phase 2b trial and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with achieving commercial readiness for the launch of a new product; the labeling and packaging for any approved product; the scope, progress and expansion of developing and commercializing UroGen's 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; 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 7, 2020, subsequent 10-Q filings, 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.

OUR BUSINESS COULD BE ADVERSELY AFFECTED BY THE EFFECTS OF HEALTH PANDEMICS OR EPIDEMICS, INCLUDING THE COVID-19 PANDEMIC

The recent outbreak of the novel strain of coronavirus, SARS-CoV-2, causing COVID-19 disease, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, potential customers, and other partners may be prevented from conducting certain business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The continued spread of COVID-19 and the measures taken by various governments could disrupt the supply chain of material needed for our product candidates and our approved product, Jelmyto, interrupt healthcare services, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our product candidates and have a material adverse effect on our business, financial condition and results of operations. In addition, as we are located in New Jersey, we are currently subject to a statewide stay-at-home order and many of our potential customers and partners worldwide are similarly impacted. While we, our clinical trials sites and certain of our vendors, including our third-party contract manufactures, are currently exempt from stay-at-home, shelter-in-place or similar orders for certain operations, any of the applicable exemptions may be curtailed or revoked, which would further adversely impact our business. In addition, our commercial launch of Jelmyto could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty. However, the worldwide spread of the COVID-19 virus has resulted and may continue to result in a global slowdown of economic activity which is likely to decrease demand for a broad variety of goods and services, including potentially for Jelmyto, while also disrupting sales channels and marketing activities for an unknown period of time until the disease is contained. Moreover, the global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

UROGEN: OUR CORPORATE STORY



VISION

Pioneering new treatments to improve patient care

MISSION

We build novel solutions to treat specialty cancers and urologic diseases because patients deserve better options

VALUES

ACT BOLDLY | BE INVENTIVE | STAY CONNECTED

RTGEL™ REVERSE-THERMAL HYDROGEL TECHNOLOGY THAT CAN SOLVE ANATOMICAL CHALLENGES IN MULTIPLE DISEASES

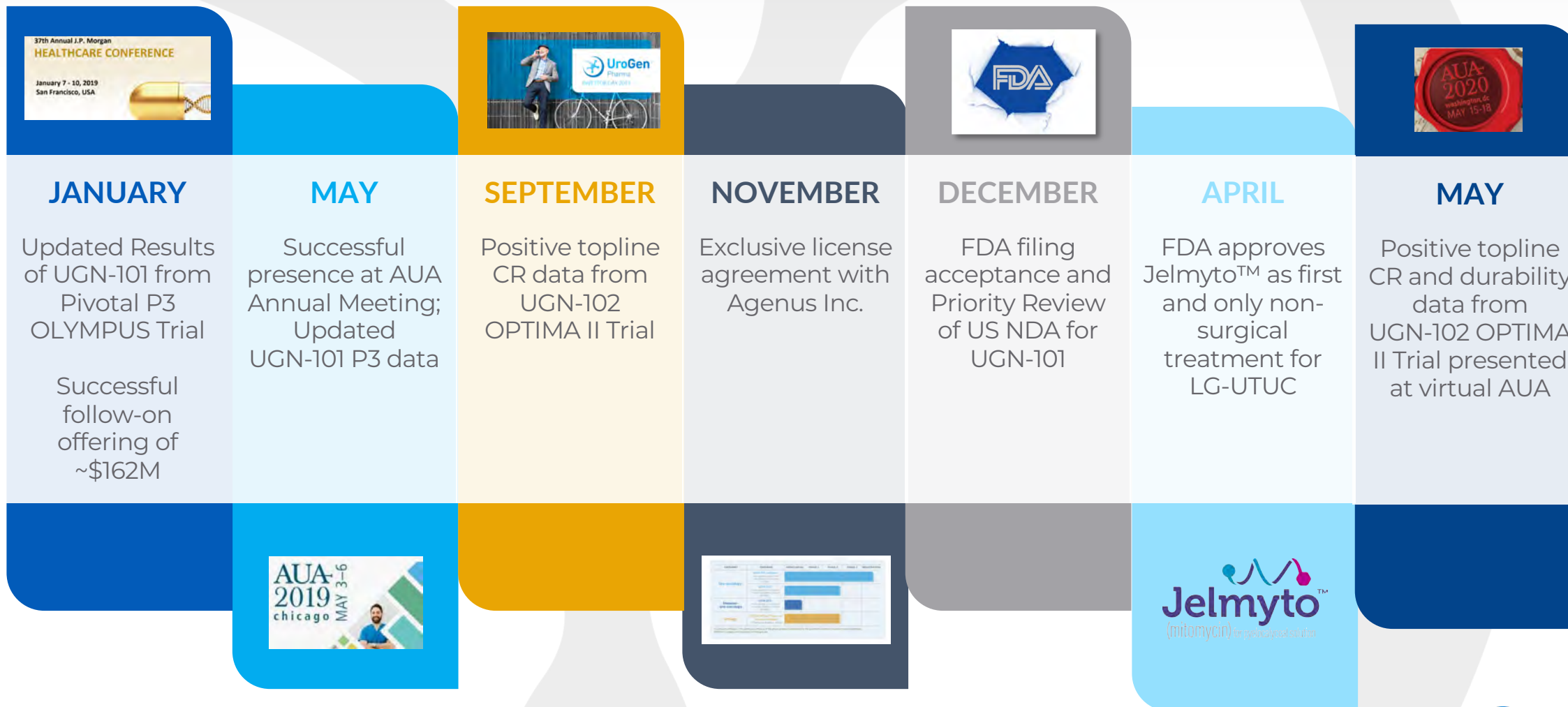


Exists as a liquid at lower temperatures and converts to gel form at body temperature

Has the potential to advance the treatment of urological conditions by:

- Increasing dwell time and exposure of active drugs, potentially improving the therapeutic effects of existing products
- Potentially increasing the viability of organ-sparing techniques and providing alternatives to radical surgery

2019-2020: DELIVERING ON OUR COMMITMENTS



STRONG MOMENTUM ACROSS PIPELINE

	NONCLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVED
URO-ONCOLOGY					
Jelmyto™ (mitomycin) for pyelocalyceal solution: Low-grade upper tract urothelial carcinoma (UTUC)					
UGN-102: Low-grade intermediate risk non-muscle invasive bladder cancer (NMIBC)					
IMMUNO-URO-ONCOLOGY					
UGN-201: High-grade non-muscle invasive bladder cancer (NMIBC)					
UGN-302*: High-grade non-muscle invasive bladder cancer (NMIBC)					
<small>*UGN-201 + zalifrelimab¹</small>					
UROLOGY					
BOTOX²/RTGel reverse-thermal hydrogel: Overactive bladder (OAB)					

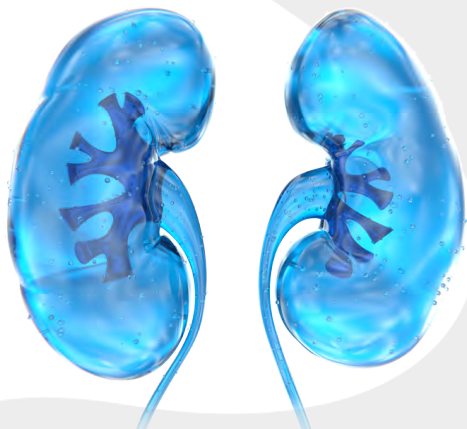
The safety and efficacy of UGN-102, UGN-201, UGN-302, and Botox/RTGel for the specific conditions have not been established.

¹ Worldwide license agreement with Agenus; does not include Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions.

² Licensed to Allergan. BOTOX is a registered trademark of Allergan Plc.

UNLOCKING THE URO-ONCOLOGY MARKET-BUILDING A COMPANY

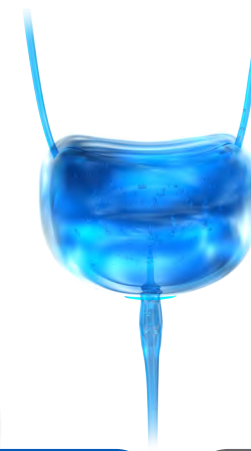
LOW-GRADE UPPER TRACT
UROTHELIAL CARCINOMA (UTUC)



~6,000 – 7,000
addressable
population

Jelmyto – only
FDA-approved
medicine

LOW-GRADE NON-MUSCULAR
INVASIVE BLADDER CANCER (NMIBC)



~80,000
intermediate-risk
LG NMIBC

Last drug
approved >15
years ago

~\$1 BILLION POTENTIAL PEAK REVENUE OPPORTUNITY

JELMYTO™

Low-grade upper tract urothelial carcinoma (LG-UTUC)

JELMYTO (mitomycin) for pyelocalyceal solution; formerly known as UGN-101

RECENT JELMYTO HIGHLIGHTS

UroGen Pharma Receives U.S. FDA Expedited Approval for Jelmyto™, the First and Only Non-Surgical Treatment for Patients with Low-Grade Upper Tract Urothelial Cancer

April 15, 2020 at 6:22 PM EDT

- Approval Based on Phase 3 Trial Results Showing a Complete Response Rate of 58%
- Median Duration of Response Has Not Been Reached
- Therapy Provides an Effective, Kidney-Sparing Option for Patients With This Rare and Difficult-To-Treat Cancer
- First-in-Class Approval Validates UroGen's Innovative Technology and Future Opportunity Across its Specialty Cancers and Urologic Diseases Portfolio
- Company to Host Conference Call on Thursday, April 16 at 8:30 AM Eastern Time

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 15, 2020-- UroGen Pharma Ltd. (Nasdaq: URGN) today announced the U.S. Food and Drug Administration (FDA) granted expedited approval for Jelmyto™ (mitomycin) for pyelocalyceal solution, a first-in-class treatment

Articles

Primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel (OLYMPUS): an open-label, single-arm, phase 3 trial



Ne Kleinmann, Suresh F. Maiti, Philip M. Fioravanti, John L. Gore, Ahmad Shabir, Brian Hu, Karim Chami, Guithame Godoy, Scott Hubbs, Marcelino Rivera, Michael D'Donnell, Marcus Quirk, Jay D. Raman, John J. Kneadler, Douglas Scher, Joshua Stern, Christopher Wright, Alan Weizer, Michael Woods, Hadas Kaimowitz, Angela B. Smith, Jennifer Linehan, Jonathan Coleman, Mitchell R. Humphreys, Raymond Pak, David L. Fichtel, Michael Varzi, Mehrad Adibi, Mahdi A. Amin, Elyse Setzer, Jiat Klein, Marina Konarty, Dahir Strauss-Ayali, Gil Hakim, Mark Schoenberg, Seth P. Lerner

Summary

Background Most patients with low-grade upper tract urothelial cancer are treated by radical nephroureterectomy. We aimed to assess the safety and activity of a non-surgical treatment using instillation of UGN-101, a mitomycin-containing reverse thermal gel.

Methods In this open-label, single-arm, phase 3 trial, participants were recruited from 24 academic sites in the USA and Israel. Patients (aged ≥18 years) with primary or recurrent biopsy-proven, low-grade upper tract urothelial cancer (measuring 5–15 mm in maximum diameter) and an Eastern Cooperative Oncology Group performance status score of less than 3 (Karnofsky Performance Status score ≥40) were registered to receive six instillations of once-weekly UGN-101 (mitomycin 4 mg per mL; dosed according to volume of patient's renal pelvis and calyces, maximum 60 mg per instillation) via retrograde catheter to the renal pelvis and calyces. All patients had a planned primary disease evaluation 4–6 weeks after the completion of initial therapy, in which the primary outcome of complete response was assessed, defined as negative 3-month ureteroscopic evaluation, negative cytology, and negative for-cause biopsy. Activity (complete response, expected to occur in >15% of patients) and safety were assessed by the investigator in all patients who received at least one dose of UGN-101. Data presented are from the data cutoff on May 22, 2019. This study is registered with ClinicalTrials.gov, NCT02793128.

Findings Between April 6, 2017, and Nov 26, 2018, 71 (96%) of 74 enrolled patients received at least one dose of UGN-101. 42 (59%, 95% CI 47–71; p=0.0001) patients had a complete response at the primary disease evaluation visit. The median follow-up for a complete response was 11.0 months (IQR 5.1–12.4). The most frequently reported all-cause adverse events were ureteric stenosis in 31 (44%) of 71 patients, urinary tract infection in 23 (32%), haematuria in 22 (31%), flank pain in 21 (30%), and nausea in 17 (24%). 19 (27%) of 71 patients had study drug-related or procedure-related serious adverse events. No deaths were regarded as related to treatment.

Interpretation Primary chemoablation of low-grade upper tract urothelial cancer with intracavitary UGN-101 results in clinically significant disease eradication and might offer a kidney-sparing treatment alternative for these patients.

Funding UroGen Pharma.

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Introduction

Upper tract urothelial cancer is a rare malignancy most commonly diagnosed in patients older than 70 years and is routinely treated by radical nephroureterectomy.¹ Biopsy grade coupled with cross-sectional imaging data and urine cytology have been integrated into European Association of Urology (EAU) guidelines for clinical stage stratification.^{2,3} Patients with high-grade cancer are routinely offered extraprostatic surgery that may include segmental removal of portions of the ureter (usually distal) or, more commonly, radical nephroureterectomy. Conversely, 10–20% of patients with low-grade disease

manifesting as a solitary, small (<20 mm), and favourably located lesion within the upper tract are offered kidney-preserving approaches such as endoscopic ablation.^{1,4} Endoscopic surgery carries specific surgical risks and is associated with a high rate of local disease recurrence.⁵ Ultimately, 70–80% of patients with low-grade and low-stage upper tract urothelial cancer undergo radical nephroureterectomy.^{1,6} This procedure is associated with the typical hazards of major surgery and the additional long-term deleterious effects of renal insufficiency, exacerbation of pre-existing comorbidities, and the potential need for dialysis dependence.^{7,8}

Lancet Oncol 2020

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April 29, 2020

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See Online Comment

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Department of Urology, Shalika

Medical Center, Barrow, Alaska

Israel (N. Kleinmann MD)

Department of Urology,

The University of Texas MD

Anderson Cancer Center,

Houston, TX, USA

(Prof S F Maiti MD, M Adibi MD)

Johns Hopkins University,

Baltimore, MD, USA

(Prof M Fioravanti MD)

Department of Urology,

University of Washington

Medical Center, Seattle, WA,

USA (Prof J L Gore MD)

Department of Urology,

The Ohio State University

Comprehensive Cancer Center,

Columbus, OH, USA

(A Shabir MD)

Department of

Urology, Loma Linda

University, Loma Linda, CA,

USA (B Smith MD)

Department of

Urology, University of

California Los Angeles,

Los Angeles, CA, USA

(K Hakim MD)

Department of

Urology, Baylor College of

Medicine, Houston, TX, USA

(S Setzer MD)

Prof S P Lerner MD)

Department of Urology, Sidney

Kimmel Medical College at

Thomas Jefferson University

Hospital, Philadelphia, PA,

USA (S Hubbs MD)

Department of Urology, Mayo

Clinic Health Systems,

Rochester, MN, USA

(M Rivera MD)

Department of

Urology, University of Iowa,

Iowa City, IA, USA

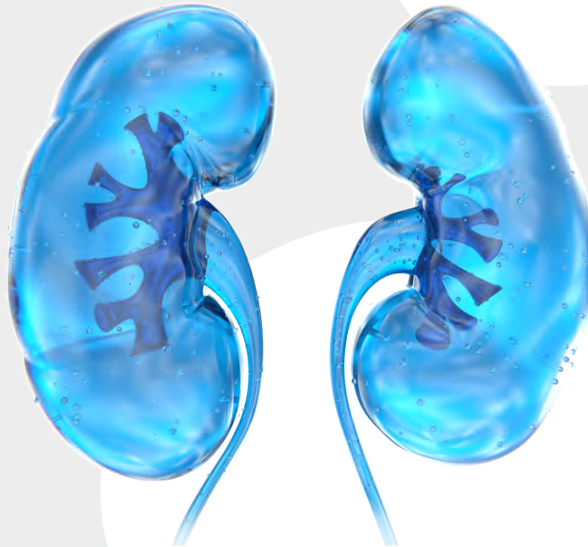
LG-UTUC, A TYPE OF UROTHELIAL CARCINOMA, IS AN ORPHAN, COSTLY CANCER WITH SIGNIFICANT QOL IMPACT

LOW-GRADE UTUC

- Kidney-sparing treatments are achievable and may decrease overtreatment and loss of renal units
- 70%-80% of LG UTUC patients receive nephroureterectomies

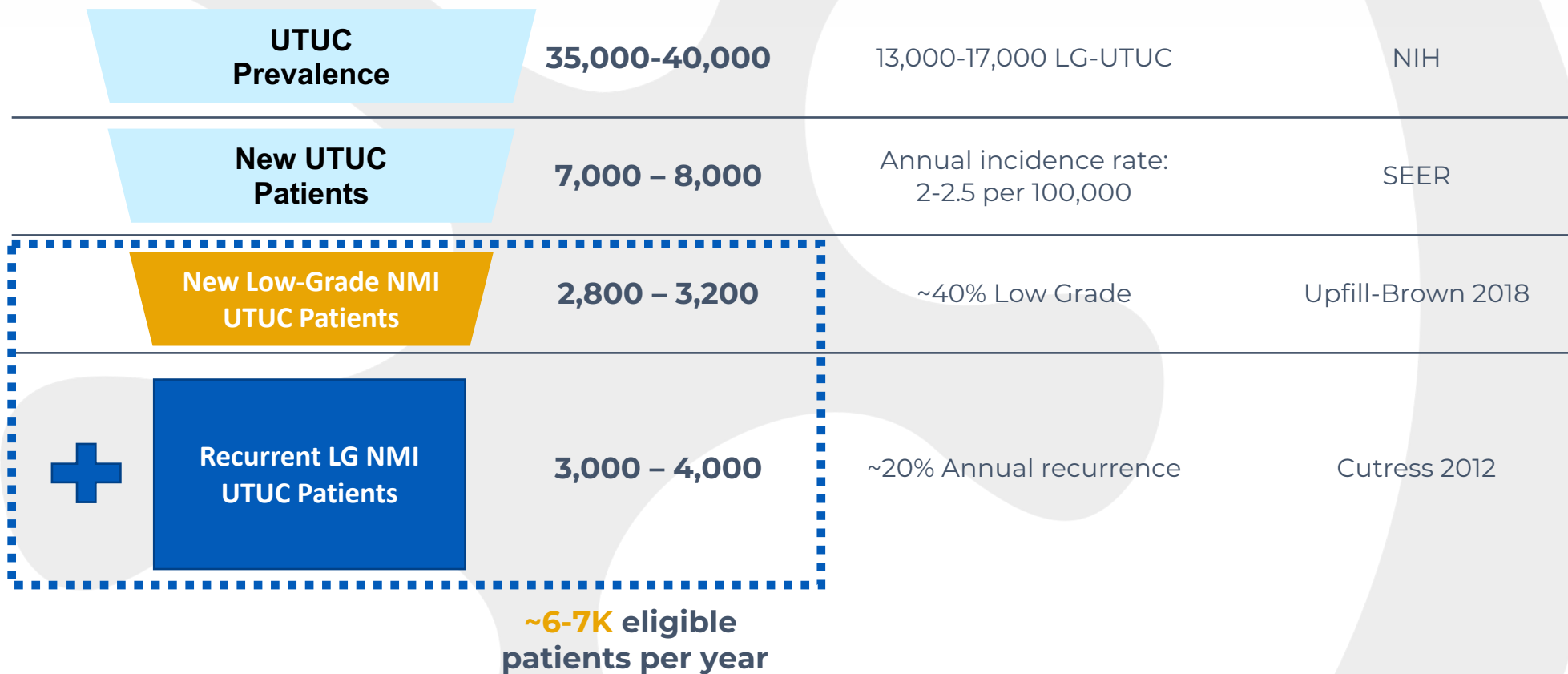
LOW-GRADE UPPER TRACT UROTHELIAL CARCINOMA (UTUC)

Cancer that happens in the lining of the kidneys or the ureters



UC is the **most costly cancer** in the US health care system on a per-patient basis¹

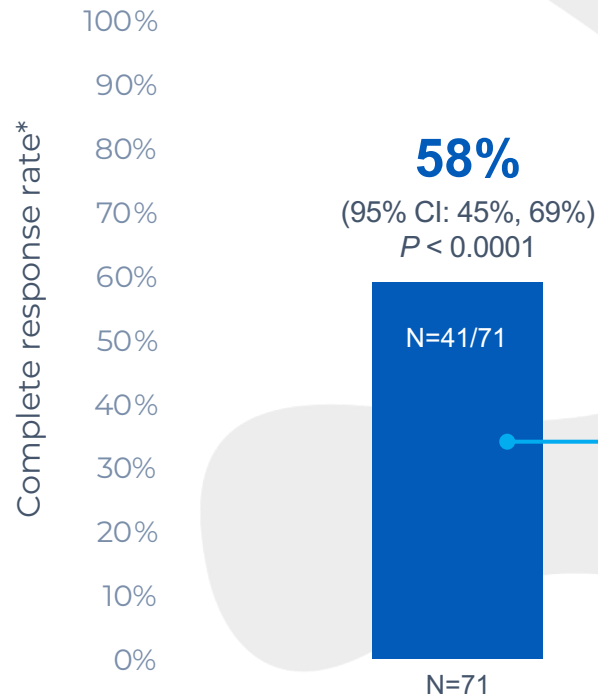
JELMYTO MARKET OPPORTUNITY: ~6-7,000 LG-UTUC ELIGIBLE PATIENTS



The First and Only Non-Surgical Treatment for Patients with LG-UTUC

OLYMPUS DEMONSTRATED CLINICALLY SIGNIFICANT RESPONSE WITH JELMYTO

Complete response was achieved in over half of patients¹



Sub-group analysis

- 48% of patients had tumors located in regions not amenable to endoscopic resection.
- Complete response was similar in patients with **unresectable tumors** at screening

Durability of response

- Kaplan-Meier analysis estimated 6-month and 12-month durability at 89% & 84%² respectively (based on interim data).
- Pending final durability data, the company will file a label update. See product label for additional information.

Most Common Adverse Events (AEs)

- Most commonly reported AEs ($\geq 20\%$): ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, dysuria, and vomiting.

*Evaluated 4-6 weeks after up to 6 weekly instillations of JELMYTO.
Complete response was determined by ureteroscopy, cytology and/or biopsy.
CI=confidence interval.

REFERENCES: 1. JELMYTO Prescribing Information. 2. Lerner, Seth. Primary Chemoablation for the treatment of Low-Grade Upper Tract Urothelial Carcinoma: The Olympus Trial. 2020 by American Urological Association Education and Research, Inc.;

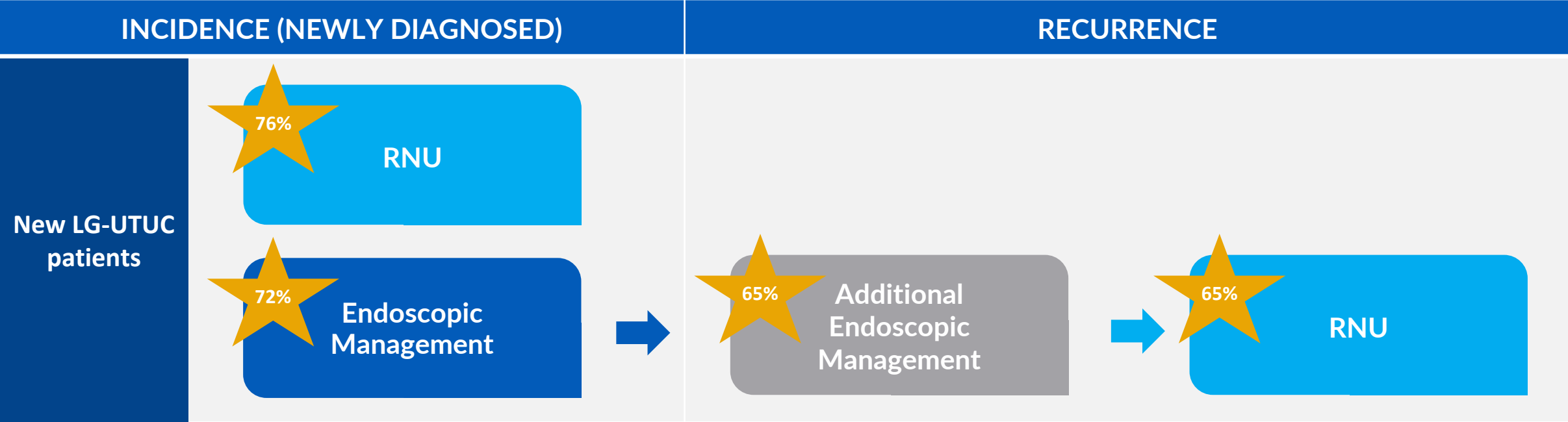
Important Safety Information and the full Prescribing Information available at https://www.urogen.com/download/pdf/jelmyto_prescribing.pdf

ACCELERATING ADOPTION: **JELMYTO**

Focusing on execution for launch

UROLOGISTS RECOGNIZE THE NEED TO AVOID RADICAL SURGERY

Treatment Continuum: Low-Grade UTUC



★ = Percent of urologists who are “likely/very likely to use” UGN-101 in each specific setting.

Multiple opportunities to incorporate Jelmyto into physician treatment of LG-UTUC, following FDA Approval

KEY COMMERCIAL SUCCESS FACTORS

PATIENT IDENTIFICATION

- ✓ **Nurse navigators** to help identify when a patient has been diagnosed with LG-UTUC

EFFICIENT REIMBURSEMENT

- ✓ Market access focused on **optimization** as well as **reimbursement for innovative therapies**
- ✓ Engaging in a **proactive access strategy** with payers
- ✓ Buy & bill programs to support reimbursement success

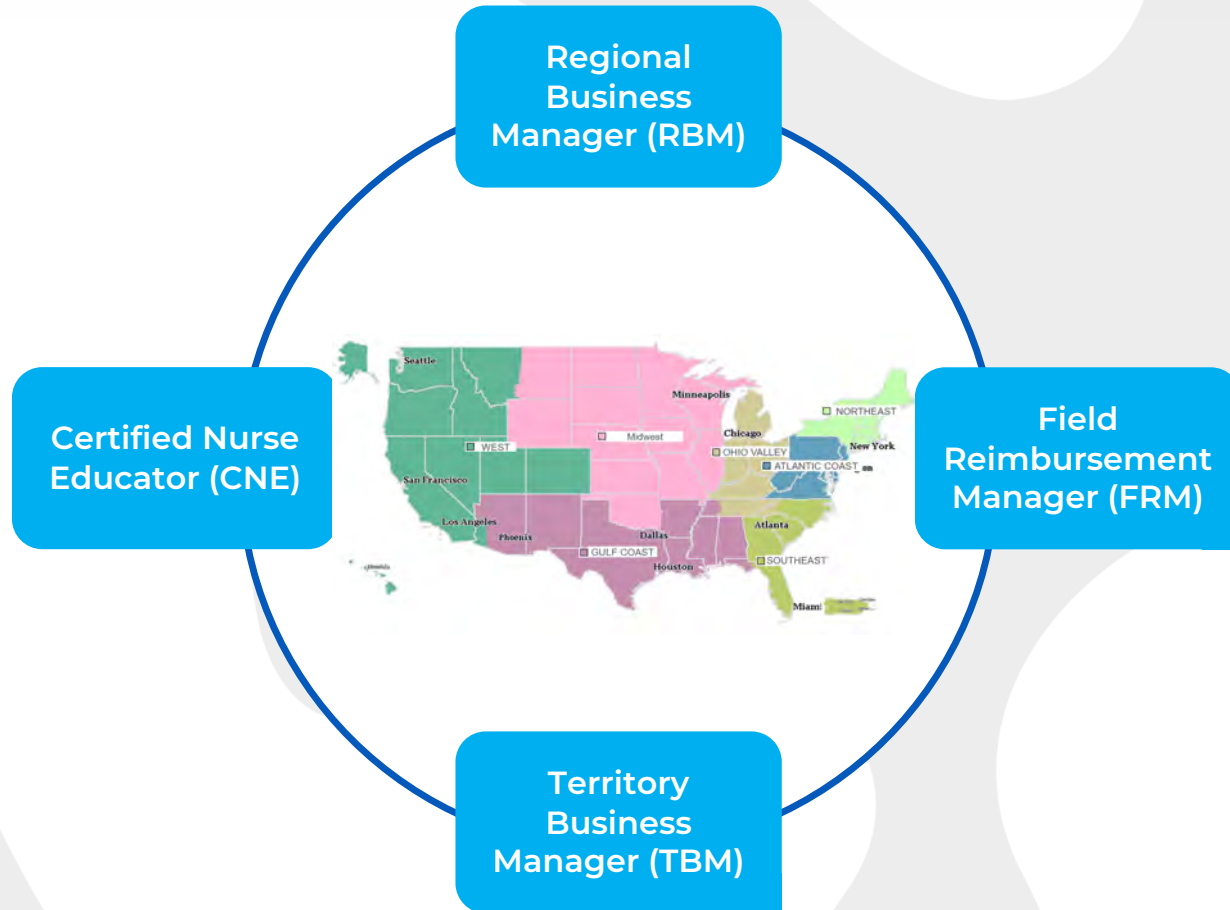
SEAMLESS INTEGRATION INTO PHYSICIAN PRACTICE

- ✓ Product support programs in place to ensure ease of use with HCPs, Pharmacists, Payers
- ✓ National Pharmacy partner will provide prepared admixture pursuant to patient-specific Rx upon request of urology clinics

Developed innovative platform of virtual resources to effectively maximize engagement with key stakeholders in current environment.

EXPERIENCED TEAM SUPPORTS ACCOUNT-BASED APPROACH

33% OF ACCOUNTS HAVE 90% OF THE PATIENT POTENTIAL



7 RBM: Regional Business Manager
Responsible for all commercial activity

48 TBM: Territory Business Manager
Customer lead and demand generation

7 FRM: Field Reimbursement Manager
Account experts on billing and coding

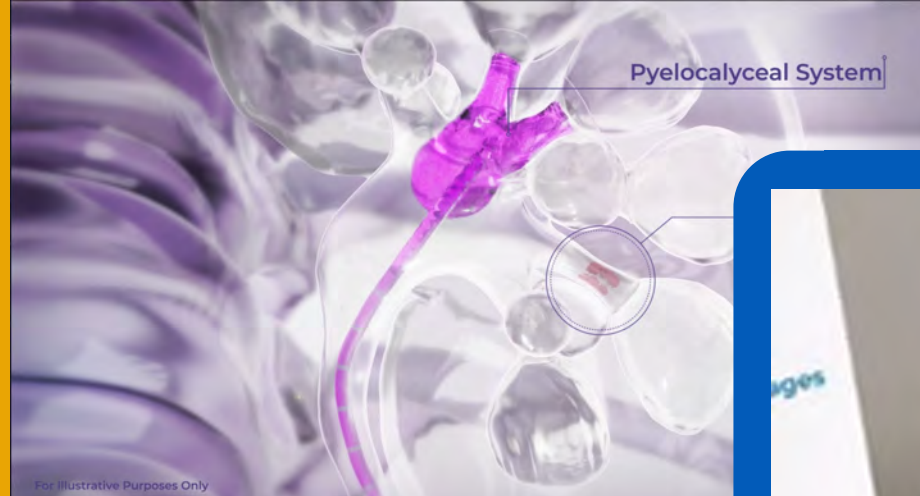
7 CNE: Certified Nurse Educator
Provide technical training and support for mixing and product instillation

7 MSL: Medical Science Liaison
Responsible for scientific exchange

MAXIMIZING STAKEHOLDER INTERACTIONS WITH VIRTUAL SOLUTIONS



VIRTUAL EXPERIENCE



INNOVATIVE MECHANISM OF DELIVERY



BRINGING JELMYTO TO PATIENTS: JUNE 1ST LAUNCH

- ✓ Hired an internal team with a **track record of success** in oncology and a veteran sales force leadership team with **deep uro-oncology relationships**
- ✓ Consulted with our customers, and we are **ready to deliver on their needs**
 - HCPs
 - Pharmacists
 - Payers
- ✓ Established high **awareness** to **drive adoption** and understanding
- ✓ Launched **HCP** campaign to educate and support customers as well as **patient** campaign
- ✓ Developed **partnerships** with seasoned vendors; distribution strategy in motion
- ✓ Reimbursement **support HUB** running and triaging requests
- ✓ Executed proactive payer strategy; C-code submitted to CMS, J-code submission in process
 - ✓ Included in the **NCCN clinical practice guidelines** in oncology

**BUILT STRONG FOUNDATION TO SUPPORT JELMYTO
AND SUBSEQUENT LAUNCHES**

OUR PIPELINE: **UGN-102**

Low-grade non-muscle invasive bladder cancer (LG Intermediate Risk NMIBC)

UGN-102 (mitomycin) for intravesical solution is an investigational agent. The safety and effectiveness of UGN-102 have not been established.

WHY LG INTERMEDIATE-RISK NMIBC?

- “Surgical failure” cohort: risk of progression low, recurrence high
- Cost & morbidity of repetitive surgery

How many of the following 4 factors does the patient have?

- Multiple tumors
- Tumor size >3cm
- Early recurrence (<1 year)
- Frequent recurrences (>1 per year)

0

Treatment as low risk

- TURBT + single immediate post-op chemotherapeutic dose, or
- Office fulguration
- Intravesical chemotherapy

1-2

Treatment as intermediate risk

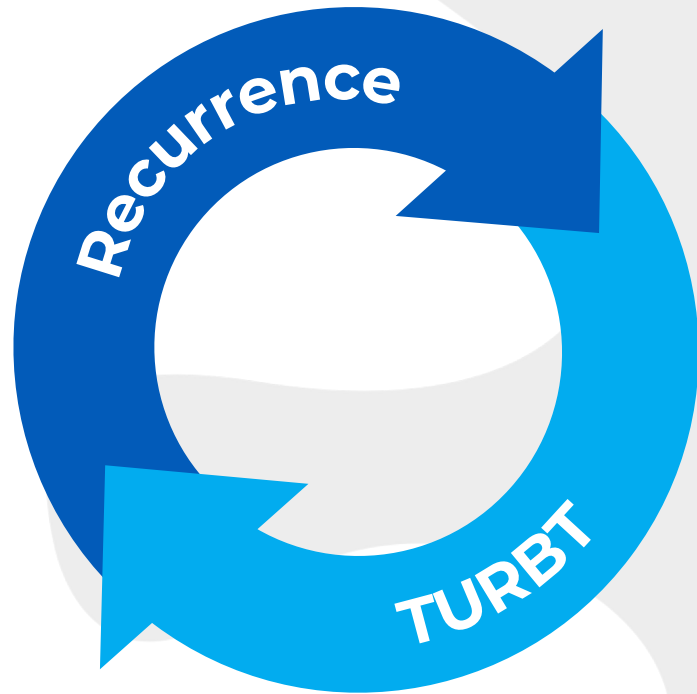
- TURBT plus adjuvant intravesical therapy

≥3

Treatment as high risk

- TURBT + BCG induction + maintenance

UROLOGISTS BECOME LESS SATISFIED WITH TURBT AMONG FREQUENTLY RECURRING PATIENTS



The subset of **LG Intermediate Risk NMIBC** patients fall into a cycle of **frequent recurrences** after repeated **TURBT failures**

UGN-102 MAY PROVIDE SIGNIFICANT ADVANTAGES TO TURBT

TURBT

Risks associated with repeated invasive surgical procedures

Potential catastrophic impact of bladder perforation

Cumulative effects from exposure to multiple rounds of general anesthesia

Long recovery time

Operating room procedure

UGN-102

Minimally-invasive instillation

Bladder perforation risk not anticipated

Anesthesia not required

Short recovery anticipated

In-office instillation anticipated

ENCOURAGING UGN-102 PHASE 2B TOPLINE DATA

UGN-102 enrollment completed ahead of schedule

- CR 65%* at 3-months (41/63)
- Of patients who achieved a CR and underwent an evaluation at each timepoint,
 - 97%, 86% and 85% remained disease free at six, nine and 12 months following initiation of therapy, respectively

Safety:

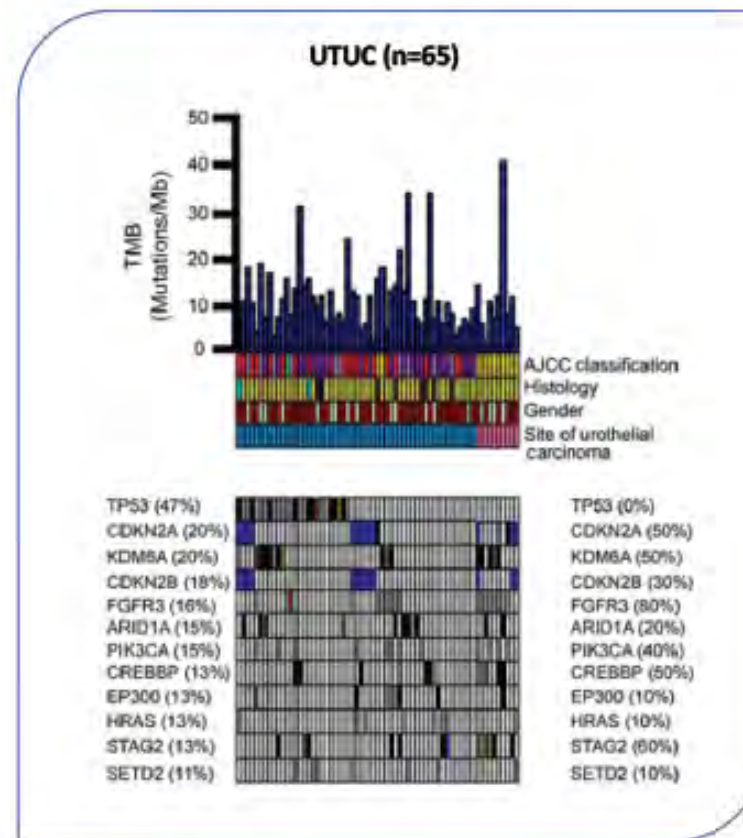
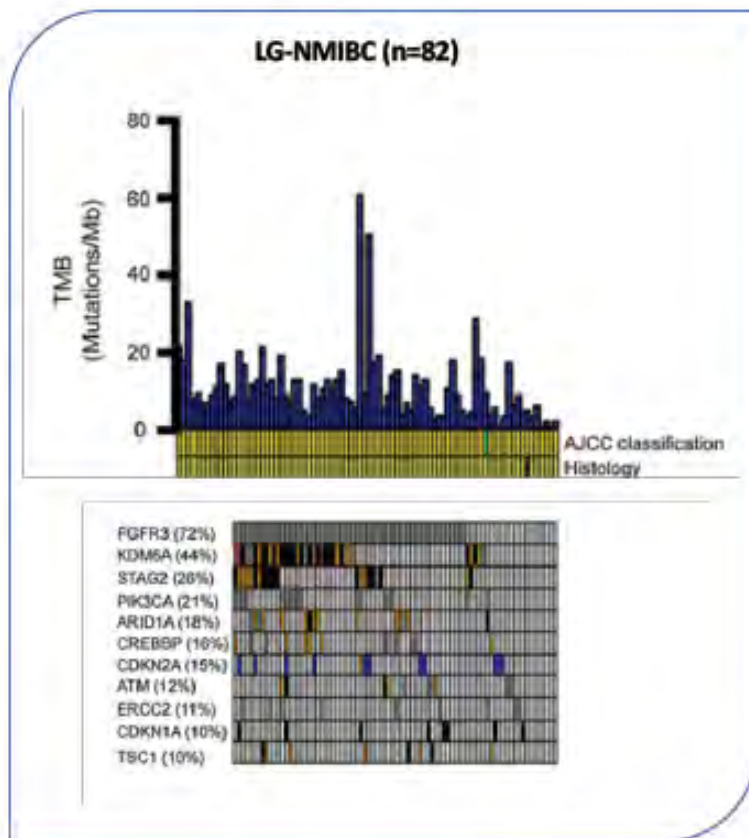
The majority of adverse events were reported as mild or moderate; the most commonly reported AEs ($\geq 10\%$) were:

- dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection

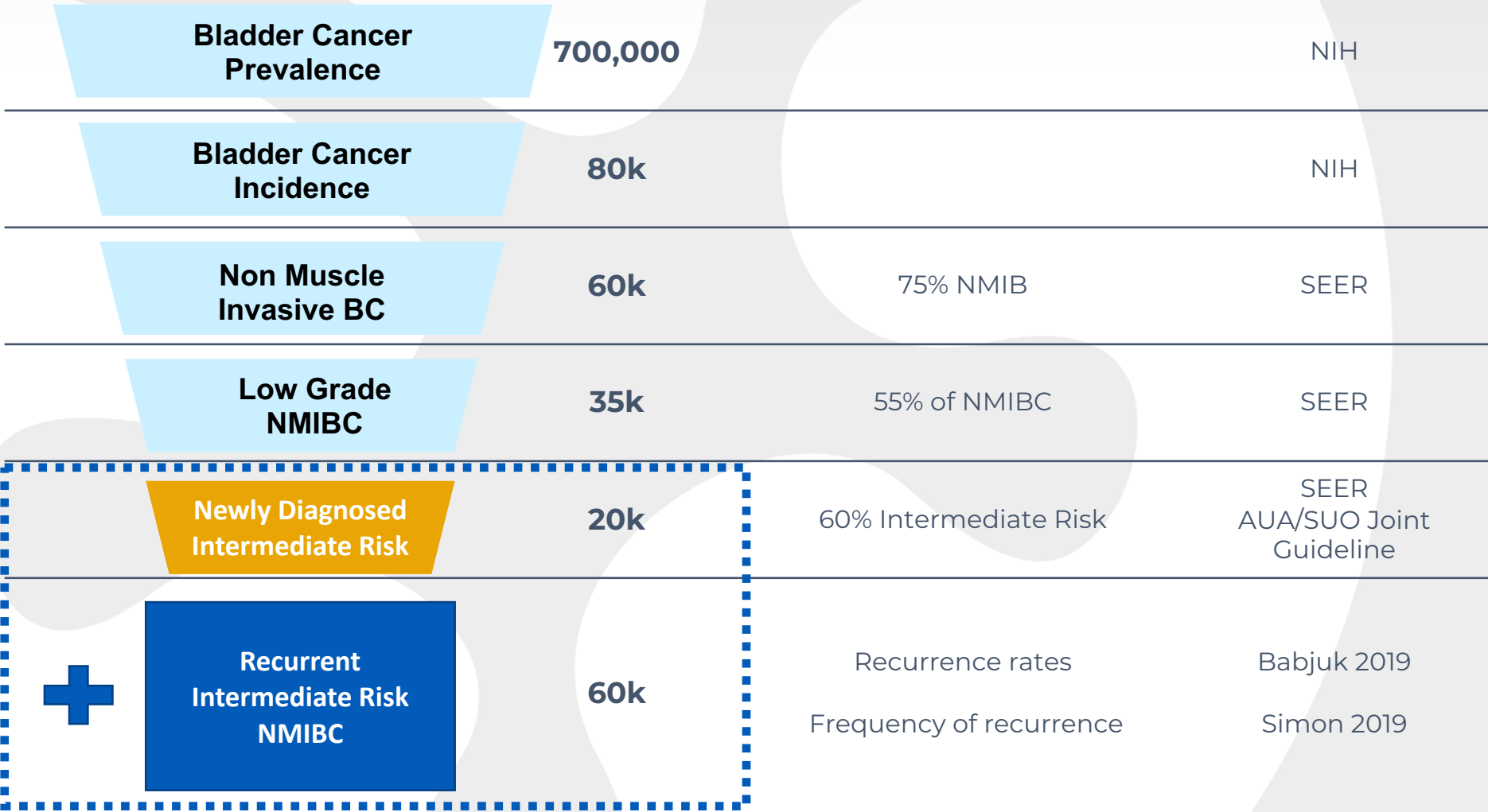
UGN-102: POTENTIAL TO REPLACE SOC:

Moves care from **OR to office/ASC** with a potential to **decrease cost** and morbidity of contemporary therapy

MOLECULAR PROFILING REVEALS LG-NMIBC SIMILAR TO LG-UTUC



UGN-102: ~80,000 LG IR NMIBC PATIENTS



~80K LG IR NMIBC

NEXT STEPS FOR UGN-102

- Continued follow-up of patients in the trial to assess durability
- Finalize pivotal trial design
- Planned Phase 3 Pivotal Study: H2H vs TURBT

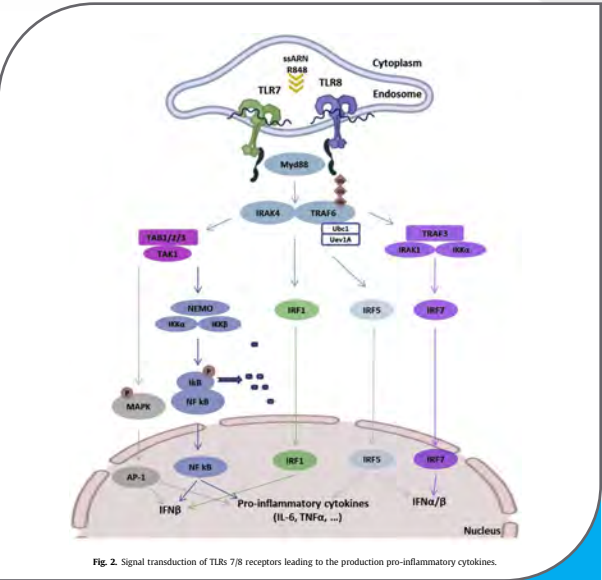
2H 2020 Study Initiation Planned

OUR PIPELINE: **UGN-302**

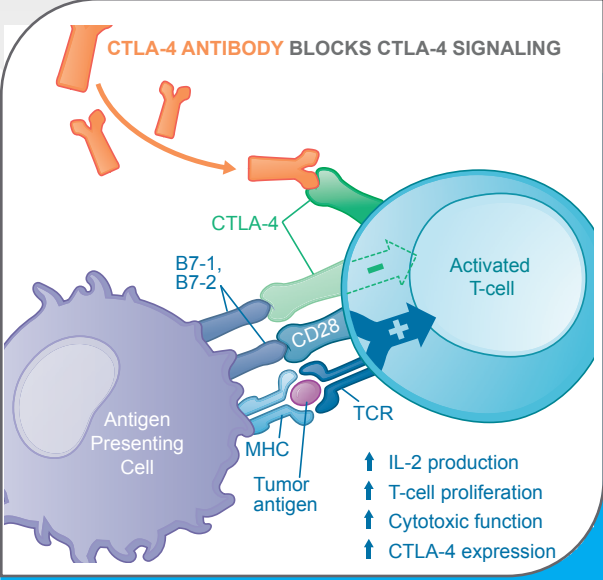
High-grade non-muscle invasive bladder cancer (HG-NMIBC)

UGN-302 is an investigational agent. The safety and effectiveness of UGN-302 have not been established.

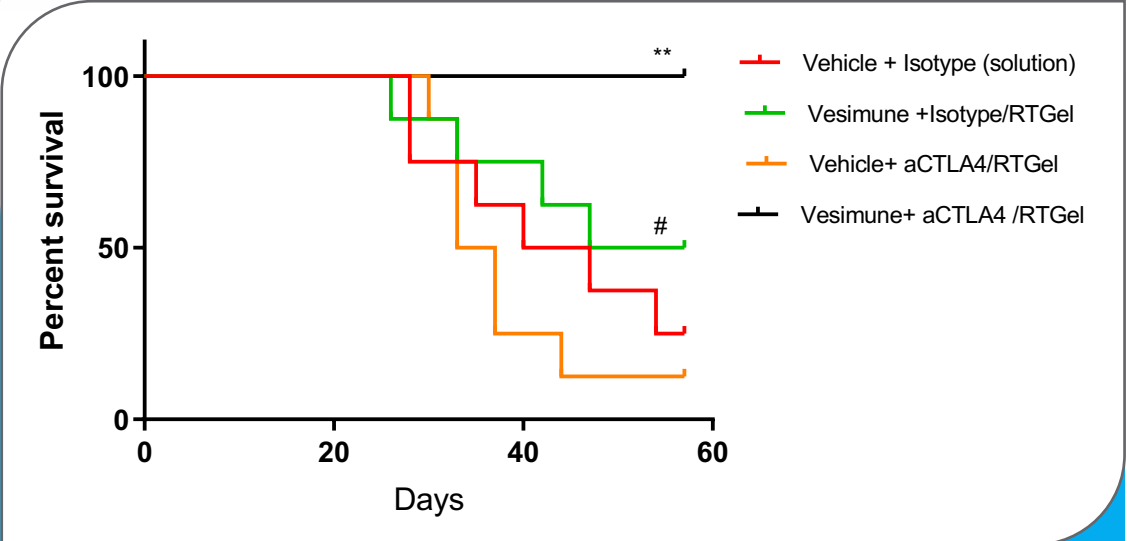
UGN-302: COMBINATION INTRAVESICAL IMMUNOTHERAPY FOR BLADDER CANCER



TLR 7/8 (UGN-201): stimulate cytokines and T & B cells



Anti-CTLA4 UGN-301 (AG-1884): blocks "cancer masking" action of CTLA4



Ph 1&2 human data suggest UGN-201 activity in human bladder cancer

UGN-201+ UGN-301= UGN-302: Non-clinical data suggest improved survival (murine) when 201 and 301 combined

LEADING IN URO-ONCOLOGY & BEYOND

Building a growth company starts with the unmet need

WE BUILD NOVEL SOLUTIONS TO TREAT SPECIALTY CANCERS AND UROLOGIC DISEASES BECAUSE PATIENTS DESERVE BETTER



ADDRESS CHALLENGING DISEASE WITH TRANSFORMATIVE THERAPIES

Addressing high unmet-need diseases in Urology & gyn/GI cancers

Must advance SOC



MAXIMIZE BENEFIT OF LOCAL DELIVERY

Leverage **RTGel capabilities and expertise** where unique solutions are needed to overcome anatomical and biological barriers

Opportunistically gain access to additional delivery platforms



PATIENT CENTRICITY

Ensure patients who can benefit from our **medicines** have **access** to them.

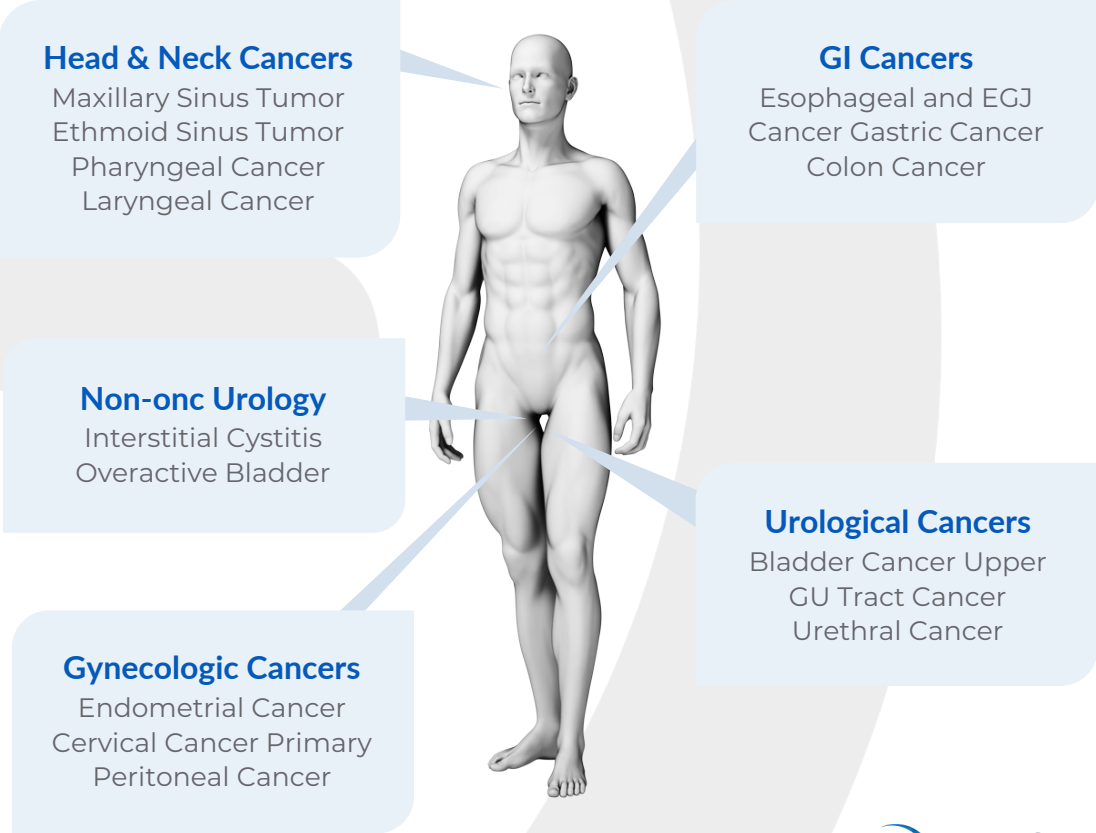
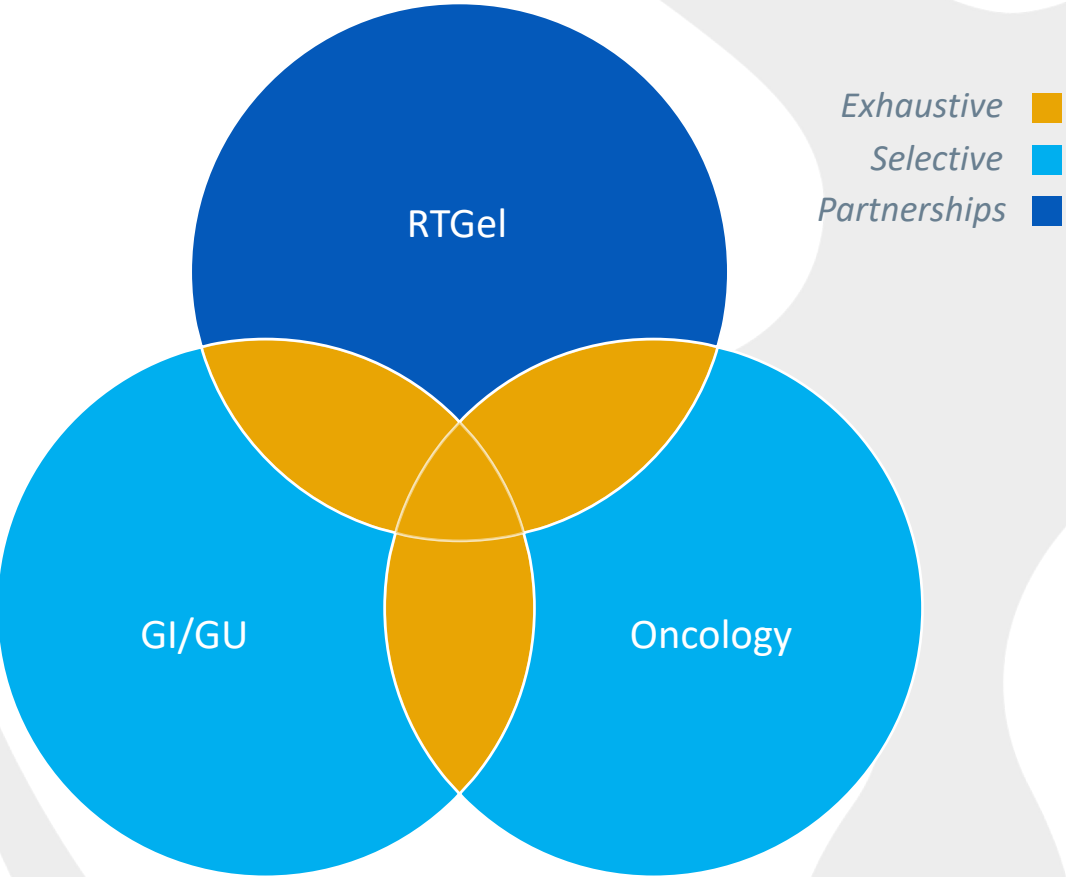
Provide a **holistic approach** with tools that help patients manage their disease and live their **best lives** possible



NIMBLE, SOLUTION-ORIENTED ORGANIZATION

Through our **nimble approach**, UroGen is designed to develop and commercialize medicines faster and more efficiently while creating a dynamic environment for employees

FOCUS ON DELIVERING LONG-TERM SUSTAINABLE GROWTH IN AREAS OF HIGH UNMET NEED VIA LOCAL DELIVERY AND NOVEL MEDICINES



STRONG FINANCIAL PROFILE

\$159.2 million in cash, cash equivalents and marketable securities, as of March 31, 2020*

Well-capitalized for Jelmyto launch and **advancement** of clinical development programs, including initiation of the UGN-102 Phase 3 trial in 2H 2020

~21.9 million shares outstanding as of March 31, 2020

Strong Balance Sheet with no Debt

NEW OPPORTUNITIES TO DELIVER ON OUR COMMITMENTS IN 2H 2020

- ☒ Launch Jelmyto, the first and only approved non-surgical treatment for patients with LG-UTUC
- ☐ Initiate UGN-102 pivotal Phase 3 trial in patients with LG Intermediate Risk NMIBC
- ☐ Report 12-month durability data from OPTIMA II for patients with LG Intermediate Risk NMIBC
- ☐ Initiate Phase 1 study for patients with HG-NMIBC
- ☐ Utilize strong financial position to take us through launch and advance the pipeline
- ☐ Gain access to novel medicines that leverage our infrastructure & expertise