

# UROGEN CORPORATE PRESENTATION

Stifel 2020 Virtual Healthcare Conference  
November 17, 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 both patient and physician uptake, including the anticipated receipt of a J Code and an anticipated label update for Jelmyto; the continued successful launch of Jelmyto; 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; the opportunity and potential of UGN-102 for LG-NMIBC and potential advantages over TURBT; plans to commence a pivotal phase 3 trial for UGN-102 in LG NMIBC in 2020; the market opportunity for UGN-102 in LG-NMIBC; plans to initiate a Phase 1 study with UGN-201 in HG-NMIBC; plans to investigate UGN-201 in combination with UGN-301 (AGEN1884) in HG-NMIBC; the market opportunity and potential of UGN-301 in HG-NMIBC; plans to build a sustainable growth company; projections of revenue opportunities in markets of interest; capitalization to advance Jelmyto launch and specific clinical development programs; and plans to continue exploration of the RTGel hydrogel formulation in combination with AbbVie's portfolio of clostridial toxins in OAB and other patient populations; and financial strength and guidance. 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, the OPTIMA II Phase 2b trial, the Atlas Phase 3 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 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 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 November 9, 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, we, our customers, partners and other collaborators are or may be subject to stay-at-home orders or other mitigation measures as a result of the ongoing COVID-19 pandemic. 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.

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# LEADING IN **URO-ONCOLOGY & BEYOND**

*Building a growth company starts with the unmet need*

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



## 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

## VALUES

ACT BOLDLY | BE INVENTIVE | STAY CONNECTED

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



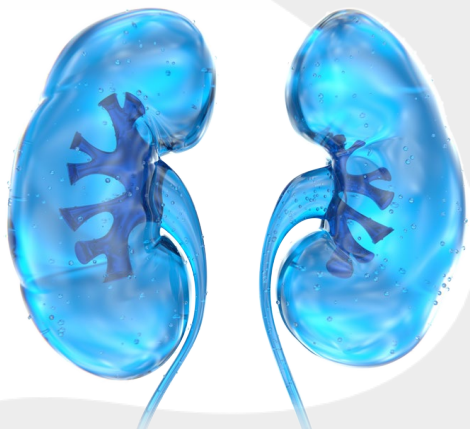
Exists as a liquid at lower temperatures and converts to gel form at body temperature

Has the potential to advance the treatment of specialty cancers and urologic diseases 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

# UNLOCKING THE URO-ONCOLOGY MARKET-BUILDING A COMPANY

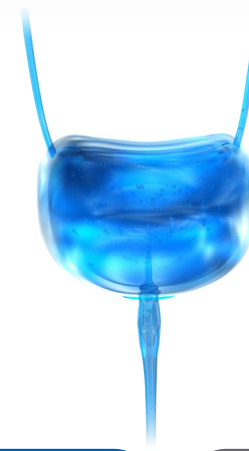
LOW-GRADE UPPER TRACT  
UROTHELIAL CARCINOMA (UTUC)



~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

# STRONG MOMENTUM ACROSS PIPELINE

PIPELINE	NONCLINICAL	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	APPROVED
URO-ONCOLOGY						
<b>Jelmyto® (mitomycin) for pyelocalyceal solution:</b> Low-grade upper tract urothelial carcinoma (UTUC)						
<b>UGN-102:</b> Low-grade intermediate risk non-muscle invasive bladder cancer (NMIBC)						
IMMUNO-URO-ONCOLOGY						
<b>UGN-201 (TLR 7/8 agonist):</b> High-grade non-muscle invasive bladder cancer (NMIBC)						
<b>UGN-302:</b> High-grade non-muscle invasive bladder cancer (NMIBC)						
<b>UGN-201 + zalifrelimab (CTLA-4) Local Delivery</b>						
PARTNERS	NONCLINICAL	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	APPROVED
UROLOGY						
<b>Abbvie Toxin proteins /RTGel reverse-thermal hydrogel</b>						

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



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# JELMYTO®

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

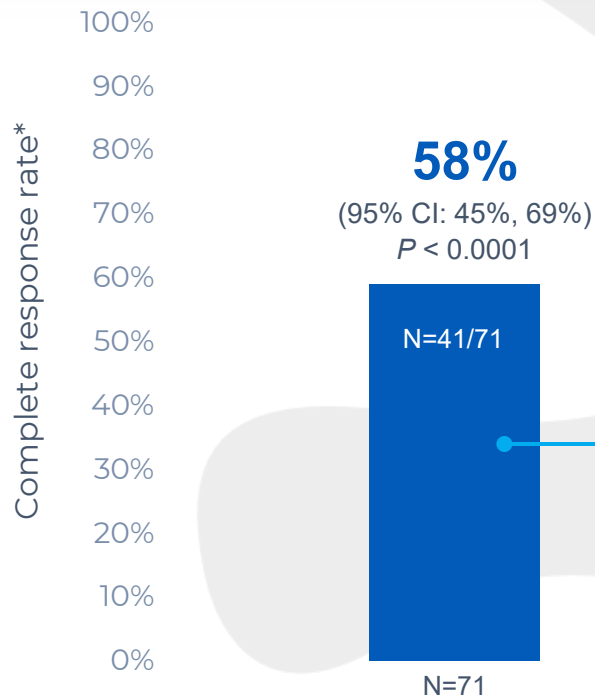
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JELMYTO (mitomycin) for pyelocalyceal solution; formerly known as UGN-101



# OLYMPUS DEMONSTRATED CLINICALLY SIGNIFICANT RESPONSE WITH JELMYTO

Complete response was achieved in over half of patients<sup>1,2</sup>

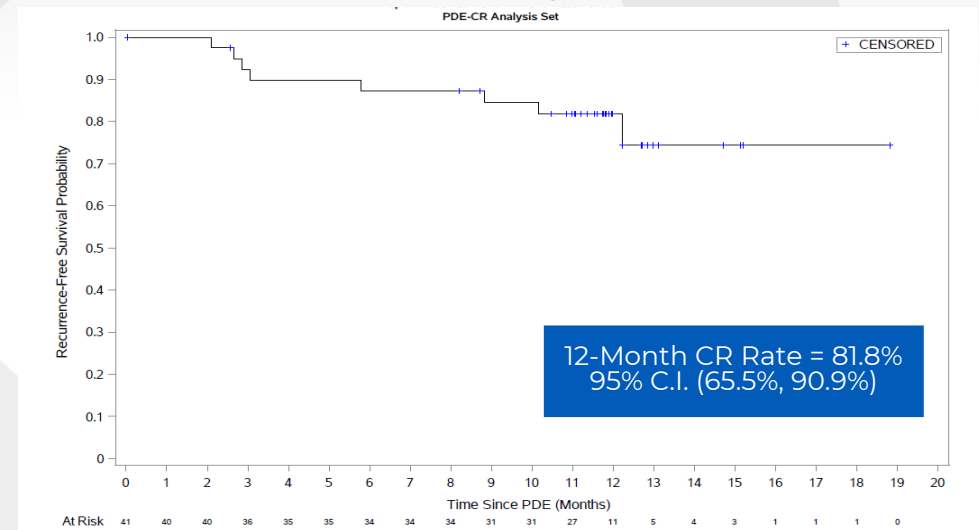


## Sub-group analysis

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

\*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.

## Kaplan-Meier Curve: Durability of CR as of June 2020




## 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.

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](https://www.urogen.com/download/pdf/jelmyto_prescribing.pdf)

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

UTUC Prevalence	35,000-40,000	13,000-17,000 LG-UTUC	NIH
New UTUC Patients	7,000 – 8,000	Annual incidence rate: 2-2.5 per 100,000	SEER
New Low-Grade NMI UTUC Patients	2,800 – 3,200	~40% Low Grade	Upfill-Brown 2018
 Recurrent LG NMI UTUC Patients	3,000 – 4,000	~20% Annual recurrence	Cutress 2012
~6,000-7,000 eligible patients per year			

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



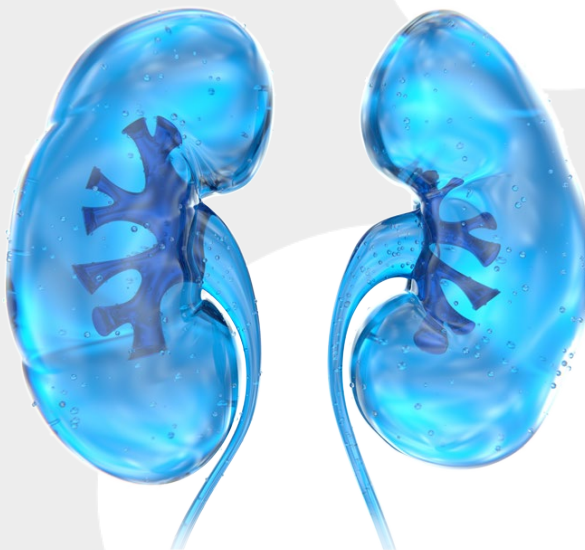
# LG-UTUC, A TYPE OF UROTHELIAL CARCINOMA, IS AN ORPHAN, COSTLY CANCER WITH SIGNIFICANT QOL IMPACT

## 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 basis<sup>1</sup>

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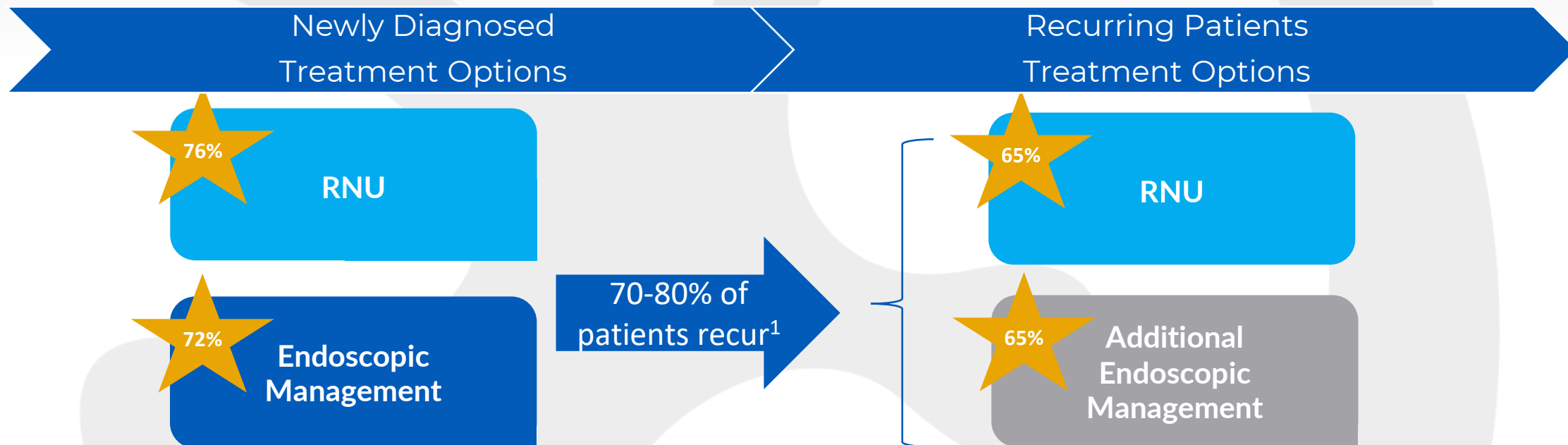
ACCELERATING EARLY ADOPTION: **JELMYTO®**

*Bringing Jelmyto to patients*

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# MULTIPLE OPPORTUNITIES TO INCORPORATE JELMYTO INTO PHYSICIAN TREATMENT OF LG-UTUC

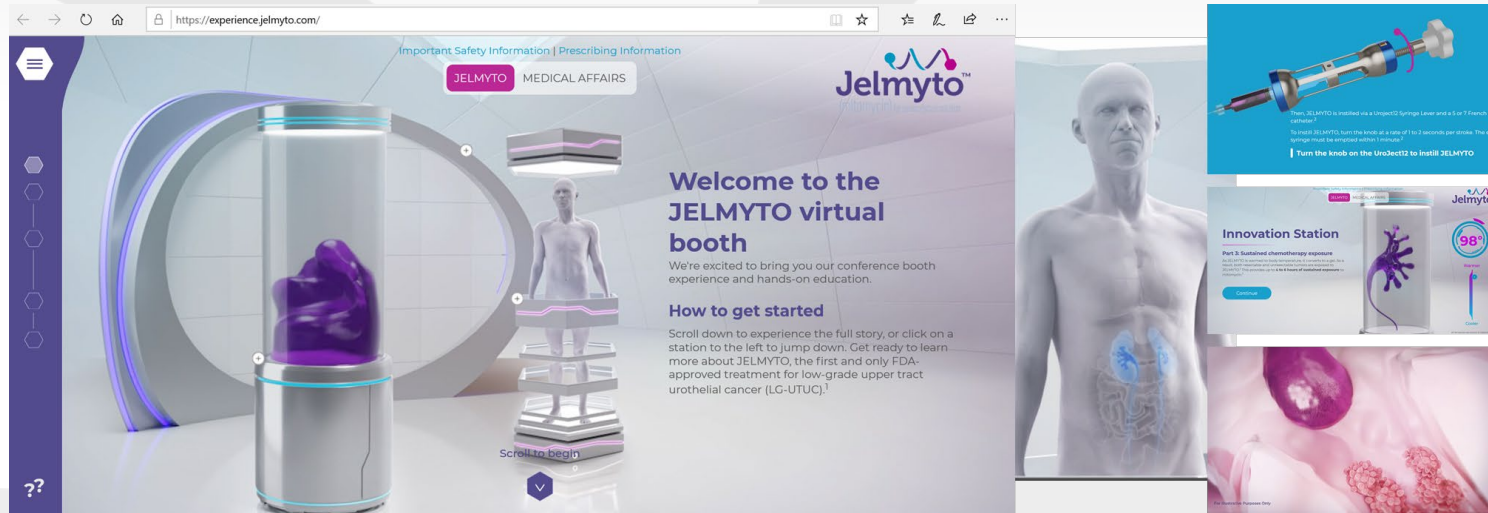
Treatment Continuum: Low-Grade UTUC



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

- **70%-80% of LG UTUC patients receive nephroureterectomies**
- **Jelmyto may decrease the need for RNU, potentially sparing the kidney**

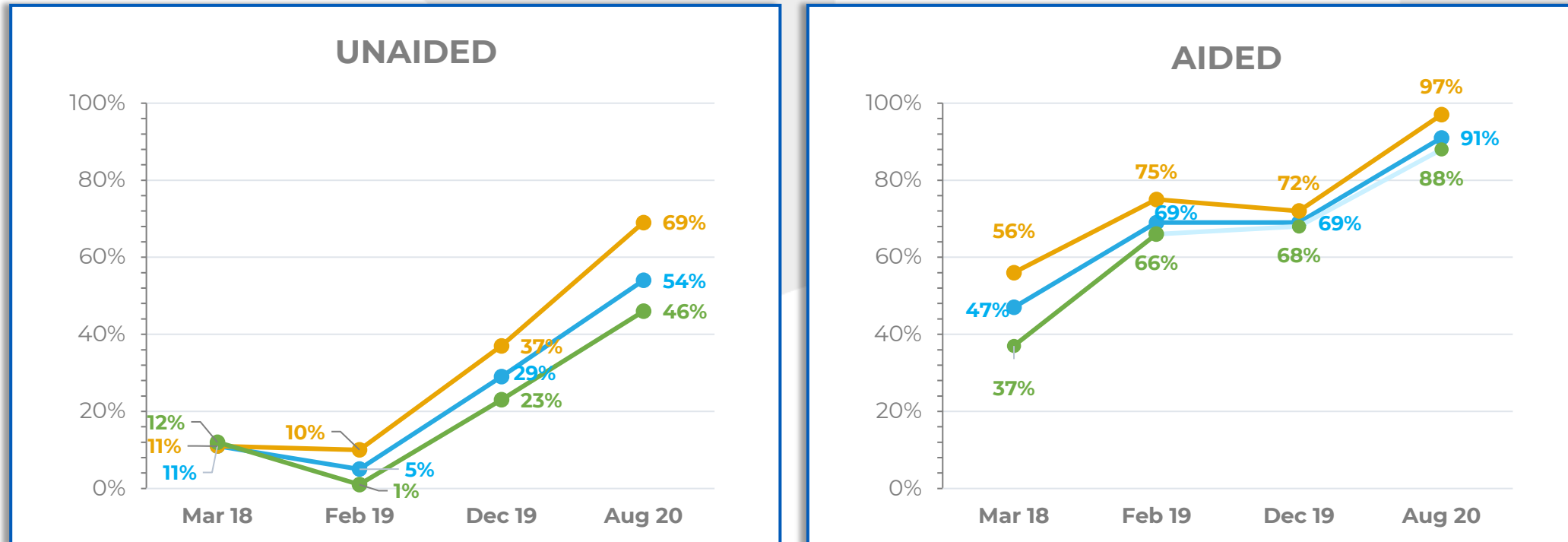
# SETTING A NEW STANDARD FOR LAUNCHING IN A DIGITAL WORLD



- Jelmyto.com continues to drive strong engagement
  - In September **650 visitors** engaged with **3 or more pages** of content, well over industry benchmarks
- Our virtual booth had over **5,000 new users** in the first 5 months, with increased engagement rates month over month (time on site is increasing)

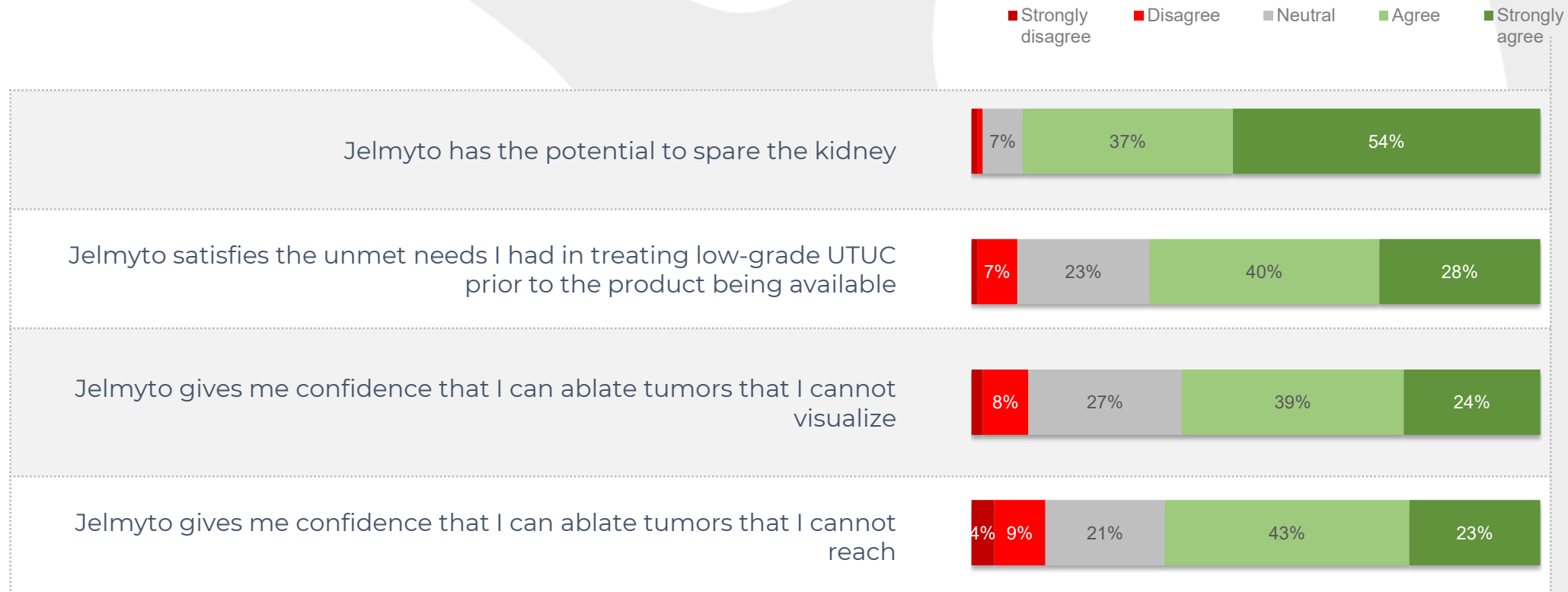


# AWARENESS OF JELMYTO CONTINUES TO GROW SIGNIFICANTLY AS A RESULT OF COMMERCIAL EFFORTS



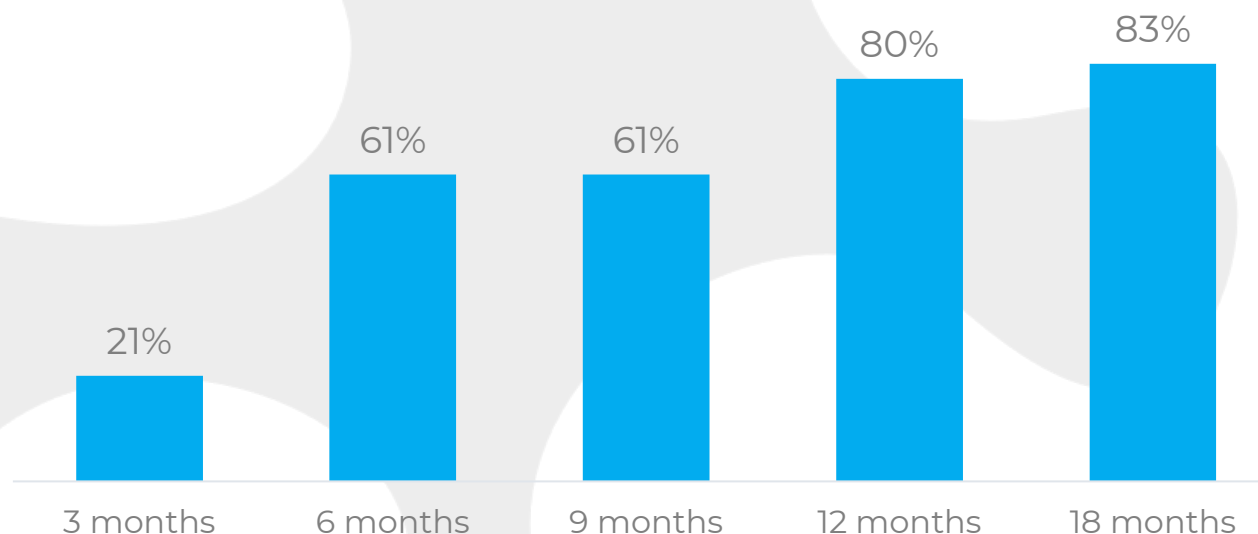
—●— Total —●— Hospital —●— Office

# PHYSICIANS EXHIBIT MANY POSITIVE ATTITUDES FOLLOWING APPROVAL THAT WE EXPECT TO DRIVE JELMYTO UPTAKE



# RESEARCH SUGGESTS CONTINUED JELMYTO UPTAKE BY UROLOGISTS OVER THE NEXT 12 MONTHS

Expected Time to Adoption of JELMYTO  
(n=87 Urologists)\*



\*UroGen market research, 87 urologists surveyed who are not currently prescribing Jelmyto (September 2020)

# KEY COMMERCIAL UPDATES: JELMYTO 3Q20 NET PRODUCT REVENUE OF \$3.5 MILLION

## JELMYTO PATIENT ADOPTION

- ✓ **Over 165 sites now activated\***
- ✓ High volume of completed patient enrollment forms indicate future uptake in patients for Jelmyto

## REIMBURSEMENT

- ✓ Claims have been paid for both commercial and Medicare to date
- ✓ **Permanent J code effective January 1, 2021** to standardize and facilitate reimbursement in surgery centers and hospitals
- ✓ Majority of large commercial plans have policies in place, covering over 150 million lives

## SEAMLESS INTEGRATION INTO PHYSICIAN PRACTICE

- ✓ **13 accounts** have treated more than one patient\*
- ✓ National Pharmacy partner provides prepared admixture to accounts on demand
- ✓ Acceptance at major institutions, including Mayo Clinic, MD Anderson, Memorial Sloan Kettering, Johns Hopkins, Loyal University, Ohio State University, University of Indiana, University of MO



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# OUR PIPELINE: **UGN-102**

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

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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

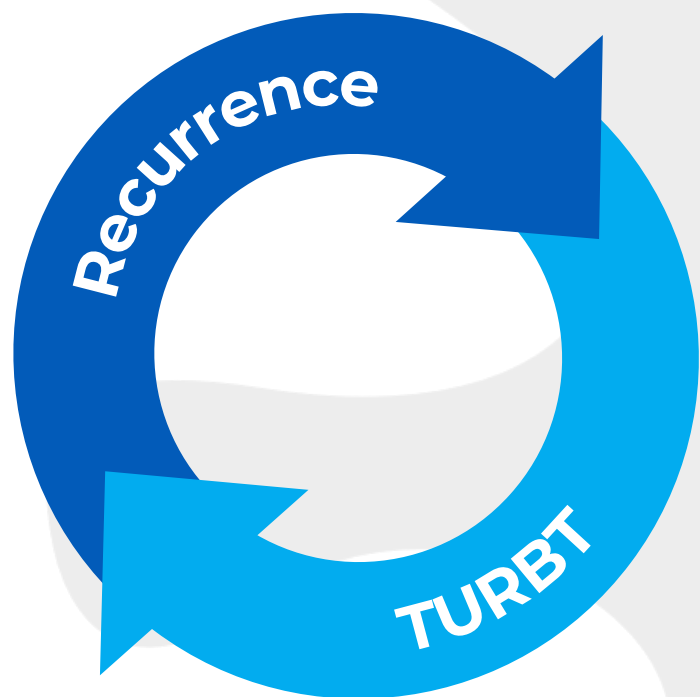
- TURBT plus adjuvant intravesical therapy

≥3

#### Treatment as high risk

- TURBT + BCG induction + maintenance

# UROLOGISTS BECOME LESS SATISFIED WITH TURBT AMONG FREQUENTLY RECURRING PATIENTS



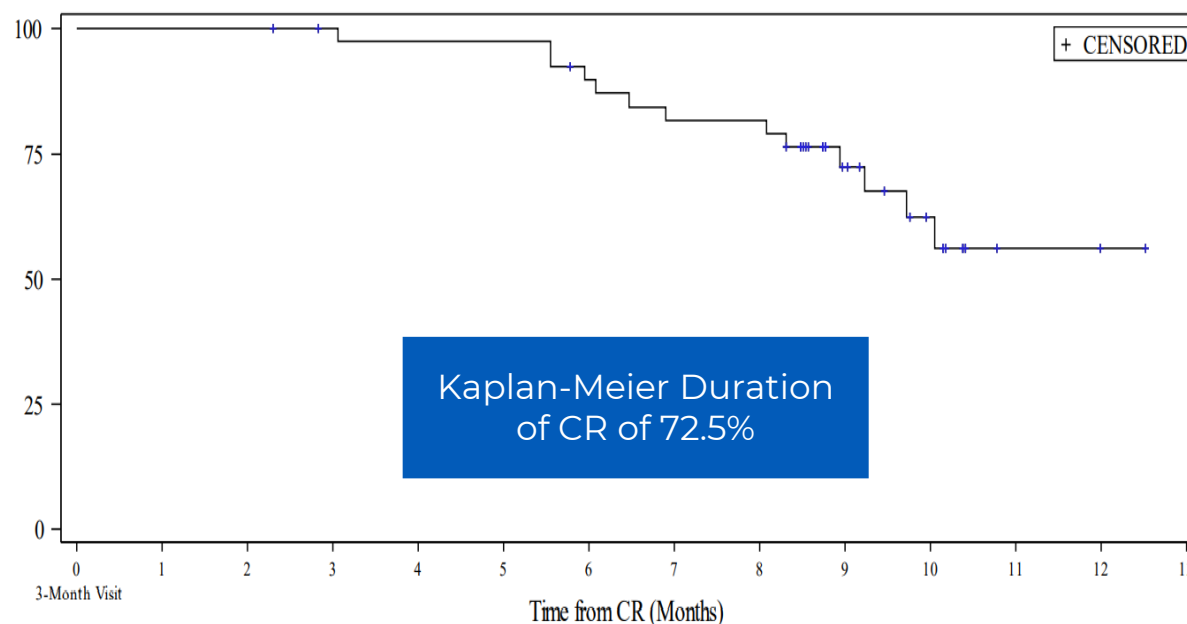
The subset of **LG Intermediate Risk NMIBC** patients fall into a cycle of **frequent recurrences** after repeated **TURBT failures**

# COMPLETE AND DURABLE RESPONSES OBSERVED WITH UGN-102 IN PHASE 2B OPTIMA II TRIAL

65% (41/63) Complete Response at 3-months\*

Duration of response estimated to be 72.5% at 12 months from initiation of therapy by Kaplan-Meier method

Median duration of response was not reached



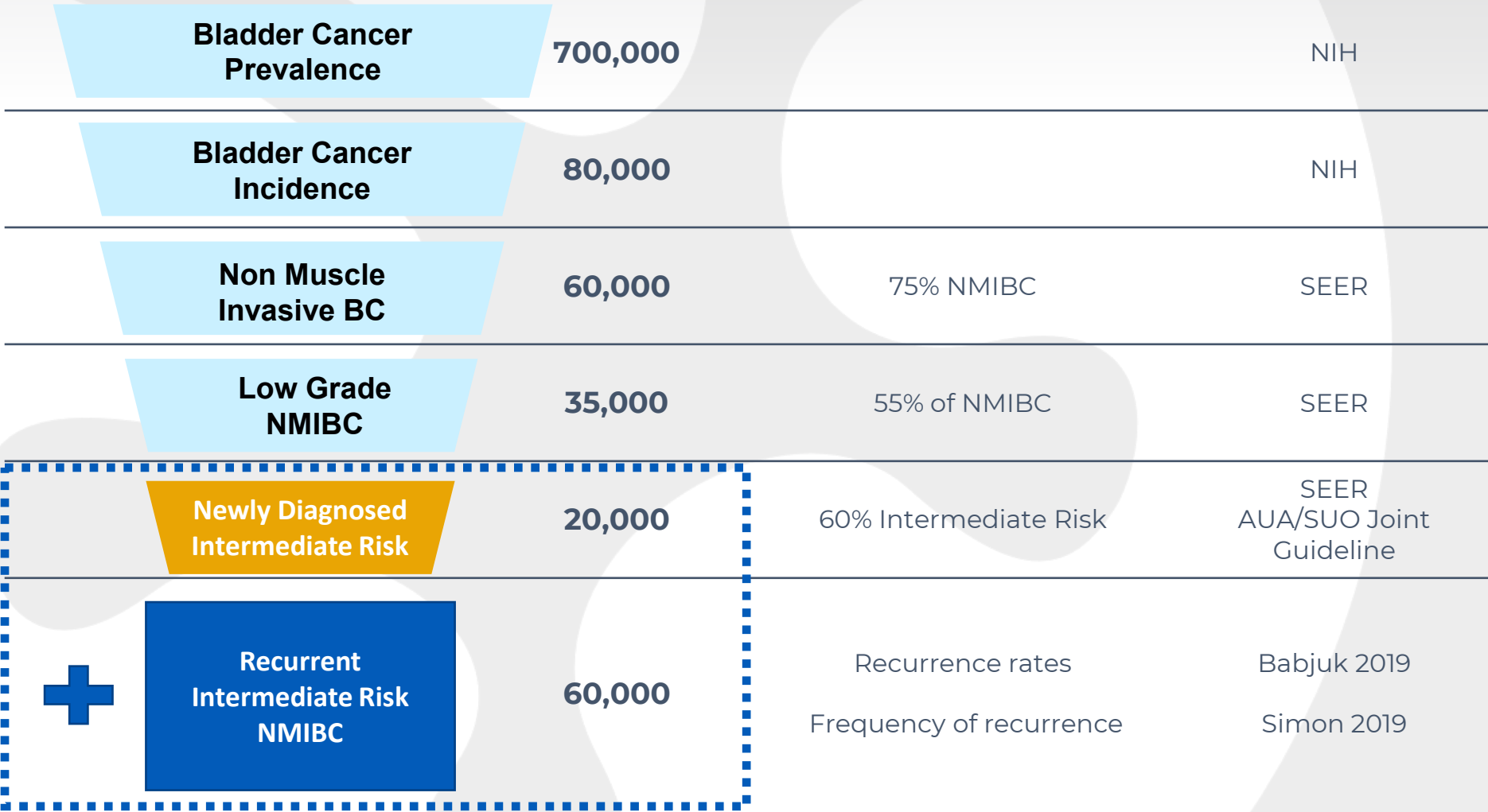
The majority of adverse events were reported as mild or moderate; the most commonly reported AEs ( $\geq 10\%$ ) were: dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection

## UGN-102: POTENTIAL TO REPLACE SOC:

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



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



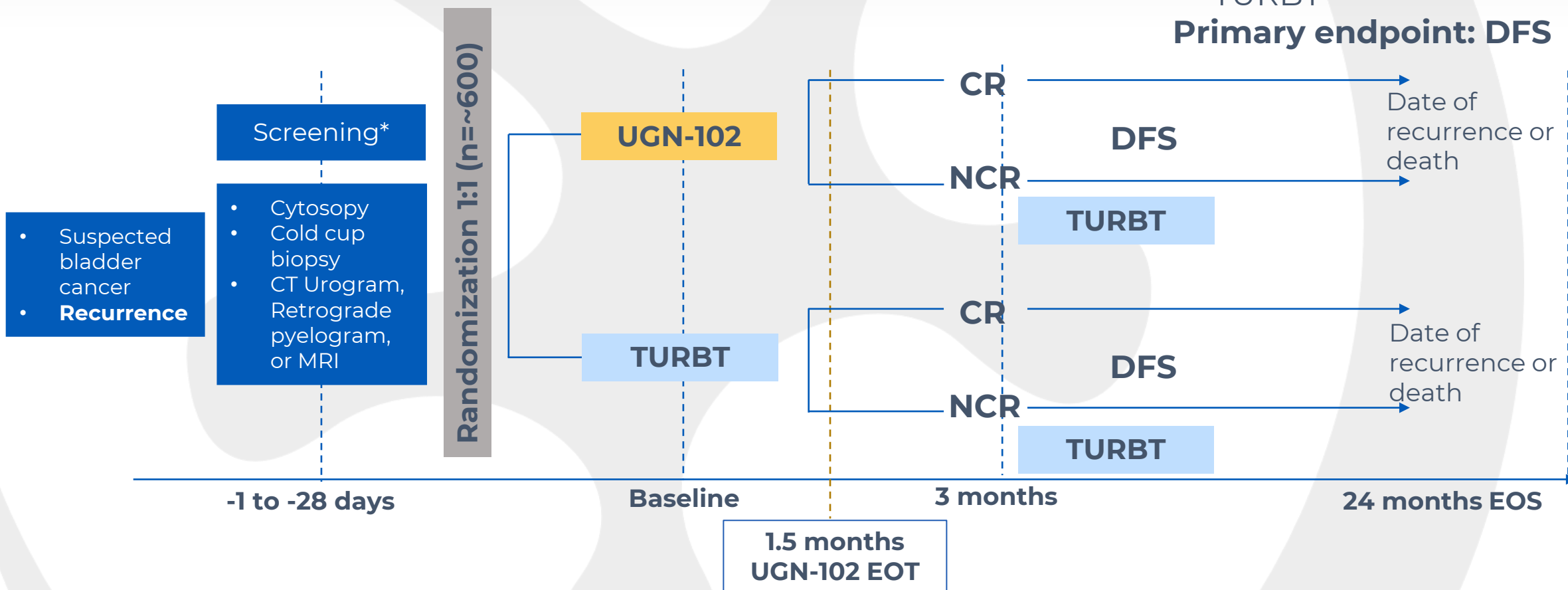
~80,000 LG IR NMIBC

# ATLAS PHASE 3 TRIAL: PHASE 3 TRIAL INITIATION EXPECTED BY YEAR-END 2020

## Treatment arms:

- UGN-102 +/- TURBT
- TURBT

**Primary endpoint: DFS**



\*Screening procedures to provide evidence of low grade NMIBC; no evidence of high grade disease

CR = complete response, CT=computed tomography, MRI=magnetic resonance imaging, NCR= non-complete response, DFS= disease-free survival, TURBT= transurethral resection of bladder tumor, EOT=end of treatment, EOS =end of study

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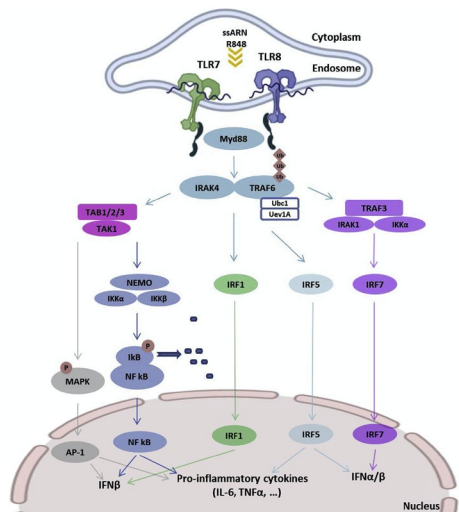
# OUR PIPELINE: **UGN-302**

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

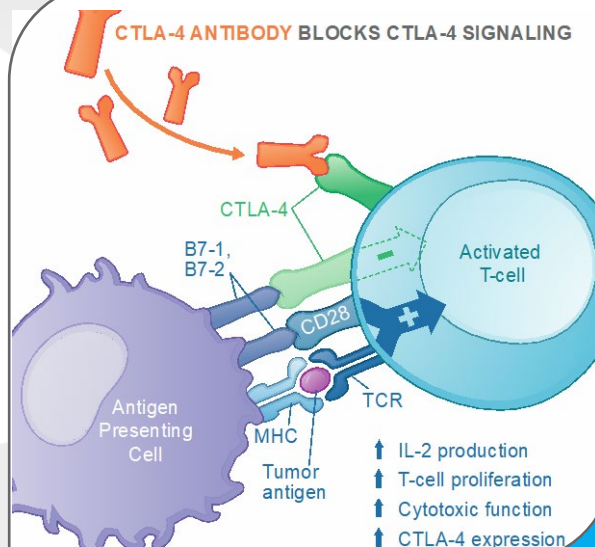
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UGN-302 is an investigational agent. The safety and effectiveness of UGN-302 have not been established.

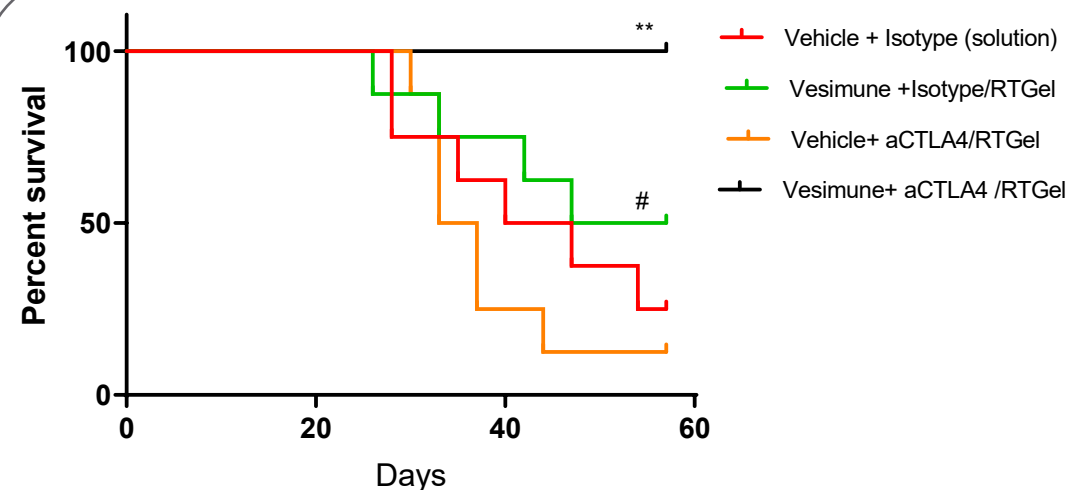
# UGN-302: COMBINATION INTRAVESICAL IMMUNOTHERAPY FOR BLADDER CANCER



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 a CTLA4 inhibitor are combined

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# STRONG BALANCE SHEET & FINANCIAL FUNDAMENTALS

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# STRONG FINANCIAL PROFILE

**\$125.5 million** in cash, cash equivalents and marketable securities, as of September 30, 2020\*

**Well-capitalized** for Jelmyto launch and **advancement** of clinical development programs, including initiation of the UGN-102 Phase 3 trial by year-end 2020

**22.1** million shares outstanding as of September 30, 2020

Company has no Debt on Balance Sheet



# DELIVERING TODAY, SETTING GROUNDWORK FOR TOMORROW

Launched Jelmyto, first and only non-surgical treatment for LG-UTUC, in June 2020

Achieving commercial milestones: patient identification, reimbursement and integration into physician practices

Experienced management team in place to lead the company forward

Establishing leadership in specialty cancers and urologic disease