

Transforming Local Therapies in Uro-Oncology

Cowen and Company 39th Annual Health Care Conference March 12, 2019



Forward-Looking Statements

This presentation and the accompanying oral presentation by UroGen Pharma Ltd. ("UroGen") contains forward-looking statements. All statements contained herein other than statements of historical fact constitute forward-looking statements, including statements regarding UroGen's anticipated results of operations and financial position, business strategy and operating plans and UroGen's expectations for future operations.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of preclinical studies and clinical trials conducted by or on behalf of UroGen, including with respect to the efficacy and safety of UroGen's product candidates; UroGen's ability to obtain and maintain regulatory approval of its product candidates, and the labeling for any approved products; the scope, progress, expansion and costs of developing and commercializing UroGen's product candidates; UroGen's ability to obtain and maintain intellectual property protection for its product candidates; UroGen's anticipated growth strategies; UroGen's expectations regarding competition; the anticipated trends and challenges in UroGen's business and the markets in which it operates; UroGen's ability to attract or retain key management and personnel; the size and growth of the potential markets for UroGen's product candidates and its ability to serve those markets; the rate and degree of market acceptance of UroGen's product candidates vis-à-vis alternative or existing therapies; UroGen's expectations regarding regulatory requirements; developments in applicable regulatory regimes; and the manner in which UroGen intends to use its cash resources and the sufficiency thereof. Moreover, UroGen operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. It is not possible for UroGen's management to predict all risks, nor can UroGen assess the impact of all factors on its business or the extent to which any such factor or combination of factors may cause actual results to differ materially from those contained herein. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied by the forward-looking statements contained herein. Except at required by law, UroGen undertakes no obligation to update any such forward-looking statements after the date hereof to conform to actual results or changes in UroGen's expectations.



UroGen – Establishing Leadership Position in Uro-Oncology

PLATFORM

Proprietary **RTGel™** technology platform has potential to reduce need for surgical intervention

UGN-101 (LG UTUC) Target Completion of Rolling NDA 2H 2019 for potential FDA Approval of first product UGN-102 (LG NMIBC) Enrolling patients in Phase 2b Trial in one of the largest and most costly indications in oncology **Pipeline** Assets in development for High-Grade Bladder Cancer and Overactive Bladder

Preparing for potential commercialization of first product

LG UTUC = Low-Grade Upper Tract Urothelial Cancer LG NMIBC = Low-Grade Non-Muscle Invasive Bladder Cancer



2019 Roadmap: Intended to Provide Strong Foundation for Sustainable Growth

3

Completion of Rolling NDA to FDA for UGN-101 Commercial Launch Ready for Potential FDA Approval of UGN-101

2

Initial UGN-102 Data and Completion of Ph2 Trial Enrollment Assessment of Potential Partnerships to Expand Pipeline/Platform

4



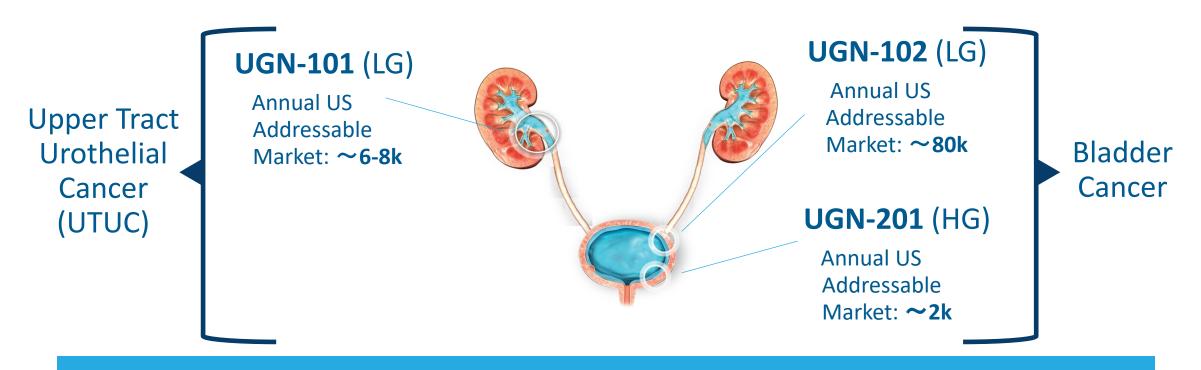
Key Investment Highlights

- As of December 31, 2018, cash, cash equivalents, and short-term investments totaled <u>\$101.3</u>
 <u>million</u>
- In addition, in January 2019, completed a successful public offering resulting in net proceeds of ~<u>\$162 million</u>
- UroGen has <u>20.4 million ordinary shares</u> outstanding post the closing of the January follow-on offering
- <u>Well-capitalized</u> to execute on strategic priorities <u>for next 24-36 months</u>, including:
 - Preparation for potential commercialization of UGN-101
 - Continued clinical development of UGN-102
 - Pipeline Advancement
 - Assessment of potential business development opportunities to enhance RTGel Platform



Strategic Approach for RTGel in Uro-Oncology

UroGen: Platform to Products



Reverse Thermal Gelation Technology at Work



Potential to Revolutionize the Practice of Uro-Oncology



Innovation versus Radical Intervention



How the RTGel Technology Works

RTGel⁽¹⁾: Liquid at low temperature (LT) and converts into gel form at body temperature (BT) following intravesical instillation





UGN-101 (mitomycin gel) for instillation

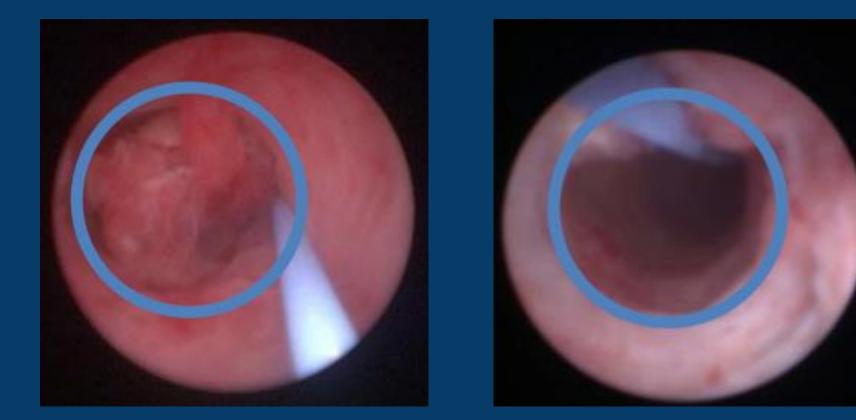


UGN-101: A Case of Complete Remission without Surgery

Patient with LG UTUC

Previously underwent repeated endoscopic surgery

Candidate for kidney removal

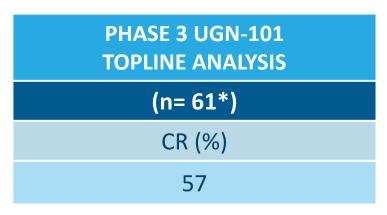


Before UGN-101

Post UGN-101



UGN-101: 57% CR Rate from OLYMPUS Study Significantly Higher than Clinically Meaningful Hurdle



•All evaluated patients in CR remained disease free at six months**

- Of the patients who achieved CR, UroGen had six-month durability on half of these patients**
- Data consistent with Interim Analysis Presented at AUA in May 2018
- Safety profile in line with common urologic procedures; majority of AEs mild to moderate and transient and included:
 - Ureteral stricture and hydronephrosis, urinary tract infection, flank pain and creatinine elevation



*Full data readout will include a total of 71 patients **As of data announcement on January 8, 2019







UGN-101: Addressing an Unmet Need in LG UTUC

78%

Nephroureterectomies Performed in Patients with LG UTUC

UGN-101 has the potential to reduce repetitive endoscopic tumor resection or kidney and ureter removal



Kohut and Zhu (2012) JUrol

Current Journey Drives Recurrent Patients to Kidney Removal Monitoring Initial Presentation Radical nephroureterectomy (RNU) Preliminary **Evaluation** Repeated Patient Ureteroscopic Management* - -Diagnostic Ureteroscopy UroGer

Pharma

*Many patients treated with repeated ureteroscopy until RNU

LG UTUC Patient Overview

Median Age:

• 70 years old

Impact of RNU:

- Hospitalization & general anesthesia
- Quality of life, lifestyle, and activity reduction
- Significantly increased risk of CKD

Multiple comorbidities:

- Chronic Kidney Disease
- Hyperlipidemia
- Coronary Artery Disease
- Diabetes

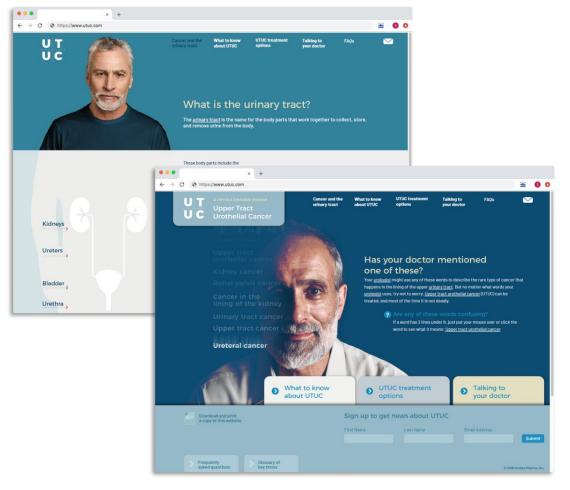
Educational Opportunity:

 Significant lack of patientfriendly education specific to UTUC





Education to Drive Adoption and Understanding of UGN-101



- UTUC.com: Designed to address a void in the urology space by educating patients about UTUC and available treatment options
- Medical Science Liaisons: hired and prepared to engage in education, scientific exchange and clinical support



Designed to Seamlessly Align with Urologic Practices

- Move care from OR to the office
- Provide physicians in general urologic practice with a simple-to-use, organ sparing approach to the management of LG UTUC

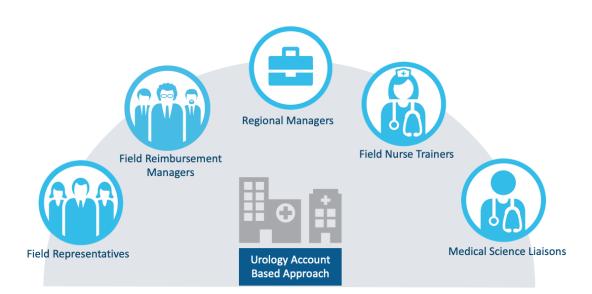
- Incorporate equipment and protocols standard to the urologic community
- Help urologists avoid short-term risks associated with surgery and anesthesia



Multifaceted, Targeted Approach to Support Uro-Oncology Practices

33% of Urology Practices Treat 90% of Patient Population

- Build awareness of the RTGel technology
- Generate/disseminate data to establish unmet need for a transformative treatment
- Develop end-to-end support program for seamless integration into practices
- Deploy a targeted, account-based approach
- Implement proactive strategy for reimbursement and access



Targeted approach lays groundwork for understanding of therapy, patient management and reimbursement



Engaging in a Proactive Market Access Strategy



Coverage and Reimbursement



UroGen Support

Defining Cost Burden to System for LG UTUC via HEOR Study

UGN-101 Has Potential to:

- <u>Reduce</u> risks of surgery and anesthesia
- <u>**Reduce</u>** high cost of surgery</u>
- <u>Reduce</u> post-operative complications & downtime
- <u>Reduce</u> need for dialysis, possible kidney transplant, chronic kidney disease-related morbidity



Preparation for Commercialization of UGN-101 Upon Approval



Current commercial plans optimized for UGN-101 and efficiently set the stage for UGN-102



UGN-102 (mitomycin gel) for intravesical instillation



UGN-102: Potential to be the First Primary Non-Surgical Chemoablative Therapy for BC

Rationale for Innovating NMIBC Treatment

- Potential to replace the standard of care (TURBT)
 - Large patient population
 - Relapse rates are high
 - Limited treatment options
- Drugs currently used only as adjuvant after surgery
- Last drug approved >15 years ago
- Moves care from OR to office
- Potential to decrease cost and morbidity of contemporary therapy

BLADDER CANCER

700,000 prevalence

81,000 incidence

LG NON-MUSCLE INVASIVE BLADDER CANCER

343,000 prevalence

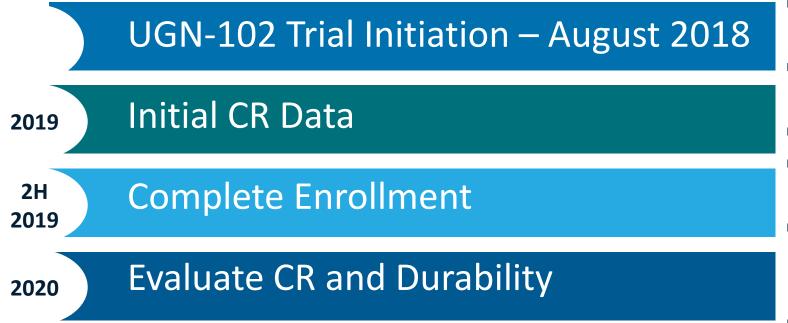
40,000 incidence

INTERMEDIATE RISK LG NMIBC

~80,000 (10-20% of total LG NMIBC population)



UGN-102: OPTIMA Trial Primary Chemoablation for Intermediate Risk LG NMIBC



- <u>Design</u>: Open-label, single-arm, Phase 2b trial
- Patient Group: "Intermediate Risk" LG NMIBC
- Number of Patients: 60 patients
- Treatment Regimen: Six weekly instillations of UGN-102
- Primary Efficacy Endpoint: CR at three months
 - Durability at 12-months also key
- Regulatory Pathway: 505(b)(2)

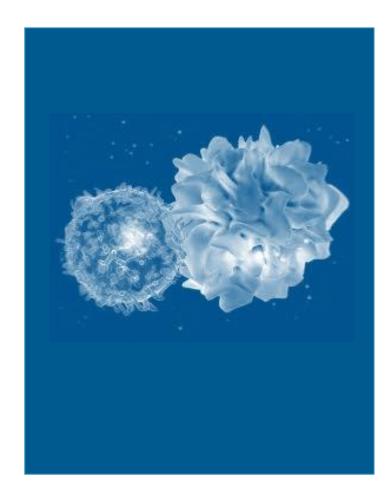


UGN-201 (imiquimod)



UGN-201: Leveraging the Platform in Immunotherapy

- Intriguing immunomodulatory asset
- Encouraging Phase 1b data in CIS suggests preliminary efficacy signal
- Pre-clinical Models Have Demonstrated Antitumor Effects of UGN-201 for High-Grade Disease
- Evaluating pathways to advance program to clinical trials





Allergan/BotuGel: Moving RTGel Beyond Oncology to OAB

Current BOTOX[®] Overactive Bladder (OAB) Sales: ~ \$500 Million

- Extends power of the platform with a new type of molecule
- Exclusive license agreement with Allergan for non-invasive approach to OAB
- Potential to replace multiple injections of BOTOX into the bladder with a single instillation
- Up to \$225 million (\$25 million already received) and tiered royalties on net sales







Intend to Drive Growth via Business Development Opportunities



Complementary technologies in uro-oncology

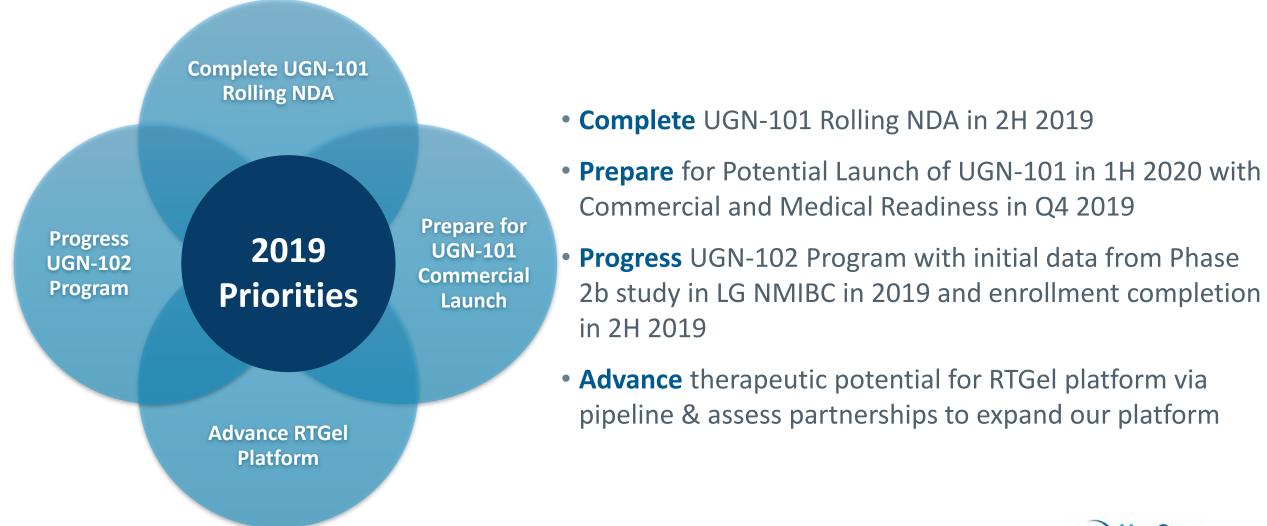
Novel molecules in combination with RTGel

Opportunities beyond uro-oncology and urology

Global Expansion



Strengthen UroGen's Position as a Global Leader in Uro-Oncology







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