INTERNATIONAL
BLADDER CANCER GROUP (IBCG)

IBCG

International Bladder Cancer Group

Newsletter

Volume 1
2024

Index

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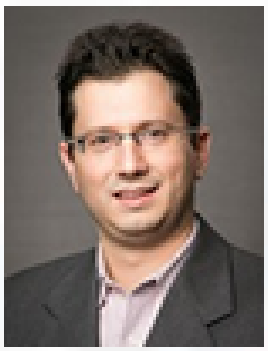

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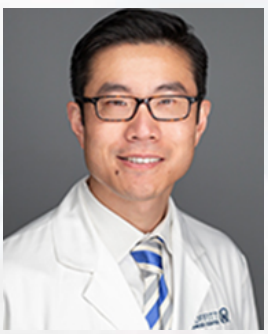
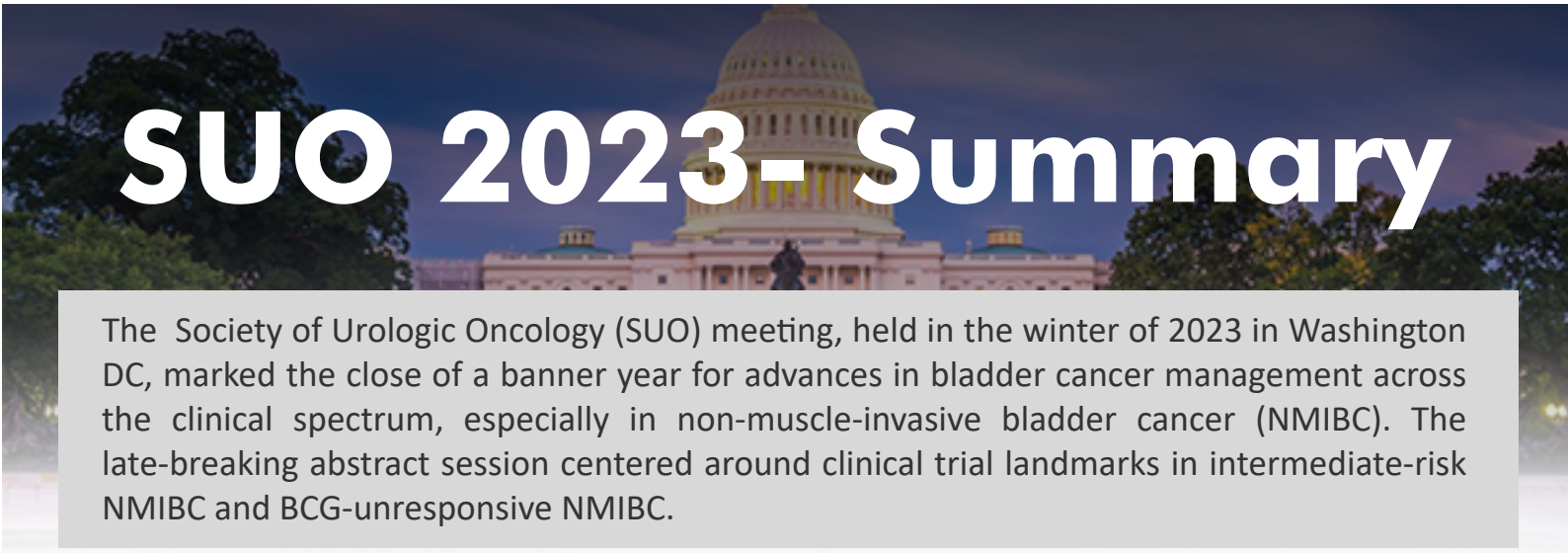


Roger Li, MD

Associate Professor - Department of Genitourinary Oncology H.LEE. MOFFIT Cancer Center

Articles



SUO 2023- Summary

The Society of Urologic Oncology (SUO) meeting, held in the winter of 2023 in Washington DC, marked the close of a banner year for advances in bladder cancer management across the clinical spectrum, especially in non-muscle-invasive bladder cancer (NMIBC). The late-breaking abstract session centered around clinical trial landmarks in intermediate-risk NMIBC and BCG-unresponsive NMIBC.

Sima Porten, MD, MPH, FACS

Associate Professor
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Results from the ENVISION trial, using primary chemoablation for recurrent low-grade (LG), intermediate-risk (IR) disease was discussed by Dr. Sandip Prasad. UGN-102 is a mitomycin-based reverse thermal gel that is not immediately excreted with urination, adheres to the bladder wall for 4–6 hours, and is currently used in the management of LG upper tract disease for organ preservation. LG IR patients (multifocal tumor, tumor volume >3 cm, and recurrent LG disease within 1 year) do not frequently progress to high-grade (HG)/invasive disease, but, due to higher recurrence rates, need multiple procedures and interventions. 240 patients were treated with induction course only (six weekly treatments) after surveillance cystoscopy, cytology, and biopsy were consistent with LG disease. The primary outcome was complete response (CR) at 3 months in this prospective single-arm, open-label trial. 79% of the patients experienced CR at 3 months and adverse events were primarily mild to moderate urinary complaints. As expected, a small proportion of the patients developed HG disease (2.5%). Importantly, the patient population in ENVISION reflected real-world management paradigms used to manage recurrent LGTa disease, especially if durability was sustained with additional follow-up.

Along with the ENVISION study, findings from the recently published Phase 3 ATLAS study were reported at an abstract session1. In contrast to ENVISION, ATLAS randomized patients to either UGN-102 +/- TURBT or TURBT alone (with no perioperative or adjuvant therapy). Although ATLAS included patients with IR disease (recurrent or newly diagnosed LGTa), 46% were patients with recurrent LGTa and 54% were newly diagnosed. The study was suspended early by the sponsor after 282 of the planned 632 patients were enrolled to pursue an alternate development strategy; so, the study results are primarily descriptive. In line with ENVISION, 65% of the patients treated with UGN-102 experienced CR at 3 months with good tolerability. In summary, primary chemoablation may be a viable treatment option in the toolbox to manage patients with LG IR disease, with more data to come with the currently enrolling Phase 3 ENVISION study.

For patients with BCG-unresponsive NMIBC (specifically CIS +/- papillary disease), the highly anticipated results of BOND-003 (intravesical Cretostimogene grenadenorepvec) were also shared at the late-breaking abstract session. Dr. Mark Tyson reported a 75.7% (95% CI 63–85%) CR rate at any time and a 63.6% (CI 51–75%) 6-month CR rate in this Phase 3, single-arm study. Cretostimogene is a highly immunogenic, conditionally replicating adenovirus with GM-CSF encoded with the insertion of the human EF2-1 promoter. Thus, it works both by viral replication in bladder cancer cells with tumor lysis and by concomitant immune stimulation of an anti-tumor response. In fact, 31% of the patients who did not have a response after induction (six weekly treatments) were salvaged with a second induction course. In patients who had a clinical CR, maintenance therapy is continued similarly to BCG at 3x weekly every 3 months for one year and then 3x weekly every 6 months in Year 2. Cretostimogene was very well tolerated with the majority of patients experiencing grades 1–2 urinary side effects. Additional data on durability will be presented this year (2024), including data on patients who have reached the 12-month mandatory biopsy assessment. The FDA has granted fast-track designation in BCG-unresponsive CIS +/- papillary disease, and the next phase of BOND-003 includes the extension of maintenance treatment to Year 3 and a purely BCG-unresponsive papillary cohort. With the support of the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC), Cretostimogene will expand into the adjuvant IR disease space with PIVOT-006.

For patients with Fibroblast Growth Factor Receptor (FGFR) alterations, two small cohorts from the THOR-2 study were presented in the abstract session, and demonstrated excellent efficacy and yet another potential treatment option for patients with NMIBC. FGFR alterations may function as oncogenic drivers in NMIBC, and are present in >50% of tumors. Erdafitinib is an oral, selective, pan-FGFR tyrosine kinase inhibitor, which is approved for adult patients with locally advanced or metastatic urothelial cancer and FGFR3/2 alterations, who have progressed during or following ≥1 line of platinum-containing chemotherapy2. THOR-2 is a multicohort Phase 2 study of erdafitinib in patients with high-risk NMIBC. Cohort 2 is an exploratory cohort of patients with BCG-unresponsive CIS who harbor FGFR alterations, with or without papillary disease, where a CR of 73% (8/11 patients) was achieved at 32 weeks. Cohort 3 is a marker lesion study in patients with IR disease and FGFR alterations with a CR of 83% (15/18 patients) durable at 12.7 months. Adverse events occurred in almost every patient with up to 38% with Grade 3 or higher, which may limit the use of erdafitinib in this patient population. To potentially reduce systemic toxicity and improve the risk/benefit ratio in patients with NMIBC, TAR-210, a novel intravesical delivery system to provide sustained, localized release of erdafitinib in the bladder, will be evaluated in upcoming trials.

Against the backdrop of these exciting clinical trials, current FDA-approved options for patients with BCG-unresponsive NMIBC are Keytruda® (pembrolizumab) and Adstiladrin® (nadofaragene firadenovec). Nadofaragene firadenovec-vncg is a non-replicating, adenoviral, vector-based gene therapy that delivers human interferon alpha-2b to urothelial cells. Initial results in 103 patients were presented in 2021 by Dr. Boorjian and colleagues with a reported CR of 53.4% at 3 months for patients with CIS +/- Ta/T1 papillary disease, with 46% maintaining this response at 12 months3. At SUO 2023, Dr. Boorjian reported mature follow-up results at 36 months after treatment with once every 3-month dosing for up to four doses. At 36 months, 26% of the patients who achieved CR at 3 months remained free of HG recurrence (14/55), with a median duration of CR of 9.7 months (95% CI 9.2–24 months). Cystectomy-free survival was 54% and 3-year overall survival was 90% in this cohort. Although intravesical nadofaragene firadenovec remains an important and novel treatment option for BCG-unresponsive NMIBC, the need for long-term follow-up and durability evaluation cannot be understated in this population, which maintained a high overall survival rate. As drug development accelerates, offering more treatment options for our patients, our focus will need to shift to logical sequencing of treatments in the pursuit of patient-focused outcomes, such as cystectomy-free survival.

In fact, this very topic was addressed by Dr. Jacob Taylor in the Young Urologic Oncologists (YUO) program, where bladder-sparing therapy was compared with upfront radical cystectomy in an international cohort of 578 BCG-unresponsive patients. Over 400 patients selected bladder-sparing therapy (a mix of various intravesical and systemic therapies) and 162 (who were more likely to have HGT1 disease) underwent upfront cystectomy. There were no statistically significant differences in overall, cancer-specific, or metastasis-free survival, and initial rates of metastasis and death were low, but increased after 12 months. Notably, 32% of the patients who initially proceeded with bladder-sparing therapy eventually needed cystectomy and had a higher upstaging rate. The 12-, 24-, and 60-month rates of metastasis were 2%, 7%, and 14%, respectively. Close surveillance is imperative as there is a real risk of disease recurrence and progression. It appears there is time to safely try bladder-preserving treatments in patients with BCG-unresponsive NMIBC: how many and in which order will need to be addressed in future studies. We look forward to the future and thank our colleagues, advocacy organizations, patients, and their families in their role as we journey closer to a cure for this disease.

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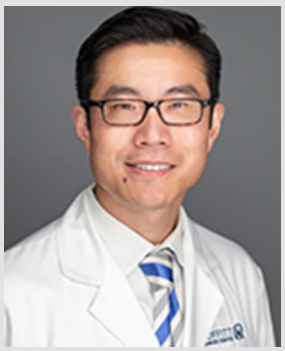
Late Breaking Abstract SUO 2023



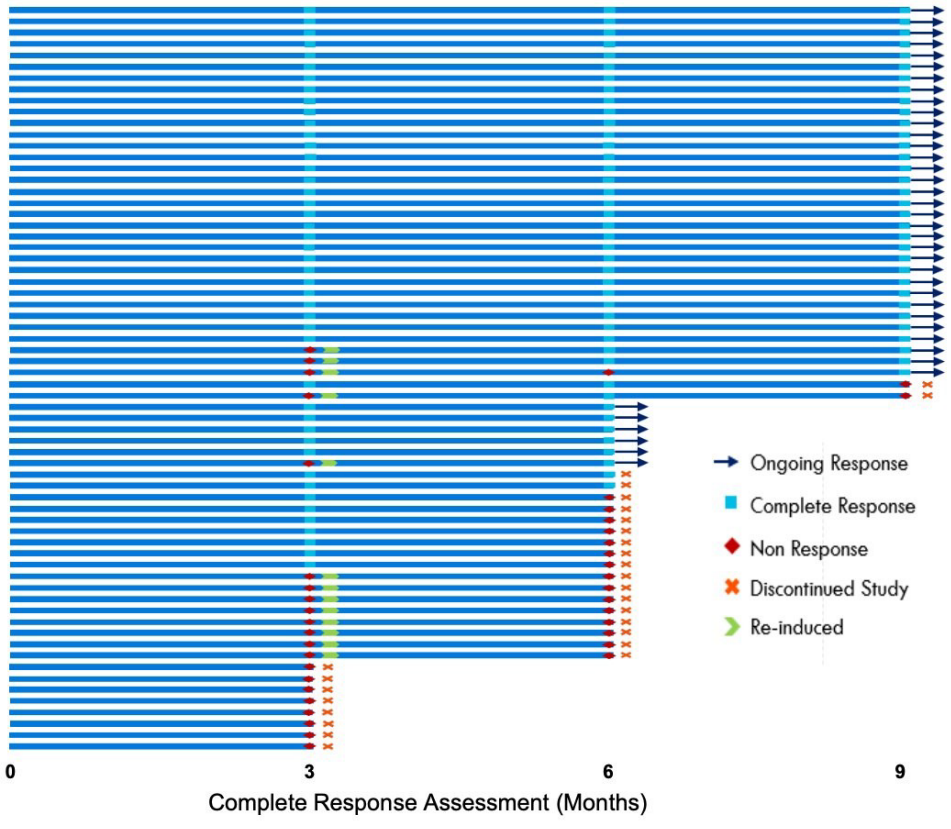
Roger Li, MD

Associate Professor - Department of Genitourinary Oncology H.LEE. MOFFIT Cancer Center

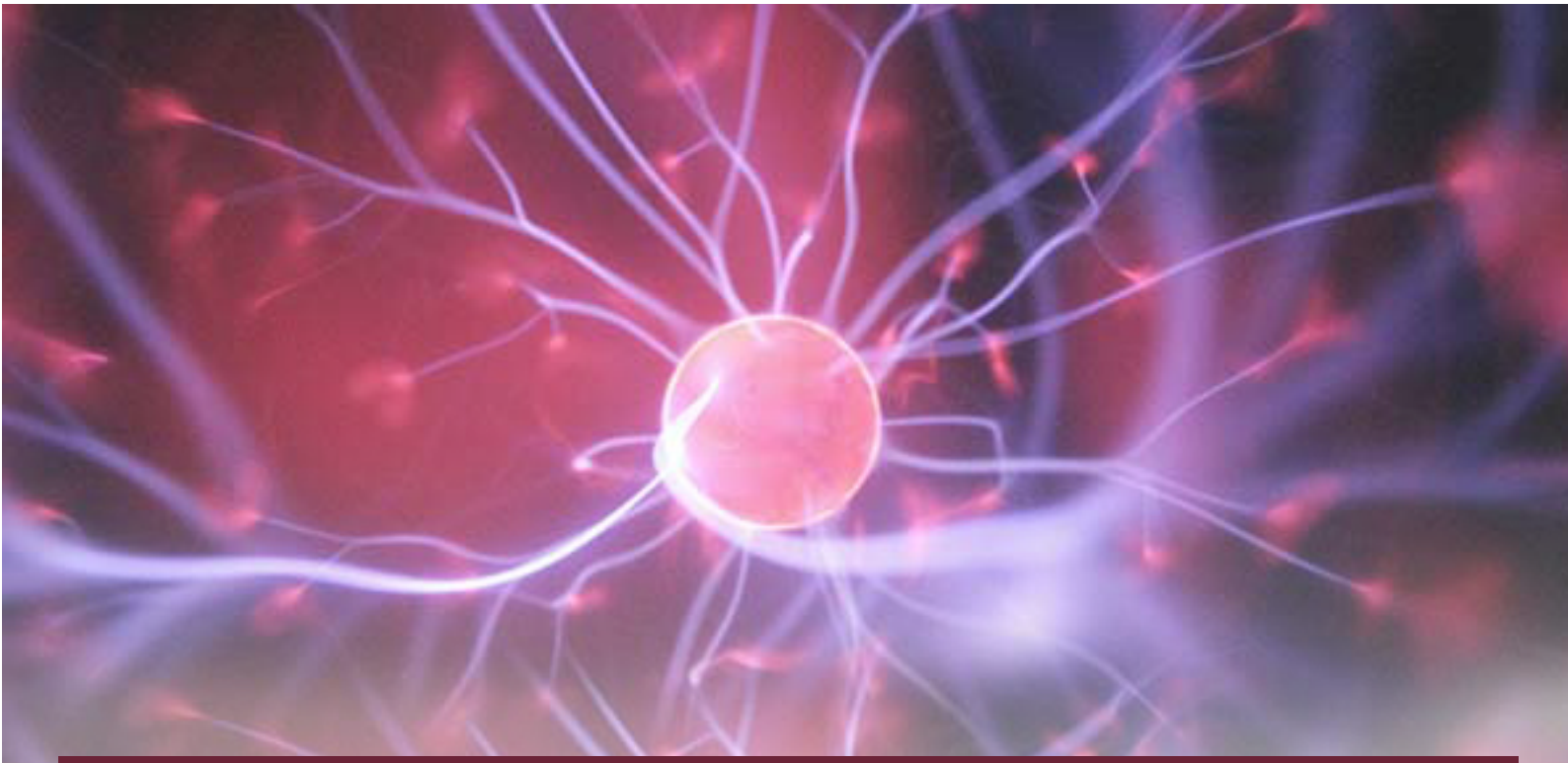
One of the two late-breaking abstracts presented at the Society of Urologic Oncology (SUO) 2023 was the first results from the BOND-003 trial, a Phase 3, single-arm, open-label study using intravesical Cretostimogene grenadenorepvec (CG0070) for patients with BCG-unresponsive carcinoma in situ (CIS). Cretostimogene is a conditionally replication-competent serotype Ad5 oncolytic virus, with high predilection for infecting cancer cells defective of the Rb pathway. This oncolytic virus also encodes a human GM-CSF transgene, aimed to recruit antigen-presenting dendritic cells to enhance anti-tumor immunity. Creto binds to the Coxsackie Adenovirus Receptor (CAR), and replicates when bound by free human E2F1 that accumulates in cancer cells. In previous Phase 1 and Phase2 studies, Cretostimogene has demonstrated safety and preliminary efficacy.

In the BOND-003 trial, 115 patients with BCG-unresponsive CIS were enrolled and treated with a 6-week induction followed by tri-weekly maintenance doses at a quarterly rate until Month 18. The primary endpoint of the study was complete response (CR) at any time, with patients having CIS/Ta HG recurrence at Month 3 eligible for re-induction. Among the first 66 evaluable patients, 75.7% (95% CI 63–85%) of the responders were able to derive CR at any time based on central review. Additionally, 74.4% (95% CI 58–86%) of the responders were able to maintain their response for ≥6 months. Of the patients who did not derive CR at Month 3, 31% were able to be salvaged with re-induction.

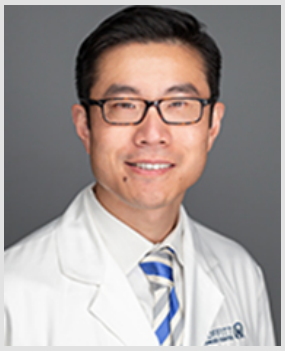
Cretostimogene was overall well tolerated, with most adverse events graded 1–2, with two patients (1.8%) having serious treatment-related adverse events (Grade 2). No grade ≥3 serious adverse events (SAEs) were reported, and no treatment discontinuation due to adverse events were recorded. Patient follow-up continues with anticipated data release at the American Urological Association (AUA) 2024 and SUO 2024.



On the heels of the results, CG Oncology successfully conducted its initial public offering in January 2024, becoming the first biotech company to go public in 2024. The company is planning on additional trials using Cretostimogene in the intermediate-risk non-muscle invasive bladder cancer (NMIBC) setting, as well as for patients with BCG-unresponsive papillary-only disease.



Patient identification and Plasma Circulating Tumor DNA (ctDNA)



Roger Li, MD

Associate Professor - Department of Genitourinary Oncology H.LEE. MOFFIT Cancer Center

The optimal selection of patients for neoadjuvant chemotherapy before surgical extirpation is hindered by the inadequacy of contemporary clinical staging methods in high-risk upper tract urothelial carcinoma (UTUC). Huelster et al performed a study aimed at assessing whether the identification of plasma circulating tumor DNA (ctDNA) can indicate muscle-invasive (MI) and non-organ-confined (NOC) UTUC.

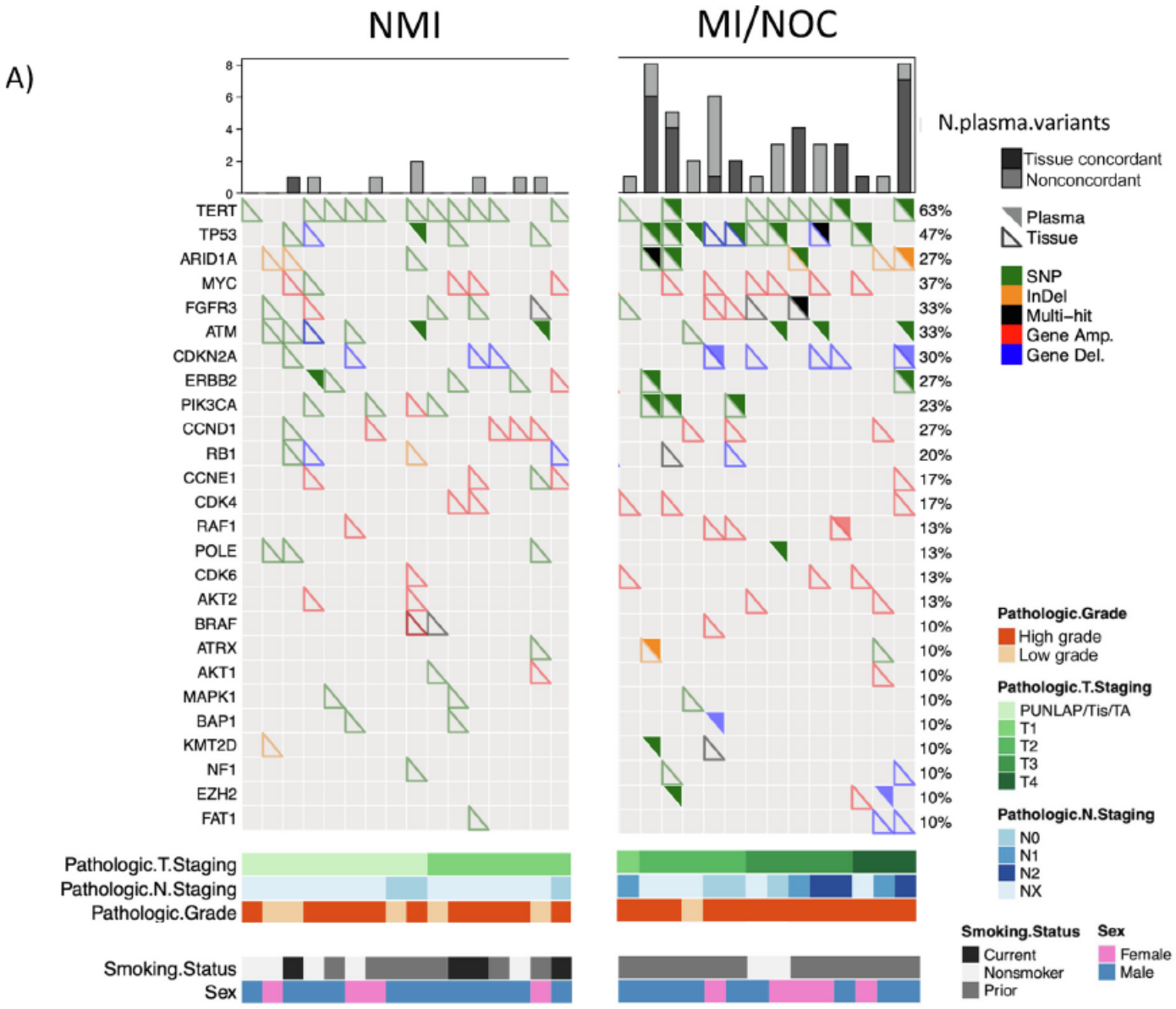
Plasma cell-free DNA was prospectively collected from chemotherapy-naive, high-risk UTUC patients undergoing surgical extirpation and subjected to sequencing using a 152-gene panel and low-pass whole-genome sequencing. Concordance testing involved whole-exome sequencing on corresponding tumor samples. The effectiveness of ctDNA in predicting MI/NOC UTUC was evaluated through the area under the receiver-operating cur ve, and a variant count threshold for predicting MI/NOC disease was established by maximizing Youden's J statistic. Survival analysis employed Kaplan-Meier methods, along with Mantel-Cox log-rank testing to assess the association between preoperative ctDNA positivity and clinical outcomes.

Of the 30 prospectively enrolled patients, 14 were diagnosed with MI/NOC UTUC. At least one ctDNA variant was detected in 21 of the 30 (70%) patients, exhibiting 52% concordance with matching tumor samples. The detection of at least two panel-based molecular

Patient identification and Plasma Circulating Tumor DNA (ctDNA)

alterations yielded 71% sensitivity at 94% specificity for predicting MI/NOC UTUC. Incorporating this threshold alongside a plasma copy number burden score of >6.5 increased the sensitivity to 79% at 94% specificity. Additionally, the presence of ctDNA significantly correlated with progression-free survival (PFS; 1-year PFS 69% vs 100%, p <0.001) and cancer-specific survival (CSS; 1-year CSS 56% vs 100%, p = 0.016).

The identification of plasma ctDNA before extirpative surgery exhibited high predictability for MI/NOC UTUC and a strong prognostic value for PFS and CSS. Preoperative ctDNA holds promise as a biomarker for selecting patients for neoadjuvant chemotherapy prior to nephroureterectomy. Future studies will incorporate the detection of ctDNA following surgical extirpation to assess minimal residual disease, to guide the implementation of adjuvant therapy. Additionally, specific alterations detected in the plasma prior to or following extirpative surgery may also serve as biomarkers for targeted/immune-based therapies.



Now in our 19th year, **the Bladder Cancer Advocacy Network has committed more than $10 million in research funding** to end bladder cancer. And we're just getting started.

At the Bladder Cancer Advocacy Network (BCAN), we believe that today's medical research is the engine that drives tomorrow's better lives for patients and those who love them.

Our goal is to identify the best and most promising medical research to advance our understanding of bladder cancer. BCAN awards grants to support early and seasoned investigators performing innovative research to develop lifesaving treatments and improve patient outcomes.

To learn more about BCAN's research program and grant funding, please visit **bcan.org/research**.

BCAN
Bladder Cancer Advocacy Network

Join us for our **Walks to End Bladder Cancer** in the Spring of 2024. Our in-person and virtual walks raise spirits and raise funds to defeat bladder cancer. Please visit **bcanwalk.org**.

Research - Bladder Cancer Imaging:

Shifting Toward Personalized Approaches

Martina Pecoraro, PhD Student

Sara Lucciola, Doctor of Medicine

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Bladder Cancer Imaging

Bladder cancer imaging research has experienced a boost in the last five years, and this is reflected in the yearly-based changes in the European urology guidelines1, especially those focused on muscle-invasive bladder tumor management2. Indeed, imaging modalities available for the diagnosis and staging of bladder cancer are many and each one can be utilized in a specific step of the diagnostic pathway.

For tumor detection, the most appropriate imaging technique is ultrasound. Ultrasound is a non-invasive, widely accessible imaging technique that can safely replace computerized tomography urography (CTU) for the assessment of kidneys and bladder in patients who have nonvisible hematuria3. On the other hand, CTU is used for evaluating the upper urothelial tract and excluding concomitant foci of urothelial tumors in the ureters and renal pelvis4.

For local staging, computed tomography (CT) is still being used as the imaging technique of choice, despite its variable accuracy, especially for the differentiation of T1 from T2 stage disease5, which increases with more advanced disease6. On the contrary, magnetic resonance imaging (MRI) has largely demonstrated its reproducible and accurate diagnostic performance for bladder cancer staging, since the Vesical Imaging-Reporting and Data System (VI-RADS) scoring system was developed7 in 2018. Indeed, provided its high-contrast resolution, MRI and VI-RADS allow an optimal differentiation of bladder wall layers, distinguishing the inner bladder layers—namely the urothelium and the lamina propria—from the muscularis propria8. Recently, a group of experts united to produce consensus-based statements on the management of bladder cancer, especially on the role of MRI in cancer care. In many of these statements, local staging experts recommend to acquire and interpret MRI images according to VI-RADS recommendations and always perform MRI before transurethral resection of bladder tumor (TURBT)9, which might revolutionize the way suspected muscle-invasive bladder cancer (MIBC) is managed, as it happened for prostate cancer10.

Nodal involvement is currently assessed using conventional imaging, including CT (usually)and MRI. However, as for other organs, cross-sectional imaging accuracy is not high enough and provides a slight concordance between clinical (cN) and pathological (pN) stages (sensitivity: 30%; specificity: 84%)11. This is the reason researchers have focused on exploring the feasibility and appropriateness of performing positron emission tomography (PET)/CT scans to evaluate nodal and distant staging. 18F-fluorodeoxyglucose (FDG) PET/CT is increasingly being used in clinical practice, but its exact role still needs to be further evaluated12. Bone scan should not be used routinely2 as it has no impact on patient management13.

Besides staging, imaging covers a pivotal role for the assessment of response to systemic therapy, for both chemotherapy and immunotherapy regimes2,14,15. Among all imaging modalities, MRI is the most promising in this setting, especially if reported using a modified version of the VI-RADS score, nac-VIRADS16. Experts agreed upon MRI's performance in assessing the response to systemic therapy to select patients for radical treatment, surveillance, and bladder-sparing surgery9.

The bladder imaging landscape is facing a time of profound changes, despite barriers such as imaging-related costs, insurance approval when needed, accessibility to facilities, and patient or doctor acceptance. The preoperative and postoperative management of bladder cancer is destined to shift toward a more personalized approach.

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AUA 2024 San Antonio MAY 3-6

AUA 2024- IBCG – Bladder Cancer Forum

AUA-IBCG Bladder Cancer Forum

Sunday, May 5, 2024 | 2 – 5 p.m. Hemisfair Ballroom 2

Program Chairs: Ashish Kamat, MD & Janet Baack Kukreja, MD, MPH, FACS

2:00 p.m. **Introduction & Pre-Test**
Ashish Kamat, Janet Kukreja

2:10 p.m. **Role of Urinary Markers in Surveillance of NMIBC Patients:**
Moderator: Yair Lotan
Debater: Kamal Pohar *(No role, cytology and cysto (+/- NBI, Flex BLC) sufficient)*
Debater: Kelly Bree *(Yes, urinary markers have a defined role)*

2:30 p.m. **Optimal TURBT: Do Skilled Urologists Really need to Perform reTUR for all HG Patients?** Moderator: Neal Shore
Debater: Jeremy Teoh *(No, en bloc and PDD are sufficient)*
Debater: Badrinath Konety *(Yes)*

2:50 p.m. **Management of Recurrent LG Intermediate Risk Bladder Tumors** Moderator: Robert Svatek
Debater: Sarah Psutka *(Time to de-escalate therapy - ablate or observe)*
Debater: Paramananthan Mariappan *(TURBT + Adjuvant therapy Needed)*

3:10 p.m. **Very High Risk NMIBC with Variant Histology**
Moderator: Juan Palou
Debater: Paolo Gontero *(Radical Cystectomy is best option)*
Debater: Michael Cookson *(Intravesical Therapy is best option)*

3:30 p.m. **BCG Unresponsive Disease: How Much Risk can my Patient Tolerate?**
Moderator: Alex Zlotta
Debater: Sima Porten *(One line of therapy before proceeding to RC)*
Debater: Roger Li *(Sequential therapies should be offered)*

3:50 p.m. **Can we Settle the Debate on PLND in Radical Cystectomy?**
Moderator: John Taylor
Debater: Seth Lerner *(Yes! Standard PLND should be SOC)*
Debater: Siamak Daneshmand *(No, EPLND still has a role)*

4:10 p.m. **Can I use Markers and Imaging to Avoid Local Consolidation for Patient who is cT0 after Neoadjuvant Chemo or IO?**
Moderator: Stephen B. Williams
Debater: Arnulf Stenzl *(No, Radical Cystectomy/XRT is needed)*
Debater: Petros Grivas *(Yes, urinary markers have a defined role)*

4:30 p.m. **First Line Therapy for Locally Advanced/Metastatic UC in 2024**
Moderator: Andrea Necchi
Debater: Karima Oualla *(EV+Pembro should be SOC)*
Debater: Shilpa Gupta *(Ciplatinum based chemo still optimal)*

4:50 p.m. **Closing Remarks and Post-Test**
Ashish Kamat, Janet Baack Kukreja

SIU Announcement

WE BRING UROLOGISTS TOGETHER

INTERNATIONAL
BLADDER CANCER GROUP(IBCG)

Société Internationale d'Urologie (SIU) announced that IBCG will hold a Masterclass in Non-Muscle Invasive Bladder Cancer at the 44th Congress to the held from October 23 to 26, 2024 in New Delhi, India.

Title -International Bladder Cancer Group (IBCG) Masterclass in Non -Muscle Invasive Bladder Cancer (NMIBC)

Chair - Shilpa Gupta, MD

Clevland Clinic Foundation - Ohio, USA

Panel Members

Ashish Kamat, MD
MD Anderson Cancer Center
Houston, US

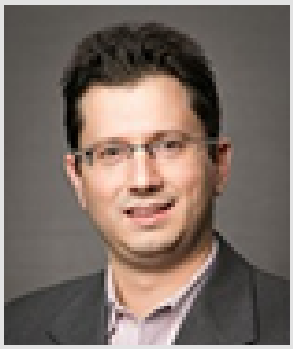
Andrea Necchi, MD
San Raffaele Research Hospital
Milan, Italy

Gagan Prakash, MD
Tata Memorial Centre
Mumbai- India

Instructional Course Description

NMIBC is a common and high burden bladder cancer state, and an unmet need exists to advance treatments and maintain quality of life of patients worldwide. The IBCG Masterclass in NMIBC will review the risk classification of NMIBC, its nuances and how to select patients for the right approach and go over the novel treatments and strategies to allow bladder preservation for BCG-unresponsive NMIBC. Dr. Gupta will present clinical cases for discussion with panelists, to get a global perspective on how experts would manage a clinical case.

GU ASCO 2024
Summary



Petros Grivas, MD, PhD

Professor, Department of Medicine, Division of Hematology and Oncology
Clinical Director, Genitourinary Cancers Program, University of Washington
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Bladder cancer is a critical health challenge globally with major burden on patients and families worldwide (estimated 82,290 new cases and 16,710 attributable deaths expected in 2023 in the US only). At the very exciting GU ASCO 2024 symposium, we saw intriguing data, including from practice-impacting trials, along with a broad repertoire/wide spectrum from biomarker-based studies with translational impact, from outcome studies to other interesting, but non-practice-changing trials. We highly encourage readers to review the virtual program, including presentations and discussions. Below, I highlight two key presentations (not an exhaustive list).

The Ambassador (Alliance A031501) Phase 3 trial data was presented by Dr. Andrea Apolo and colleagues (abstract LBA531). Eligible patients with muscle-invasive urothelial carcinoma (MIUC) of the lower or upper tract, who were 4–16 weeks post radical surgery, e.g., cystectomy or (nephro)ureterectomy, with the following pathologic findings were included:

- After neoadjuvant chemotherapy: ≥ypT2-4 and/or ypN+ stage
- Cisplatin-ineligible or -refusing patients: ≥pT3 and/or pN+ stage

Patients were randomized 1:1 to pembrolizumab for up to a year vs observation (active surveillance); dual primary endpoints were disease-free and overall survival. Key secondary endpoints were survival by PD-L1 status and toxicity/safety. Overall, 702 of the planned 734 patients were enrolled (the trial closed early due to the FDA approval of adjuvant nivolumab in MIUC in August 2021). At a median follow-up of 22 months, pembrolizumab prolonged Disease Free Survival (DFS) in the intent-to-treat population from 14 to 29 months (HR 0.69, 95% CI 0.54–0.87, p = 0.001). The DFS benefit was noted regardless of PD-L1 expression. In exploratory subgroup analyses, the DFS benefit appeared significant in patients with bladder cancer but remained uncertain in those with upper tract primary tumors (HR 1.05, 95% CI 0.61–1.82). This subset was underpowered with a low number of patients and events. This challenge of an underpowered subset analysis for upper tract tumors was also noted in the Checkmate 274 trial and underscores the need for dedicated upper tract trials, e.g., EA8192, POUT, and PROOF-302. At the time of presentation, the interim Overall Survival (OS) analyses did not show any benefit with adjuvant pembrolizumab (HR 0.98, 95% CI 0.76–1.26, p = 0.88). While the OS data is based on an interim analysis (not final), it seems unlikely that a significant OS benefit will be shown in this trial. However, OS can be impacted by censoring, “drop out” rate, crossover to checkpoint inhibitor before recurrence, access to subsequent/salvage therapies upon recurrence, and duration of follow-up, among other factors. Further follow-up continues for final survival analyses, ctDNA analyses, and additional correlative biomarkers. Overall, the results support adjuvant pembrolizumab as a new therapeutic option for patients with MIUC with a high recurrence risk, and relatively align with the findings from the Checkmate 274 trial (as opposed to the IMvigor010 trial).

Data from the EV-302 trial had been presented at the 2023 ESMO Congress, and we saw updated results also across patient subsets at the GU ASCO 2024 symposium. EV-302 has been an international, Phase 3, randomized clinical trial of 886 patients with previously untreated advanced/metastatic urothelial carcinoma, eligible for platinum-based chemotherapy, who were randomized (1:1) to gemcitabine + (cisplatin or carboplatin) for up to six cycles or enfortumab vedotin (EV) + pembrolizumab (P). Co-primary endpoints were Progression Free Survival (PFS) and OS; secondary endpoints included Overall Response Rate (ORR) and safety. A median PFS of 12.5 vs 6.3 months (HR 0.45, 95% CI 0.38–0.54) and a median OS of 31.5 vs 16.1 months (HR 0.47, 95% CI 0.38–0.58) strongly favored EV/P. ORR was 68% and 44%, while ≥G3 therapy-related adverse events occurred in approximately 56% and 70% with EV/P and platinum-based chemotherapy, respectively. Only about a third of the patients received switch maintenance anti-PD-L1 before progression, and 60% received anti-PD-L1 at any point in time in the chemotherapy group. The data was very impressive and transformative with subsequent regular FDA approval of EV/P for patients with advanced/metastatic urothelial carcinoma regardless of cisplatin eligibility (December 2023). At the GU ASCO 2024 symposium, we saw that the survival benefit strongly favored EV/P across several patient subsets as presented by Dr. Michiel Van der Heijden and colleagues (abstract LBA530). The data was also placed in context with other first-line trials that had met their primary endpoints, e.g., Checkmate 901 and JavelinBladder100. Access to EV/P outside the US was also discussed in detail, especially in the context of broad efforts to reduce geographical disparities in accessing life-prolonging therapies. The issue of disparities and the need for diversity, equity, and inclusion across genitourinary oncology (GU) was also the theme of the exceptional keynote lecture by Dr. Cheryl T Lee (Charting new paths: Increasing patient representation in genitourinary malignancy trials).

Several other sessions, podium/poster presentations, and discussions were outstanding and worth reviewing in the virtual platform. We thank all the presenters, discussants, chairs, and moderators, as well as the patients, families, and advocates for their vital role in the studies and the progress made.