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Congress Coverage: ASCO GU 2022 Highlights

February 22, 2022

Report Contents

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Meeting Snapshot

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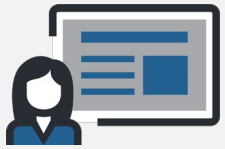
VIRTUAL CLOSED-DOOR ROUNDTABLE

DATE:
February 22, 2022



DISEASE STATE AND DATA PRESENTATIONS by key experts

INSIGHTS REPORT including postmeeting analyses and actionable recommendations

PANEL: Key experts in GU malignancies

- > 7 from US
- > 1 from Europe

GU CANCER-SPECIFIC DISCUSSIONS on therapeutic advances and their application in clinical decision-making

Panel Consisting of 7 US and 1 EU GU Cancer Experts

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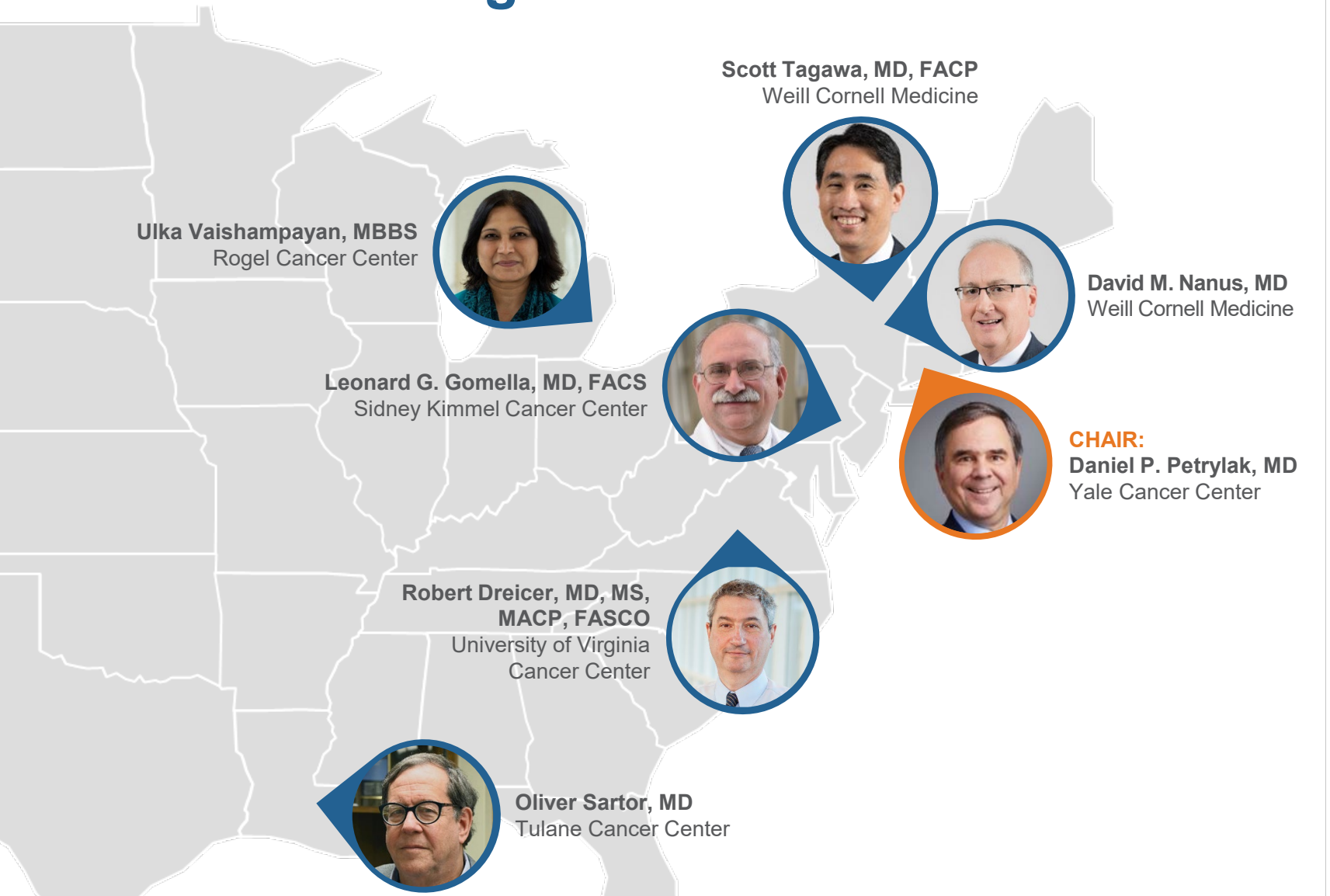

Scott Tagawa, MD, FACP
Weill Cornell Medicine

Ulka Vaishampayan, MBBS
Rogel Cancer Center

David M. Nanus, MD
Weill Cornell Medicine

Leonard G. Gomella, MD, FACS
Sidney Kimmel Cancer Center

CHAIR:
Daniel P. Petrylak, MD
Yale Cancer Center

Robert Dreicer, MD, MS, MACP, FASCO
University of Virginia Cancer Center

Karim Fizazi, MD, PhD
Gustave Roussy Institute

Oliver Sartor, MD
Tulane Cancer Center

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Meeting Agenda

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Time (EST)	Topic	Speaker/Moderator
8.30 AM – 8.35 AM	Welcome and Introductions	Daniel Petrylak, MD
8.35 AM – 8.45 AM	Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies	Oliver Sartor, MD
8.45 AM – 9.05 AM	Discussion and Key Takeaways	
9.05 AM – 9.15 AM	Prostate Cancer Part 2 – Targeted Therapies	Karim Fizazi, MD, PhD
9.15 AM – 9.35 AM	Discussion and Key Takeaways	
9.35 AM – 9.45 AM	Bladder Cancer Part 1 – ADCs	Scott Tagawa, MD, FACP
9.45 AM – 10.00 AM	Discussion and Key Takeaways	
10.00 AM – 10.10 AM	Break	
10.10 AM – 10.20 AM	Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies	Robert Dreicer, MD, MS, MACP, FASCO Leonard Gomella, MD, FACS
10.20 AM – 10.45 AM	Discussion and Key Takeaways	
10.45 AM – 11.00 AM	Renal Cell Carcinoma	David Nanus, MD Ulka Vaishampayan, MBBS
11.00 AM – 11.25 AM	Discussion and Key Takeaways	
11.25 AM – 11.30 AM	Summary and Closing Remarks	Daniel Petrylak, MD

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Congress Highlights

Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies

Overall survival with darolutamide versus placebo in combination with ADT and docetaxel for mHSPC in the phase 3 ARASENS trial

Smith, et al. 2022, ASCO GU 13

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STUDY POPULATION

> 1306 pts with mHSPC were randomized to darolutamide or

OVERALL SURVIVAL

PEACE-1: Bone mineral density in men with de novo mCSPC treated with or without abiraterone plus prednisone

Roubaud, et al. 2022, ASCO GU 19

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Randomized phase II trial of neoadjuvant abiraterone plus or minus cabazitaxel in high-risk prostate cancer: ACDC-RP

Fleshner, et al. 2022, ASCO GU 224

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PRESIDE: A phase 3b study of continuing enzalutamide with docetaxel in chemotherapy-naïve mCRPC after progression on enzalutamide

Merseburger, et al. 2022, ASCO GU 15

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Key Insights

Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies

Experts Debated the Role of Triplet Therapy for Patients With mHSPC

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ARASENS

Results from the ARASENS trial showing an improvement in OS when darolutamide was

Experts Discussed the Broader Implications of the ARASENS and PEACE-1 Trials

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POTENTIAL BIOMARKERS

Experts would like to see the data from PEACE-1 and ARASENS analyzed by whether patients

Experts Discussed Investigational Strategies Combining Chemotherapy With Hormonal Agents

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NEOADJUVANT CABAZITAXEL PLUS ABIRATERONE

The randomized phase II neoadjuvant trial investigating the addition of cabazitaxel to

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Congress Highlights

Prostate Cancer Part 2 – Targeted Therapies

Phase 3 MAGNITUDE study: Niraparib + abiraterone as 1L therapy in mCRPC with and without HRR gene alterations

Chi, et al. 2022, ASCO GU 12

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STUDY POPULATION

OUTCOMES

EXPERT CONCLUSIONS

PROpel: Phase III trial of olaparib/placebo plus abiraterone 1L therapy for patients with mCRPC

Saad, et al. 2022, ASCO GU 11

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STUDY POPULATION

- [illegible]

OUTCOME

- [illegible]

EXPERT CONCLUSIONS

[illegible]

Phase 1/2 study of ARV-110, an androgen receptor PROTAC degrader, in mCRPC

Gao, et al. 2022, ASCO GU 17

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Phase 1 results of the ODM-208 first-in-human phase 1-2 trial in patients with mCRPC (CYPIDES)

Fizazi, et al. 2022, ASCO GU 18

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STUDY POPULATION

- [illegible]

OUTCOME

- [illegible]

EXPERT CONCLUSIONS

[illegible]

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Key Insights

Prostate Cancer Part 2 – Targeted Therapies

Experts Debated Results of First-Line Trials of PARP Inhibitors Plus Abiraterone for mCRPC

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MAGNITUDE AND PROpel

Experts consider the results of the PROpel and MAGNITUDE trials showing that

Experts Discussed Considerations for Future First-Line Hormonal Therapy Trials for mCRPC

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FUTURE STUDIES AND PRACTICAL IMPLICATIONS

First-line hormonal therapy trials for antiandrogen-naive mCRPC such as MAGNITUDE

Experts Assessed Novel AR-Targeted Agents for mCRPC

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ARV-110

Experts were enthusiastic about the activity ARV-110, noting it appears to be more active against

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Bladder Cancer Part 1 – ADCs

TROPHY-U-01 Cohort 3: Sacituzumab govitecan plus pembrolizumab in patients with mUC that progressed after platinum-based regimens

Grivas, et al. 2022, ASCO GU 434

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Study EV-103 Cohort H: Neoadjuvant treatment with enfortumab vedotin monotherapy in patients with MIBC who are cisplatin-ineligible

Petrylak, et al. 2022, ASCO GU 435

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DS8201-A-U105: A phase 1b study of trastuzumab deruxtecan (T-DXd) with nivolumab in patients with HER2-expressing urothelial carcinoma

Galsky, et al. 2022, ASCO GU 438

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STUDY POPULATION

- [illegible]

OUTCOME

- [illegible]

EXPERT CONCLUSIONS

[illegible]

RC48-C014: Preliminary results of RC48-ADC combined with toripalimab in patients with locally advanced or metastatic urothelial carcinoma

Zhou, et al. 2022, ASCO GU 515

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Key Insights

Bladder Cancer Part 1 – ADCs

Experts Assessed Investigational Approaches Utilizing ADCs Currently in Use for mUC

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SACITUZUMAB GOVITECAN PLUS PEMBROLIZUMAB

The activity of SG plus pembrolizumab in platinum-pretreated mUC is considered interesting, but

Experts Discussed HER2-Targeted ADCs in Combination With Immune Checkpoint Inhibitors for HER2+ mUC

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TRASTUZUMAB DERUXTECAN AND RC48-C014

Results of the 2 studies suggest the HER2-targeted ADCs (trastuzumab deruxtecan

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Congress Highlights

Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies

Phase 3 results in both CIS and papillary cohorts BCG-unresponsive NMIBC after IL-15RαFc superagonist N-803 and BCG infusion

Chang, et al. 2022, ASCO GU 431

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A randomized, biomarker selected, phase II trial of maintenance PARPi following chemotherapy for mUC: the ATLANTIS rucaparib arm

Crabb, et al. 2022, ASCO GU 436

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Meet-URO 12: BSC +/- niraparib as maintenance in patients with mUC whose disease did not progress after 1L platinum-based chemotherapy

Vignani, et al. 2022, ASCO GU 442

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ARIES: First line avelumab in patients with PD-L1+ve metastatic or locally advanced UC unfit for cisplatin

Iacovelli, et al. 2022, ASCO GU 439

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BAYOU: A phase II, randomized study of durvalumab plus olaparib for the 1L treatment of platinum-ineligible unresectable, stage IV UC

Rosenberg, et al. 2022, ASCO GU 437

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Avelumab 1L maintenance for advanced UC: Long-term follow-up results from the JAVELIN Bladder 100 trial

Powles, et al. 2022, ASCO GU 438

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STUDY POPULATION

- [redacted]

OUTCOME

- [redacted]

EXPERT CONCLUSIONS

[redacted]

Avelumab 1L maintenance + BSC versus BSC alone in Asian patients with advanced UC: JAVELIN Bladder 100 subgroup analysis

Eto, et al. 2022, ASCO GU 486

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Key Insights

Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies

Experts Discussed Investigational Strategies for BCG-Unresponsive NMIBC

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INTRAVESICAL THERAPIES

Experts found the results of the QUILT 3.032 trial evaluating the IL-15RαFc superagonist N-803 plus

Experts Reviewed Immune Checkpoint Inhibitors for mUC

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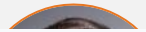
MAINTENANCE AVELUMAB

Experts were happy to see the longer follow-up of the JAVELIN Bladder 100 trial confirming prior



Experts Assessed the Data With PARP Inhibitors for mUC

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ATLANTIS, Meet-URO 12, AND BAYOU

Efficacy results from the ATLANTIS and Meet-URO 12 trials evaluating maintenance

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Renal Cell Carcinoma

NeoAvAx: Neoadjuvant avelumab/axitinib in patients with localized RCC who are at high risk of relapse after nephrectomy

Bex, et al. 2022, ASCO GU 289

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Pembrolizumab as post nephrectomy adjuvant therapy for patients with RCC: 30-month follow-up results of KEYNOTE-564

Choueiri, et al. 2022, ASCO GU 290

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A phase I/II study of nivolumab and axitinib in patients with advanced renal cell carcinoma

Zibelman, et al. 2022, ASCO GU 291

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Novel predictive biomarkers of response to immune checkpoint blockade with nivolumab ± ipilimumab in the TITAN-RCC phase 2 trial

Grimm, et al. 2022, ASCO GU 367

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Final OS analysis in CheckMate 9ER: Nivolumab plus cabozantinib versus sunitinib for patients with aRCC

Powles, et al. 2022, ASCO GU 350

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HRQoL in previously untreated patients with aRCC: CheckMate 9ER updated results

Cella, et al. 2022, ASCO GU 285

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HRQoL in previously untreated patients with aRCC in CheckMate 214: Five-year follow-up results

Cella, et al. 2022, ASCO GU 307

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Initial results from the phase 1 study of ARO-HIF2 to silence HIF2-alpha in patients with advanced ccRCC (AROHIF21001)

Brugarolas, et al. 2022, ASCO GU 339

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Key Insights

Renal Cell Carcinoma

Experts Reviewed Data From Adjuvant and Neoadjuvant Trials for RCC

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KEYNOTE-564

Updated results from KEYNOTE-564 show an increasing DFS benefit with adjuvant

Experts Discussed First-Line Therapies for mRCC

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QUALITY OF LIFE ANALYSES

The QOL data from CheckMate 9ER and 214 show that disease-specific QOL improves with

Experts Assessed Novel Agents and Biomarkers for mRCC

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ARO-HIF2

Preliminary data from the phase I study suggest this HIF2-alpha–targeted agent has