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EPICS

GENITOURINARY (GU) MALIGNANCIES IN 2021 AND BEYOND

December 7 and 8, 2021

Report Contents

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Meeting Snapshot

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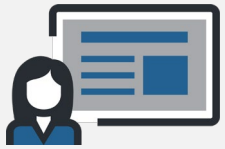
VIRTUAL CLOSED-DOOR ROUNDTABLE

DATE:
December 7 and 8, 2021



DISEASE STATE AND DATA PRESENTATIONS by key experts

INSIGHTS REPORT including postmeeting analyses and actionable recommendations

PANEL: Key experts in GU cancers

> 9 from US

GENITOURINARY CANCER-SPECIFIC DISCUSSIONS on therapeutic advances and their application into clinical decision-making

Panel Consisting of 9 US GU Cancer Experts

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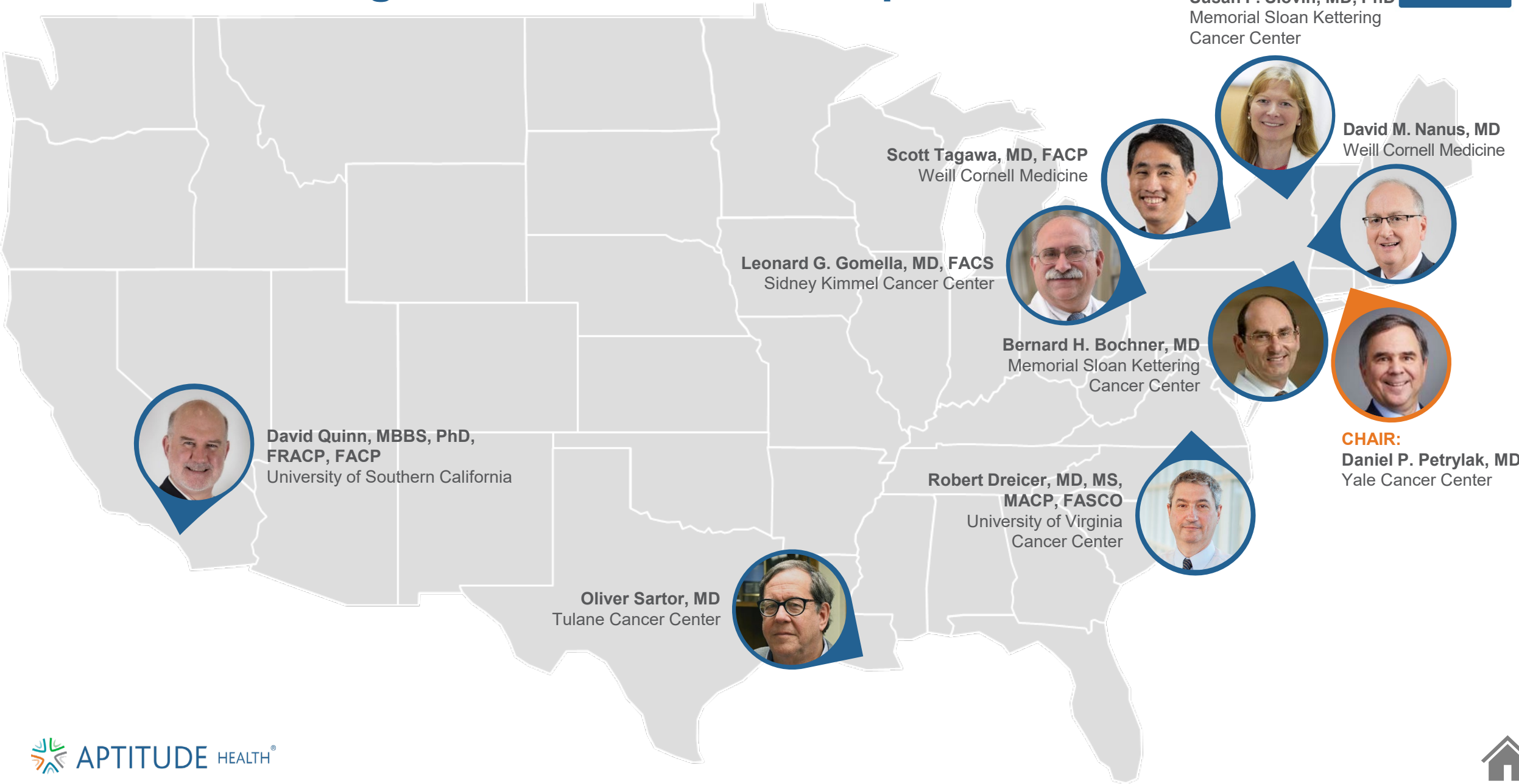

Susan F. Slovin, MD, PhD
Memorial Sloan Kettering Cancer Center

David M. Nanus, MD
Weill Cornell Medicine

Scott Tagawa, MD, FACP
Weill Cornell Medicine

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

Bernard H. Bochner, MD
Memorial Sloan Kettering Cancer Center

CHAIR:
Daniel P. Petrylak, MD
Yale Cancer Center

David Quinn, MBBS, PhD, FRACP, FACP
University of Southern California

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

Oliver Sartor, MD
Tulane Cancer Center

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Agenda (Day 1)

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Time	Topic	Speaker/Moderator
4.00 PM – 4.05 PM	**Welcome and Introductions**	Daniel Petrylak, MD
4.05 PM – 4.15 PM	**Advances in Imaging Technologies for GU Cancers**	Leonard G. Gomella, MD, FACS
4.15 PM – 4.35 PM	***Key Questions and Topics for Discussion***	All
4.35 PM – 4.40 PM	**Summary and Key Takeaways**	
4.40 PM – 4.50 PM	**Diagnosing and Managing Localized/Locally Advanced Prostate Cancer**	Susan Slovin, MD, PhD
4.50 PM – 5.10 PM	***Key Questions and Topics for Discussion***	
5.10 PM – 5.15 PM	**Summary and Key Takeaways**	
5.15 PM – 5.30 PM	**Treatment Paradigms for Advanced Prostate Cancer**	Oliver Sartor, MD
5.30 PM – 6.05 PM	***Key Questions and Topics for Discussion***	All
6.05 PM – 6.10 PM	**Summary and Key Takeaways**	
6.10 PM – 6.20 PM	**BREAK**	
6.20 PM – 6.35 PM	**Investigational Therapies for Metastatic CRPC**	Scott Tagawa, MD, MS, FACP
6.35 PM – 7.05 PM	***Key Questions and Topics for Discussion***	All
7.05 PM – 7.10 PM	**Summary and Key Takeaways**	
7.10 PM – 7.25 PM	**Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC)**	Bernard Bochner, MD, FACS
7.25 PM – 7.50 PM	***Key Questions and Topics for Discussion***	All
7.50 PM – 7.55 PM	**Summary and Key Takeaways**	
7.55 PM – 8.00 PM	**Conclusions and Wrap-up**	Daniel Petrylak, MD

Agenda (Day 2)

EPICS

Time	Topic	Speaker/Moderator
4.00 PM – 4.05 PM	**Welcome and Introductions**	Daniel Petrylak, MD
4.05 PM – 4.20 PM	**Current Paradigms and Future Directions in Metastatic Bladder Cancer**	Robert Dreicer, MD, MS, MACP, FASCO
4.20 PM – 5.05 PM	***Key Questions and Topics for Discussion***	
5.05 PM – 5.10 PM	**Summary and Key Takeaways**	
5.10 PM – 5.25 PM	**Evolving Paradigms for Metastatic RCC**	David Nanus, MD
5.25 PM – 6.10 PM	***Key Questions and Topics for Discussion***	All
6.10 PM – 6.15 PM	**Summary and Key Takeaways**	
6.15 PM – 6.25 PM	**BREAK**	
6.25 PM – 6.40 PM	**Neo/Adjuvant Treatment of RCC**	David Quinn, MBBS, PhD, FRACP, FACP
6.40 PM – 7.05 PM	***Key Questions and Topics for Discussion***	
7.05 PM – 7.10 PM	**Summary and Key Takeaways**	
7.10 PM – 7.20 PM	**Current and Future Management of Non-clear Cell RCC**	David Quinn, MBBS, PhD, FRACP, FACP
7.20 PM – 7.45 PM	***Key Questions and Topics for Discussion***	All
7.45 PM – 7.50 PM	**Summary and Key Takeaways**	
7.50 PM – 8.00 PM	**Wrap-up and Adjourn**	Daniel Petrylak, MD

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Summary of Faculty Presentations and Key Insights

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Advances in Imaging Technologies for GU Cancers

Advances in Imaging Technologies for GU Cancers (1/2)

Presented by Leonard G. Gomella, MD, FACS

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IMAGING OPTIONS FOR PROSTATE CANCER ARE RAPIDLY EXPANDING

Advances in Imaging Technologies for GU Cancers (2/2)

Presented by Leonard G. Gomella, MD, FACS

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PSMA-TARGETED PET IMAGING

STUDY POPULATION

- [redacted]

OUTCOME

- [redacted]

EXPERT CONCLUSIONS

[redacted]

RESEARCH AND FUTURE DIRECTIONS

[redacted]

RESPONSE INDICATORS ACROSS ANALYSIS PERIODS

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Key Insights

Imaging Technologies for GU Cancers

Experts Debated the Evolving Role for PSMA PET Scans in Prostate Cancer

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POTENTIAL USES FOR PSMA PET SCANS

The clinical utility of PSMA PET scans is evolving and will be better defined over

Experts Discussed Other Considerations Regarding Imaging Modalities in Patients With Prostate Cancer

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PSMA PET SCANS

- Several experts noted they are having difficulty getting PSMA PET scans reimbursed by

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Diagnosing and Managing Localized/Locally Advanced Prostate Cancer

Diagnosing and Managing Localized/Locally Advanced Prostate Cancer (1/2)

Presented by Susan Slovin, MD, PhD

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SELECTING PATIENTS FOR ACTIVE SURVEILLANCE

Diagnosing and Managing Localized/Locally Advanced Prostate Cancer (2/2)

Presented by Susan Slovin, MD, PhD

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TRANSITIONING FROM ACTIVE SURVEILLANCE TO TREATMENT

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Key Insights

Localized/Locally Advanced Prostate Cancer

Experts Discussed Factors Impacting Patient Selection for Active Surveillance

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CLINICAL AND MOLECULAR CONSIDERATIONS

Active surveillance remains an area of uncertainty and debate focused on 2 key questions: who are the ideal candidates for active

Experts Discussed Evolving Treatment Options for Patients With Localized Prostate Cancer

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ANTIANDROGEN THERAPY

Several experts indicated they are comfortable adding abiraterone to ADT for patients with high-risk localized CSPC, on the basis of

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Treatment Paradigms for Advanced Prostate Cancer

Treatment Paradigms for Advanced Prostate Cancer (1/3)

Presented by Oliver Sartor, MD

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Treatment Paradigms for Advanced Prostate Cancer (2/3)

Presented by Oliver Sartor, MD

Treatment Paradigms for Advanced Prostate Cancer (3/3)

Presented by Oliver Sartor, MD

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STUDY POPULATION

- [illegible]

OUTCOME

- [illegible]

EXPERT CONCLUSIONS

[illegible]

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Key Insights

Advanced Prostate Cancer

Experts Debated Management Options for Nonmetastatic CRPC

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IMAGING

Several experts are now using more-sensitive imaging modalities such as PSMA PET to determine if patients with CRPC have metastatic or nonmetastatic disease

Experts Discussed Treatment Options for Patients With Metastatic Castration-Sensitive PC

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CURRENT AND EVOLVING PARADIGMS

ADT + an antiandrogen is typically used for most patients with mCSPC, or

Experts Reviewed Sequencing Considerations for Patients With mCRPC

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Experts Reviewed Approved and Investigational Targeted Therapies for mCRPC

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PARP INHIBITORS

> All of the experts test their patients with metastatic PC for germline mutations, but expressed concern that community practitioners are not

Experts Discussed Neuroendocrine Variants of mCRPC

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IDENTIFICATION

> Neuroendocrine-emergent mCRPC may be suspected in patients with visceral disease and low PSA

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Investigational Therapies for Metastatic CRPC

Investigational Therapies for Metastatic CRPC (1/2)

Presented by Scott Tagawa, MD, MS, FACP

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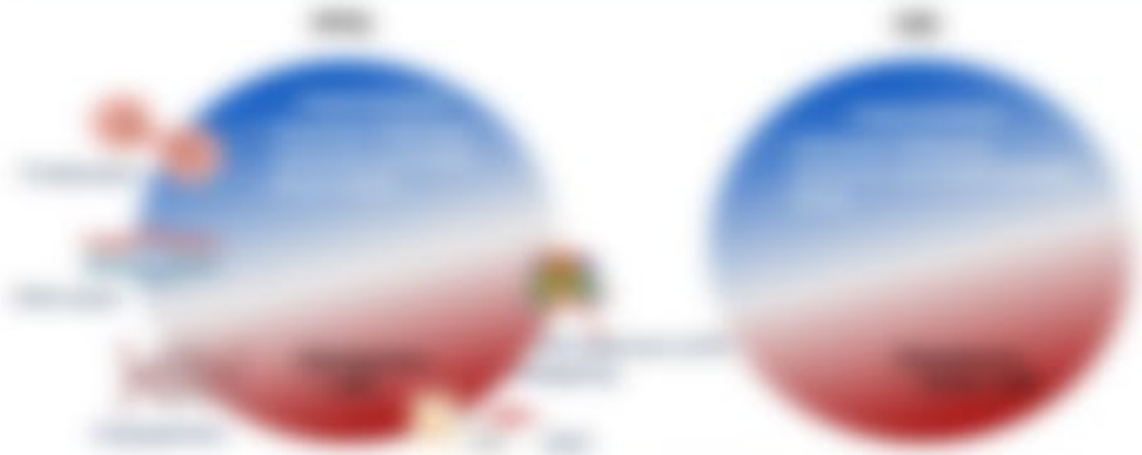
PSMA-TARGETED AGENTS



Investigational Therapies for Metastatic CRPC (2/2)

Presented by Scott Tagawa, MD, MS, FACP

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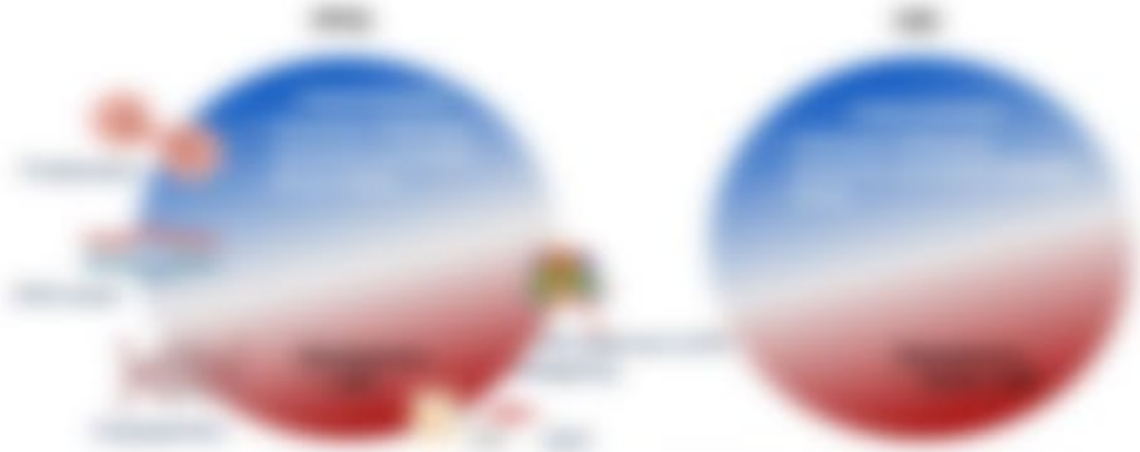
INVESTIGATIONAL DIRECTIONS – AVAILABLE AGENTS

NOVEL TARGETED AGENTS



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Key Insights

Investigational Therapies for Metastatic CRPC

Experts Discussed the Potential of Novel Agents in Development for Prostate Cancer

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PSMA-TARGETED THERAPIES

Experts Discussed Early Phase Investigational Agents and Shifting Paradigms

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Experts Discussed Challenges and Opportunities for New Drug Development in mCRPC

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OPPORTUNITIES AND CHALLENGES IN NEW THERAPY DEVELOPMENT

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Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC)

Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC) (1/4)

Presented by Bernard Bochner, MD, FACS

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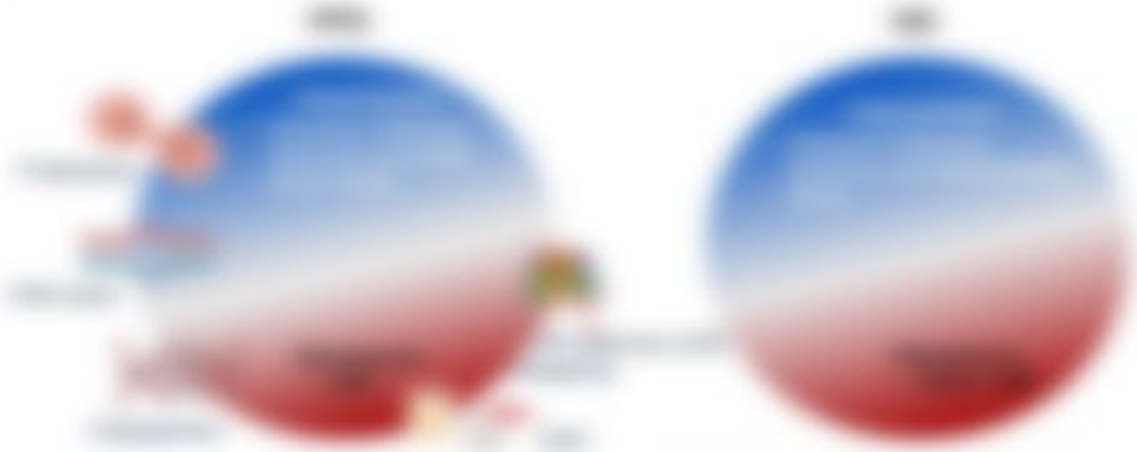
NON–MUSCLE-INVASIVE BLADDER CANCER – CONVENTIONAL APPROACHES



Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC) (2/4)

Presented by Bernard Bochner, MD, FACS

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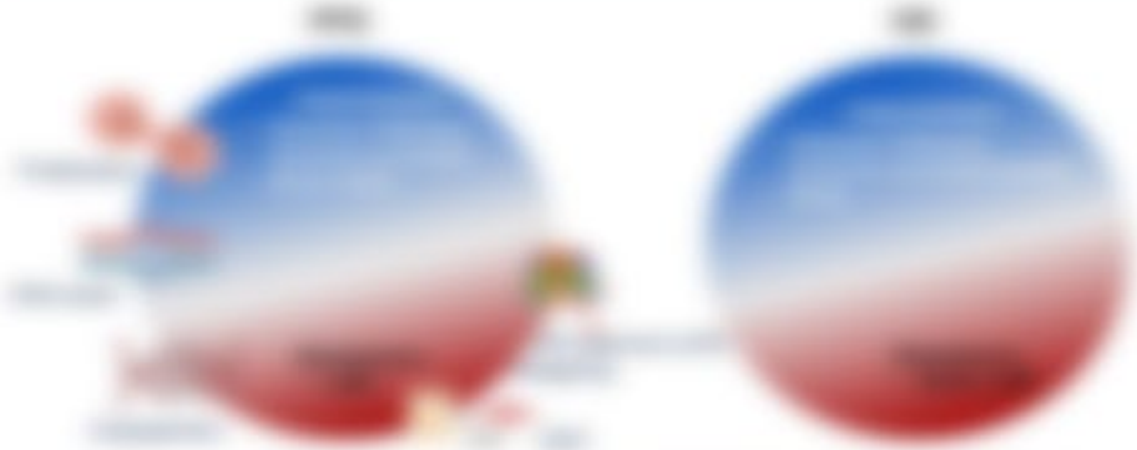
IMMUNE CHECKPOINT INHIBITORS – NMIBC

INVESTIGATIONAL AGENTS – NMIBC



Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC) (3/4)

Presented by Bernard Bochner, MD, FACS

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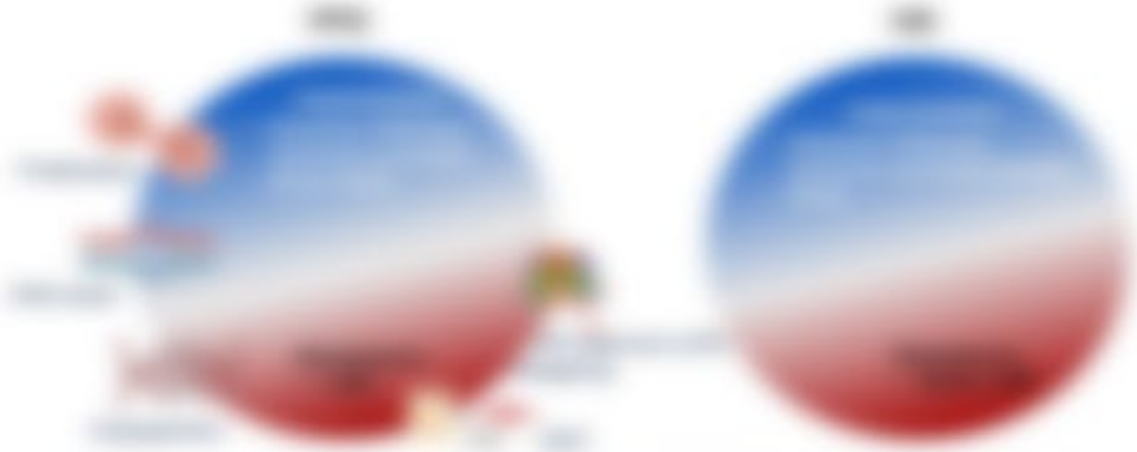
MUSCLE-INVASIVE BLADDER CANCER – CONVENTIONAL APPROACHES



Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC) (4/4)

Presented by Bernard Bochner, MD, FACS

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NEOADJUVANT ICIs – MIBC

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ADJUVANT ICIs – MIBC

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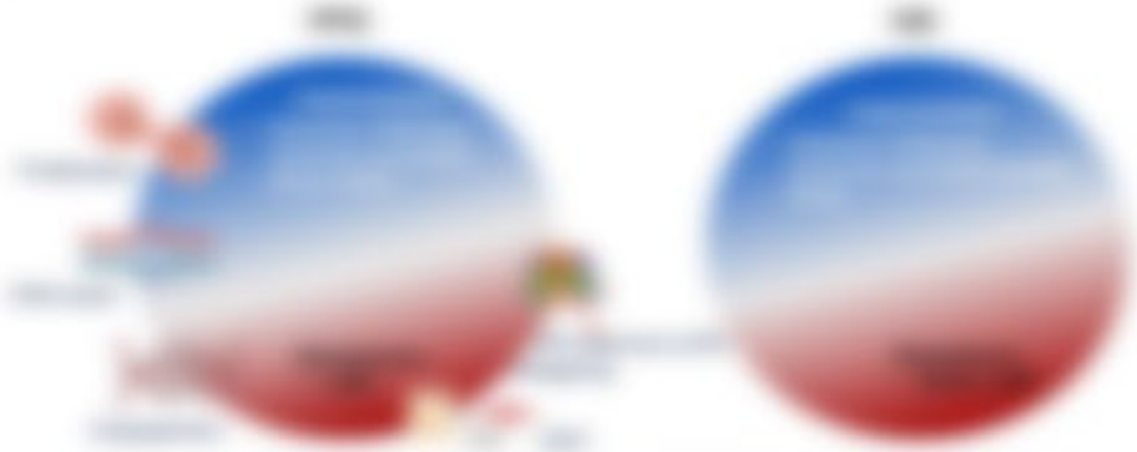

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Key Insights

Early Stage Bladder Cancer (BCG-Resistant NMIBC; MIBC)

Experts Reviewed Current and Emerging Options for BCG-Unresponsive NMIBC

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SURGERY

- FGFR-targeted agents are perceived to be particularly challenging

Experts Discussed Neoadjuvant and Adjuvant Approaches for MIBC

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NEOADJUVANT THERAPY

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Experts Discussed Challenges to Clinical Development for Early Stage Bladder Cancer

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PATIENT AVAILABILITY

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Current Paradigms and Future Directions in Metastatic Bladder Cancer

Current Paradigms and Future Directions in Metastatic Bladder Cancer (1/2)

Presented by Robert Dreicer, MD, MS, MACP, FASCO

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TREATMENT ALGORITHM FOR mUC

Current Paradigms and Future Directions in Metastatic Bladder Cancer (2/2)

Presented by Robert Dreicer, MD, MS, MACP, FASCO

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TREATMENT DECISION-MAKING

MOLECULARLY TARGETED THERAPIES

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Key Insights

Metastatic Bladder Cancer

Experts Discussed First-Line Options for mUC

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EVOLVING FIRST-LINE STANDARDS

Experts Discussed Sequencing Treatments for mUC in the Second Line and Beyond

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ENFORTUMAB VEDOTIN

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Evolving Paradigms for Metastatic RCC

Evolving Paradigms for Metastatic RCC (1/3)

Presented by David Nanus, MD

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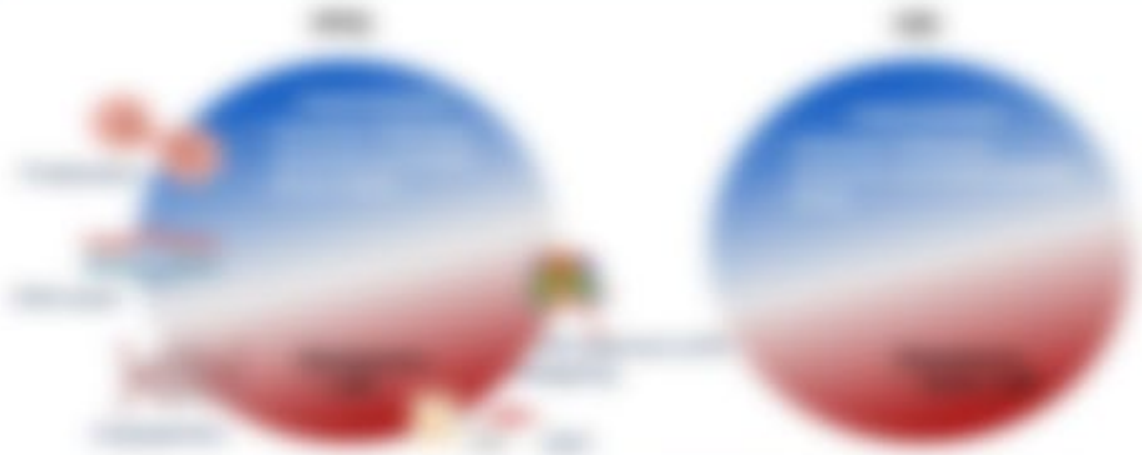
FIRST-LINE LANDSCAPE



Evolving Paradigms for Metastatic RCC (2/3)

Presented by David Nanus, MD

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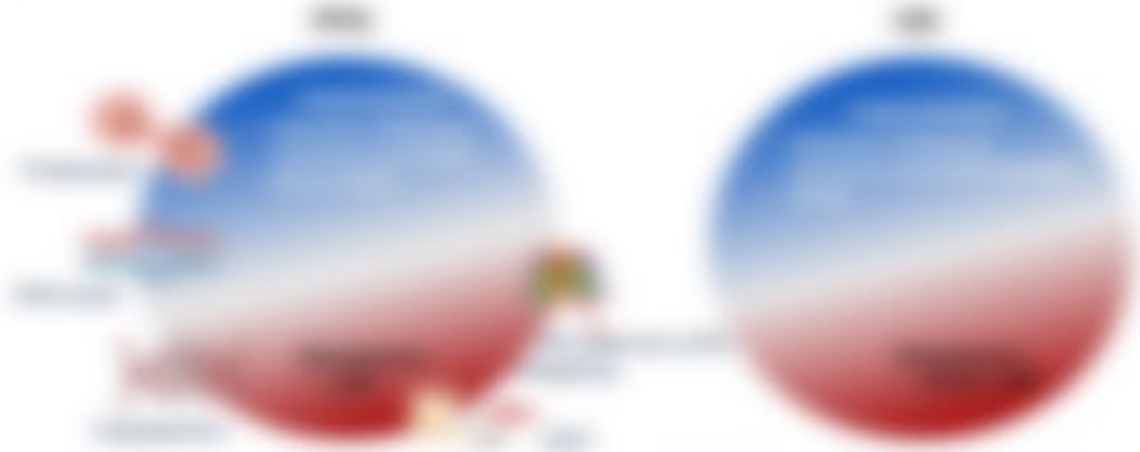
FIRST-LINE THERAPY – UNMET NEEDS AND AREAS OF INVESTIGATION



Evolving Paradigms for Metastatic RCC (3/3)

Presented by David Nanus, MD

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SECOND LINE AND BEYOND

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INVESTIGATIONAL THERAPIES

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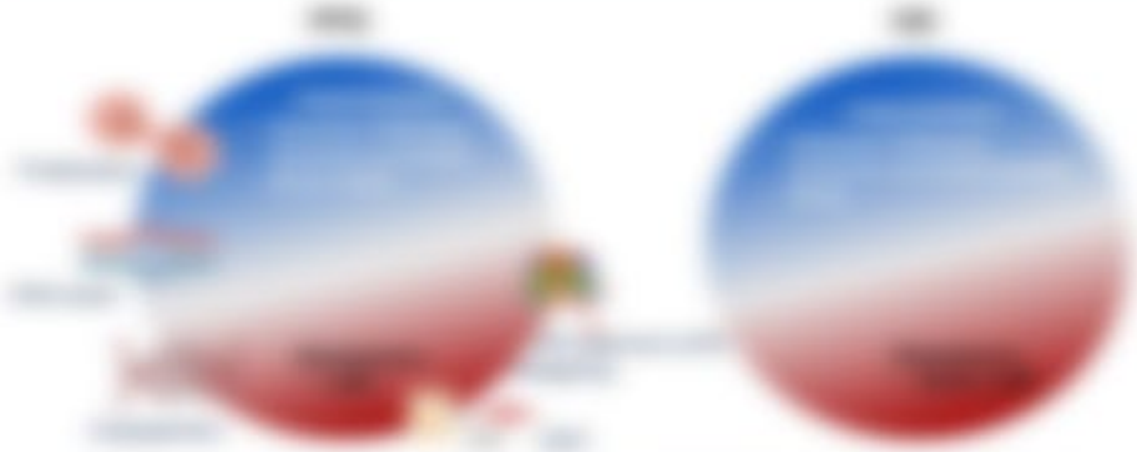

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Key Insights

Metastatic RCC

Experts Debated First-Line Treatment Considerations for Metastatic ccRCC

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IO-IO VS IO-TKI

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Experts Discussed Second-Line-and-Later Options and the Impact of Toxicities

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CONSIDERATIONS BEYOND FIRST-LINE THERAPY

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Neo/Adjuvant Treatment of RCC

Neo/Adjuvant Treatment of RCC (1/2)

Presented by David Quinn, MBBS, PhD, FRACP, FACP

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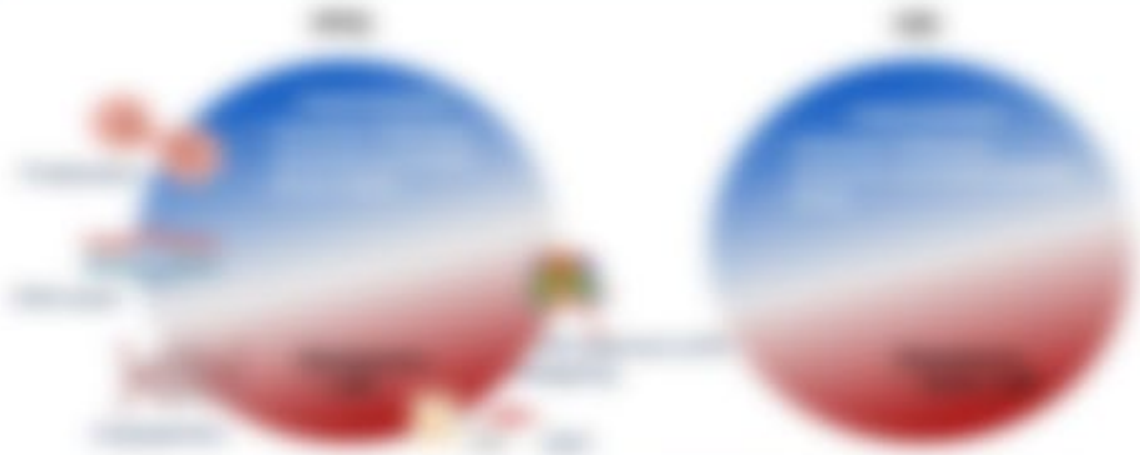
PREOPERATIVE AND SURGICAL MANAGEMENT



Neo/Adjuvant Treatment of RCC (2/2)

Presented by David Quinn, MBBS, PhD, FRACP, FACP

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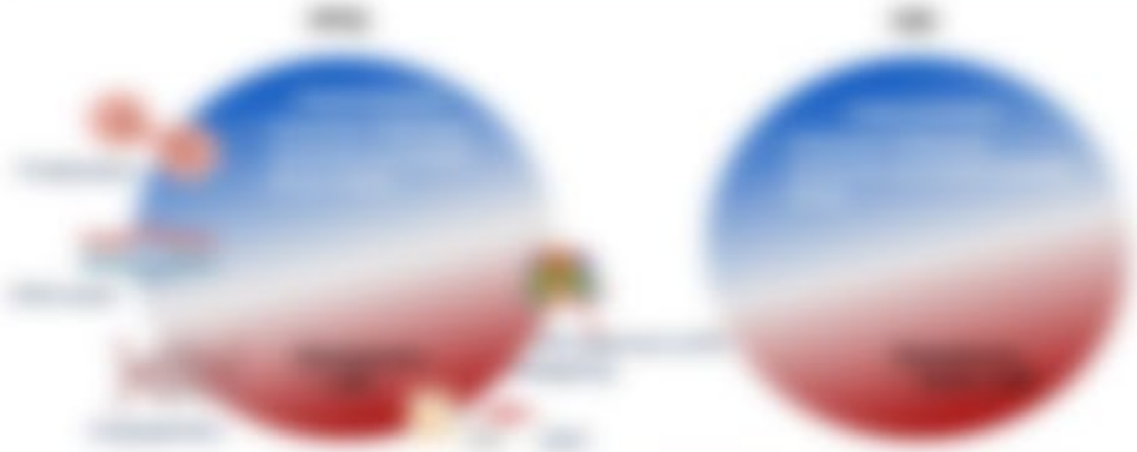
ADJUVANT THERAPY



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Key Insights

Neo/Adjuvant Treatment of RCC

Experts Discussed the Impact of KEYNOTE-564 on the Management of Early Stage RCC

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ADJUVANT PEMBROLIZUMAB

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Experts Discussed Research Directions, Unmet Needs, and Evolving Standards of Care in ccRCC

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CLINICAL TRIAL CONSIDERATIONS

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Current and Future Management of Non-clear Cell RCC

Current and Future Management of Non-clear Cell RCC (1/1)

Presented by David Quinn, MBBS, PhD, FRACP, FACP

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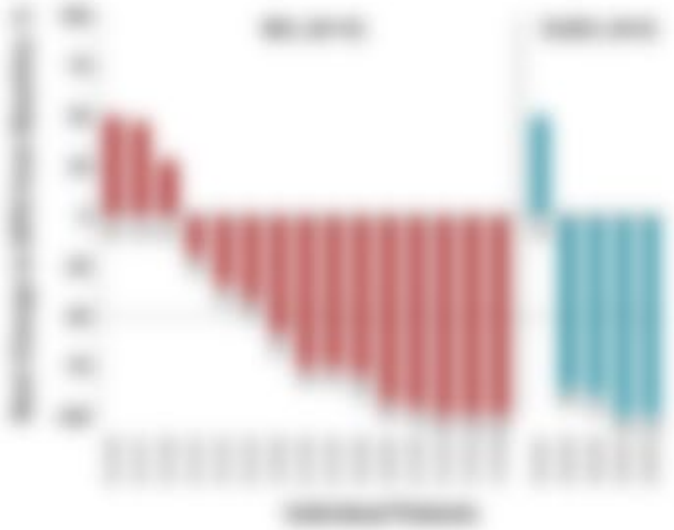
Background

- Phase I dose-escalation study of VLS-101, a ROR1-targeting ADC, in patients with heavily pretreated MCC and DLBCL
- Primary objective was to refine estimates of MTD and recommended dosing regimen

Results

- 32 patients were enrolled, including 15 patients with MCC
- DLTs were G4 neutropenia and G3 diarrhea
- G4 neutropenia occurred in 28% of patients; G-CSF successfully ameliorated neutropenia
- On-study reversible G3 neuropathy occurred in 9% of patients; no G4 neuropathy occurred
- ORR was 47% (3 CR, 4 PR) for MCC cohort and 80% (2 CR, 2 PR) for DLBCL cohort
- 8 responding patients have ongoing responses ranging from 23 weeks to 58 weeks



Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCC and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

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Key Insights

Non-clear Cell RCC

Experts Reviewed Current Treatment Paradigms for Non-clear Cell mRCC Subtypes

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PAPILLARY mRCC