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# EPICS – Lung Cancer in 2021 and Beyond

December 3–4, 2021

# Report Contents

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# Meeting Snapshot

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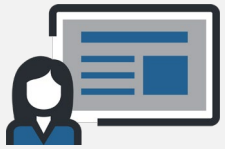
## VIRTUAL CLOSED-DOOR ROUNDTABLE

**DATE:**
December 3–4, 2021



**DISEASE STATE AND DATA PRESENTATIONS** by key experts

**INSIGHT REPORT** including postmeeting analyses and actionable recommendations

**PANEL:** Key experts in lung cancer
- 8 from US
- 1 from Canada

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

# Panel Consisting of 8 US and 1 Canadian Lung Cancer Experts

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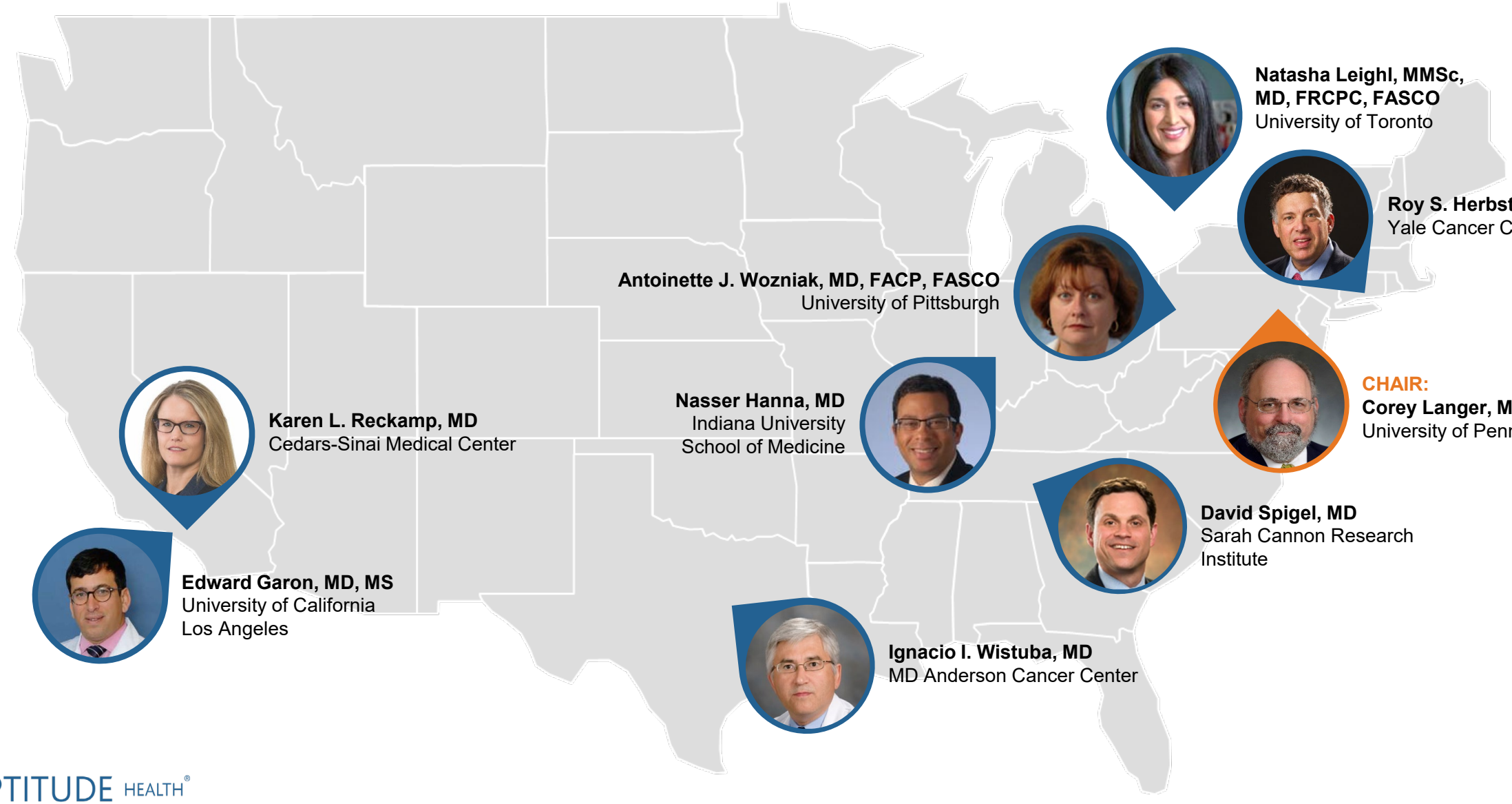

**Natasha Leighl, MMSc, MD, FRCPC, FASCO**
University of Toronto

**Roy S. Herbst, MD, PhD**
Yale Cancer Center

**Antoinette J. Wozniak, MD, FACP, FASCO**
University of Pittsburgh

**CHAIR:**
**Corey Langer, MD, FACP**
University of Pennsylvania

**Nasser Hanna, MD**
Indiana University School of Medicine

**Karen L. Reckamp, MD**
Cedars-Sinai Medical Center

**David Spigel, MD**
Sarah Cannon Research Institute

**Edward Garon, MD, MS**
University of California Los Angeles

**Ignacio I. Wistuba, MD**
MD Anderson Cancer Center

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# Meeting Agenda – Day 1 (1/2)

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| Time – Eastern Time (US) | Topic | Speaker/Moderator |
|---|---|---|
| 5.00 PM – 5.05 PM (5 min) | Welcome and Introductions | Corey J. Langer, MD, FACP |
| 5.05 PM – 5.25 PM (20 min) | Prognostic and Predictive Biomarkers in NSCLC – Clinical vs Research Relevance (excluding *EGFR/ALK*) | Ignacio Wistuba, MD |
| 5.25 PM – 5.55 PM (30 min) | Discussion – Prognostic and Predictive Biomarkers in NSCLC – Clinical vs Research Relevance (excluding *EGFR/ALK*) | Moderator: Corey J. Langer, MD, FACP |
| 5.55 PM – 6.10 PM (15 min) | New Directions for *EGFR*-Mutant NSCLC | Antoinette Wozniak, MD, FACP, FASCO |
| 6.10 PM – 6.30 PM (20 min) | Discussion – New Directions for *EGFR*-Mutant NSCLC | Moderator: Corey J. Langer, MD, FACP |
| 6.30 PM – 6.40 PM (10 min) | Emergence of Immunotherapy and Bispecifics in SCLC | Antoinette Wozniak, MD, FACP, FASCO |
| 6.40 PM – 6.50 PM (10 min) | Discussion – Emergence of Immunotherapy and Bispecifics in SCLC | Moderator: Corey J. Langer, MD, FACP |
| 6.50 AM – 7.00 PM (10 min) | BREAK | |

# Meeting Agenda – Day 1 (2/2)

EPICS

| Time – Eastern Time (US) | Topic | Speaker/Moderator |
|---|---|---|
| 7.00 PM – 7.15 PM (15 min) | Therapeutic Landscape for Fusion-Positive NSCLC (*ALK, ROS1, NTRK, RET*) | Karen Reckamp, MD, MS |
| 7.15 PM – 7.45 PM (30 min) | Discussion – Therapeutic Landscape for Fusion-Positive NSCLC (*ALK, ROS1, NTRK, RET*) | Moderator: Corey J. Langer, MD, FACP |
| 7.45 PM – 8.00 PM (15 min) | Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS, HER2, MET*, and *BRAF* | David Spigel, MD |
| 8.00 PM – 8.30 PM (30 min) | Discussion – Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS, HER2, MET*, and *BRAF* | Moderator: Corey J. Langer, MD, FACP |
| 8.30 PM – 8.40 PM (10 min) | New Directions for Second-Line Therapy | Edward Garon, MD |
| 8.40 PM – 9.00 PM (20 min) | Discussion – New Directions for Second-Line Therapy | Moderator: Corey J. Langer, MD, FACP |
| | Adjourn | Corey J. Langer, MD, FACP |

# Meeting Agenda – Day 2 (1/2)

EPICS

| Time – Eastern Time (US) | Topic | Speaker/Moderator |
|---|---|---|
| 9.00 AM – 9.05 AM (5 min) | Welcome and Introductions | Corey J. Langer, MD, FACP |
| 9.05 AM – 9.20 AM (15 min) | Perioperative Immunotherapy in Early NSCLC | Karen Reckamp, MD, MS |
| 9.20 AM – 9.50 AM (30 min) | Discussion – Perioperative Immunotherapy in Early NSCLC | Moderator: Corey J. Langer, MD, FACP |
| 9.50 AM – 10.00 AM (10 min) | Immunotherapy in Unresectable Stage III NSCLC | Nasser Hanna, MD |
| 10.00 AM – 10.20 AM (20 min) | Discussion – Immunotherapy in Unresectable Stage III NSCLC | Moderator: Corey J. Langer, MD, FACP |
| 10.20 AM – 10.35 AM (15 min) | First-Line Immunotherapy in Metastatic NSCLC – Single Agent or Combination? | Roy Herbst, MD, PhD |
| 10.35 AM – 11.05 AM (30 min) | Discussion – First-Line Immunotherapy in Metastatic NSCLC: Single Agent or Combination? | Moderator: Corey J. Langer, MD, FACP |
| 11.05 AM – 11.15 AM (10 min) | BREAK | |

# Meeting Agenda – Day 2 (2/2)

EPICS

| Time – Eastern Time (US) | Topic | Speaker/Moderator |
|---|---|---|
| 11.15 AM – 11.30 AM (15 min) | Biomarkers for Immunotherapy – Making Sense of the Chaos | Roy Herbst, MD, PhD |
| 11.30 AM – 11.50 AM (20 min) | Discussion – Biomarkers for Immunotherapy – Making Sense of the Chaos | Moderator: Corey J. Langer, MD, FACP |
| 11.50 AM – 12.00 PM (10 min) | *EGFR* (Less Common Mutations, Including Exon 20 Insertions) | Natasha Leighl, MD, MMSc, FRCPC, FASCO |
| 12.00 PM – 12.10 PM (25 min) | Discussion – *EGFR* (Less Common Mutations, Including Exon 20 Insertions) | Moderator: Corey J. Langer, MD, FACP |
| 12.10 PM – 12.20 PM (10 min) | Promising New Targets/Agents in Lung Cancer | David Spigel, MD |
| 12.20 PM – 12.40 PM (20 min) | Discussion – Promising New Targets/Agents in Lung Cancer | Moderator: Corey J. Langer, MD, FACP |
| | Conclusions and Adjourn | Corey J. Langer, MD, FACP |

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# Summaries of Faculty Presentations

# Prognostic and Predictive Biomarkers in NSCLC (1/2)

## Presented by Ignacio Wistuba, MD

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# Prognostic and Predictive Biomarkers in NSCLC (2/2)

## Presented by Ignacio Wistuba, MD

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# New Directions for *EGFR*-Mutant NSCLC (1/2)

Presented by Antoinette Wozniak, MD, FACP, FASCO

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- The most significant advance in the


STUDY POPULATION

OUTCOME

EXPERT CONCLUSIONS



RESPONSE INDICATORS ACROSS ANALYSIS PERIODS

# New Directions for *EGFR*-Mutant NSCLC (2/2)

**Presented by Antoinette Wozniak, MD, FACP, FASCO**

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> Key areas of investigation include improving the efficacy of first-line



# *EGFR* (Less Common Mutations, Including Exon 20 Insertions) (1/2)

**Presented by Natasha Leighl, MD, MMSc, FRCPC, FASCO**

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- *EGFR* exon 20 insertions represent 4% to

- Patients with EGFR exon20ins are a population with significant unmet needs

# *EGFR* (Less Common Mutations, Including Exon 20 Insertions) (2/2)

**Presented by Natasha Leighl, MD, MMSc, FRCPC, FASCO**

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- In 2021, 2 agents were approved as subsequent therapy specifically

# Therapeutic Landscape for Fusion-Positive NSCLC (*ALK, ROS1, NTRK, RET*) (1/2)

**Presented by Karen Reckamp, MD, MS**

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- A key consideration for oncogenic fusions is

**Methods for Fusion Detection:**



# Therapeutic Landscape for Fusion-Positive NSCLC (*ALK, ROS1, NTRK, RET*) (2/2)

**Presented by Karen Reckamp, MD, MS**

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- *NRG1* represents an emerging class of oncogenic fusions, with a

# Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS, HER2, MET,* and *BRAF* (1/2)

**Presented by David Spigel, MD**

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> The most recent development in actionable

## Sotorasib



# Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS, HER2, MET,* and *BRAF* (2/2)

**Presented by David Spigel, MD**

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- For *HER2*, *MET*, and *BRAF*, targeted agents have either been

# Promising New Targets/Agents in Lung Cancer

## Presented by David Spigel, MD

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> Antibody-drug conjugates (ADCs) have

# Perioperative Immunotherapy in Early NSCLC

## Presented by Karen Reckamp, MD, MS

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> The use of immunotherapy in patients with resectable



# Immunotherapy in Unresectable Stage III NSCLC

## Presented by Nasser Hanna, MD

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> The phase III PACIFIC trial continues to



# First-Line Immunotherapy in Metastatic NSCLC – Single Agent or Combination? (1/2)

**Presented by Roy Herbst, MD, PhD**

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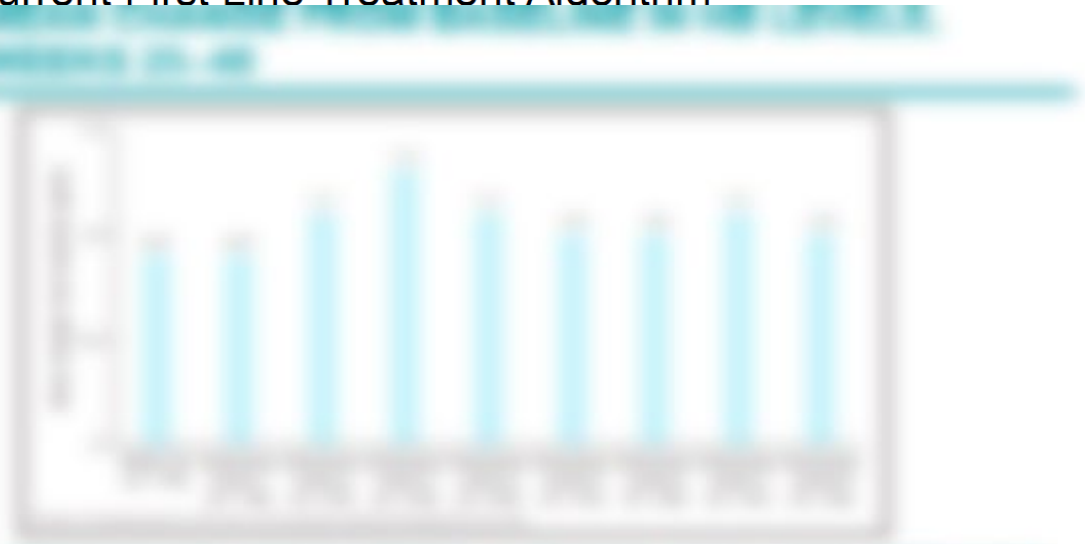
> There are currently multiple options for first-

A Current First Line Treatment Algorithm



# First-Line Immunotherapy in Metastatic NSCLC – Single Agent or Combination? (2/2)

**Presented by Roy Herbst, MD, PhD**

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> Data presented in 2021 reinforced the concept that immunotherapy

# Biomarkers for Immunotherapy – Making Sense of the Chaos

## Presented by Roy Herbst, MD, PhD

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> PD-L1 is still the main biomarker for



# New Directions for Second-Line Therapy

## Presented by Edward Garon, MD

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> Treatment of patients with advanced



# Emergence of Immunotherapy and Bispecifics in SCLC

## Presented by Antoinette Wozniak, MD, FACP, FASCO

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> After several decades with little progress, a new first-



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# Key Insights

# Prognostic and Predictive Biomarkers in NSCLC (1/2)

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The experts would use liquid-based testing primarily for patients who were diagnosed outside their institution and/or if there is concern about

# Prognostic and Predictive Biomarkers in NSCLC (2/2)

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Expert opinion is that *MET* amplification is an actionable marker, and

# New Directions for *EGFR*-Mutant NSCLC (1/2)

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Molecular testing of patients with early stage NSCLC varied, ranging from *EGFR* only (n = 1), to *EGFR* and *ALK* (n = 1) and NGS-based testing

# New Directions for *EGFR*-Mutant NSCLC (2/2)

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In the metastatic setting, the experts generally administer carboplatin-

# *EGFR* (Less Common Mutations, Including Exon 20 Insertions)

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For patients with an *EGFR* exon 20 insertion, the experts would recommend chemotherapy without immunotherapy in the frontline setting

# Therapeutic Landscape for Fusion-Positive NSCLC (*ALK, ROS1, NTRK, RET*)

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Expert opinion is that more education is needed to ensure that all appropriate patients have access to molecular testing for oncogenic fusions;

# Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS*, *HER2*, *MET*, and *BRAF* (1/2)

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Testing results for *KRAS* are seen as an area of educational need for community oncologists

# Inhibiting Oncogenic Mutations: Overcoming Mutant *KRAS, HER2, MET*, and *BRAF* (2/2)

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In patients with *HER2* mutations, the experts currently would use

Regarding amivantamab, one of the experts with extensive

# Promising New Targets/Agents in Lung Cancer

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Antibody-drug conjugates are of interest to the experts

# Perioperative Immunotherapy in Early NSCLC (1/2)

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The experts discussed the assessment of pathologic complete response (pCR) and major pathologic response (MPR) in patients with NSCLC who

# Perioperative Immunotherapy in Early NSCLC (2/2)

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Expert opinion is that it will be important to develop a management strategy for patients who

# Immunotherapy in Unresectable Stage III NSCLC

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The experts generally do not use PD-L1 in deciding whether to offer a patient consolidation immunotherapy after CRT

# First-Line Immunotherapy in Metastatic NSCLC – Single Agent or Combination? (1/2)

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The experts were asked about turnaround time for PD-L1 testing; most are able to obtain results within 1 to 2 days

# First-Line Immunotherapy in Metastatic NSCLC – Single Agent or Combination? (2/2)

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Regarding the anti–PD-(L)1 antibodies being developed in China (eg,

# Biomarkers for Immunotherapy – Making Sense of the Chaos

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The experts do not think it is necessary to subdivide the PD-L1 ≥50% population to isolate “very high expressors” (eg, ≥90%)

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# New Directions for Second-Line Therapy

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Therapy post-chemotherapy/immunotherapy remains the biggest challenge in NSCLC

# Emergence of Immunotherapy and Bispecifics in SCLC

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Regarding biomarkers in SCLC, the pathology expert mentioned that a major challenge is obtaining high-quality tissue; crush artifacts are common,