Practical Management Pearls for Immunotherapy for the Treatment of Lung Cancer and Mesothelioma

August 23, 2022
12:30 – 1:30 p.m. ET
Webinar Agenda

12:30 - 12:35 p.m. ET  Overview: Welcome and Introductions
12:35 - 1:15 p.m. ET  Presentation and Discussion
1:15 - 1:25 p.m. ET  Question and Answer Session
1:25 - 1:30 p.m. ET  Closing Remarks
How to Submit Questions

• Click the “Q&A” icon located on at the bottom of your Zoom control panel
• Type your question in the Q&A box, then click “Send”
• Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)
Webinar faculty

Moderator: Ramaswamy Govindan, MD
Expert Panel Chair
*Washington University School of Medicine*

Sarah B. Goldberg, MD, MPH
Expert Panel Member
*Yale Cancer Center*

Jyoti D. Patel, MD
Expert Panel Member
*Northwestern University*
Learning objectives

• Outline practical considerations for diagnostic testing and classification in Lung Cancer and Mesothelioma and the implications for immunotherapy treatment planning

• Appropriately manage challenging and/or uncommon toxicities/irAEs associated with immunotherapy in Lung Cancer and Mesothelioma

• Determine optimal sequencing of immunotherapies in all stages of Lung Cancer and Mesothelioma treatment, including treatment for persistent or relapsed/refractory disease after initial therapy
Poll question

What is your preferred regimen for 1\textsuperscript{st} line treatment of advanced non-squamous NSCLC with PD-L1 1-49%?

A. Pembrolizumab
B. Carboplatin/pemetrexed/pembrolizumab
C. Nivolumab/ipilimumab
D. Carboplatin/pemetrexed/nivolumab/ipilimumab
E. Carboplatin/paclitaxel/atezolizumab/bevacizumab
Single-agent PD-(L)1 inhibitor therapy for advanced NSCLC with PD-L1 ≥ 50%

**Pembrolizumab (KEYNOTE-024)**
- Median OS, Mo (95% CI)
  - Pembrolizumab (Pembro) (n = 154): 26.3 (18.3-40.4)
  - CT (n = 151): 13.4 (9.4-18.3)
- HR: 0.62 (95% CI: 0.48-0.81)

**Atezolizumab (IMpower110)**
- Median OS, Mo (95% CI)
  - Atezolizumab (Atezo) (n = 107): 20.2 (16.5-NE)
  - CT (n = 98): 13.1 (7.4-16.5)
- HR: 0.59 (95% CI: 0.40-0.89; P = .01)

**Cemiplimab (EMPOWER-Lung 1)**
- Median OS, Mo (95% CI)
  - Cemiplimab (n = 283): NR (17.9-NE)
  - CT (n = 280): 14.2 (11.2-17.5)
- HR: 0.57 (95% CI: 0.42-0.77; P = .0002)

Reck. JCO. 2021;39:2339.
Herbst. NEJM. 2020;383:1328.
Pembrolizumab for advanced NSCLC with PD-L1 ≥ 1%

Tumor PD-L1 1%-49%
(Exploratory Analysis)

Mok TSK, et al. Lancet 2019
Pembrolizumab plus chemotherapy for advanced non-squamous NSCLC

Final OS in ITT Population

Median OS, Mo (95% CI)

- Pembro + CT (n = 410) 22.0 (19.5-24.5)
- Pbo + CT (n = 206) 10.6 (8.7-13.6)

HR: 0.56 (95% CI: 0.46-0.69)

OS (%) at 2 years

- Pembro + CT: 69.8%
- Pbo + CT: 48.0%

- Pembro + CT: 45.7%
- Pbo + CT: 27.3%

Chemo/IO/VEGF inhibition for advanced non-squamous NSCLC

<table>
<thead>
<tr>
<th>Landmark OS, %</th>
<th>Arm B: atezo + bev + CP</th>
<th>Arm C: bev + CP</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-month</td>
<td>67%</td>
<td>61%</td>
</tr>
<tr>
<td>18-month</td>
<td>53%</td>
<td>41%</td>
</tr>
<tr>
<td>24-month</td>
<td>43%</td>
<td>34%</td>
</tr>
</tbody>
</table>

HR\(^a\), 0.78
(95% CI: 0.64, 0.96)
\(P = 0.0164\)

Median follow-up: ~20 mo

Socinski et al, NEJM 2018
Pembrolizumab plus chemotherapy for advanced squamous NSCLC

A Overall Survival

No. at Risk
Pembrolizumab combination 278 256 188 124 62 17 2 0
Placebo combination 281 246 175 93 45 16 4 0

Hazard ratio for death, 0.64 (95% CI, 0.49–0.85) P<0.001

Pooled analysis of PD-(L)1 therapy +/- chemo in advanced NSCLC with PD-L1 ≥ 50%

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Median OS (months)</th>
<th>HR (95% CI)</th>
<th>Median PFS (months)</th>
<th>HR (95% CI)</th>
<th>ORR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt;65</td>
<td>25.0 (23.3)</td>
<td>0.67 (0.46, 0.99)</td>
<td>9.4 (7.7)</td>
<td>0.54 (0.39, 0.75)</td>
<td>62 vs 43</td>
<td>2.2 (1.3, 3.7)</td>
</tr>
<tr>
<td>65-74</td>
<td>22.2 (18.6)</td>
<td>0.83 (0.54, 1.28)</td>
<td>9.7 (6.8)</td>
<td>0.80 (0.55, 1.13)</td>
<td>62 vs 43</td>
<td>1.9 (1.1, 3.4)</td>
</tr>
<tr>
<td>≥75</td>
<td>NE vs 18.9</td>
<td>1.68 (0.69, 4.06)</td>
<td>11.8 vs 7.2</td>
<td>1.22 (0.58, 2.57)</td>
<td>52 vs 45</td>
<td>1.2 (0.4, 3.8)</td>
</tr>
<tr>
<td>ECOG 0</td>
<td>NE vs 31.8</td>
<td>0.70 (0.40, 1.21)</td>
<td>13.7 vs 8.5</td>
<td>0.61 (0.40, 0.92)</td>
<td>66 vs 47</td>
<td>2.6 (1.5, 4.7)</td>
</tr>
<tr>
<td>1+</td>
<td>17.7 (18.0)</td>
<td>0.87 (0.64, 1.19)</td>
<td>8.2 vs 6.3</td>
<td>0.75 (0.57, 0.98)</td>
<td>58 vs 41</td>
<td>1.7 (1.1, 2.6)</td>
</tr>
</tbody>
</table>

Smoking Status

<table>
<thead>
<tr>
<th>Smoking</th>
<th>Median OS (months)</th>
<th>HR (95% CI)</th>
<th>Median PFS (months)</th>
<th>HR (95% CI)</th>
<th>ORR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>14.4</td>
<td>0.39 (0.15, 0.98)</td>
<td>10.2 vs 3.7</td>
<td>0.46 (0.23, 0.92)</td>
<td>69 vs 28</td>
<td>4.6 (1.5, 14.5)</td>
</tr>
<tr>
<td>Ever</td>
<td>23.0 (22.1)</td>
<td>0.92 (0.69, 1.22)</td>
<td>9.3 vs 8.2</td>
<td>0.75 (0.59, 0.95)</td>
<td>60 vs 45</td>
<td>1.7 (1.2, 2.5)</td>
</tr>
</tbody>
</table>

1 Patients in the pooled chemo-IO and IO-only arms.
Combination immunotherapy for advanced NSCLC

Nivo/Ipi (Checkmate-227)

PD-L1 ≥ 1%

- Nivo/Ipi (n = 398)
- Chemo (n = 397)
- Median OS, mo: 17.1 vs 14.1
- DRR: 36.4% vs 23.2%
- Nivo/Ipi vs Chemo

Nivo/Ipi/Chemo (Checkmate-9LA)

PD-L1 < 1%

- Nivo/Ipi (n = 187)
- Nivo + chemo (n = 177)
- Chemo (n = 185)
- Median OS, mo: 17.2 vs 15.2 vs 12.2
- Nivo/Ipi vs Nivo + chemo vs Chemo

Non-immunotherapy-based strategy

• Should be considered in the following situations:
  • Severe autoimmune disease
  • History of organ transplant
  • EGFR/ALK/other molecular subsets associated with non-response to immunotherapy

• Typically platinum-based doublet (+/- bevacizumab for non-squamous NSCLC)
Summary of first-line immunotherapy strategies in advanced NSCLC

• Single-agent pembrolizumab, atezolizumab and cemiplimab are more effective than chemotherapy in PD-L1 high NSCLC

• Pembrolizumab is superior to chemotherapy in NSCLC with PD-L1 >1%, however the benefit was driven by the patients with PD-L1 high tumors

• Chemo plus IO (with or without bevacizumab) can be an effective strategy regardless of PD-L1 status, however its role in PD-L1 high tumors is less clear

• Combination IO with ipi/nivo or ipi/nivo/chemo is superior to chemotherapy but has not been sufficiently compared to other IO-containing regimens
Polling Questions – Discussion

No live questions – a review of answers

What treatment strategy would you consider for a patient with no significant co-morbidities and a good performance status who has stage IIIA non-squamous NSCLC with PD-L1 80% and multi-station mediastinal lymph node involvement (N2+)?

A. Neoadjuvant chemotherapy plus nivolumab followed by resection
B. Upfront resection followed by adjuvant chemotherapy and atezolizumab
C. Definitive concurrent chemoradiation followed by durvalumab
D. A or C
E. I would consider any of the above
Post-immunotherapy treatment strategies

• Platinum-based doublet if immunotherapy was given as first-line treatment
• Docetaxel +/- ramucirumab after chemotherapy and immunotherapy
• Local therapy for oligoprogression
• Clinical trials!
Novel strategies in development

Current Lung-MAP Schema

- Actively Accruing
- In Development
- Development on HOLD
- Completed/Closed

**Screening Protocols**

**LUNGMAP**

**Biomarker-Driven Sub-Studies**

- Closed/Completed
  - $14000B$: PI3K/FGFR+ Taselisib
  - $14000C$: CCGA+/Palbociclib
  - $14000D$: FGFR+/AZD4547
  - $14000E$: c-MET+/Ribotumumab+Erlotinib
  - $14000F$: HHHD+/Talazoparib
  - $14000K$: Teiso-V (ABBV-399)

- Open
  - $1900A$: LOH/BRCA+
  - $1900C$: STK11+ mut
  - $1900B$: RET fus +
  - $1900D$: NTRK1/REAP1+
  - $1900E$: KRAS+/TP53
  - $1900F$: UX1/STK11

- On Hold

- Q4 2020

**Non-match Sub-Studies**

- Closed/Completed
  - ICi Naive:
    - $14000A$: Durvalumab
    - $14000I$: Nivo+Ipilimumab
  - ICi Refractory:
    - $14000F$: Durvalumab + Tremelimunab (both cohorts)

- Open
  - $1800A$: Checkpoint Refractorily
  - Pembrolizumab+ Ramucirumab vs. SoC
Poll question

What treatment strategy would you consider for a patient with no significant co-morbidities and a good performance status who has stage IIIA non-squamous NSCLC with PD-L1 80% and multi-station mediastinal lymph node involvement (N2+)?

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C. Definitive concurrent chemoradiation followed by durvalumab
D. A or C
E. I would consider any of the above
Early-stage NSCLC

### Adjuvant atezolizumab

- **DFS benefit by PD-L1 status:** HR (95% CI)
  - TC ≥50%: 0.43 (0.27-0.68)
  - TC ≥1%: 0.66 (0.49-0.87)
  - TC <1%: 0.97 (0.72-1.31)

### Neoadjuvant nivolumab/chemotherapy

- Forde P, et al. NEJM 2022
Locally advanced unresectable NSCLC

PACIFIC: Consolidation durvalumab after definitive concurrent chemoradiation

Polling Questions – Discussion

No live questions – a review of answers

What is your preferred regimen for 1st line treatment of advanced non-squamous NSCLC with PD-L1 1-49%?

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B. Carboplatin/pemetrexed/pembrolizumab
C. Nivolumab/ipilimumab
D. Carboplatin/pemetrexed/nivolumab/ipilimumab
E. Carboplatin/paclitaxel/atezolizumab/bevacizumab
Immunotherapy for extensive-stage SCLC

Carbo/etoposide +/- atezolizumab (IMpower 133)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Median OS (95% CI)</th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab + CPET (n = 201)</td>
<td>12.3 (10.8 to 15.8)</td>
<td>0.76 (0.60 to 0.95)</td>
<td>&lt;0.004</td>
</tr>
<tr>
<td>Placebo + CPET (n = 203)</td>
<td>13.3 (9.3 to 15.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Liu SV, et al. JCO 2022


Carbo/etoposide +/- durvalumab (CASPIAN)
Immunotherapy for mesothelioma

All patients

Epithelioid histology

Non-epithelioid histology

Summary

• Immunotherapy now has a role in nearly all patients with NSCLC, SCLC, and mesothelioma, including:
  • First-line treatment in patients with:
    • Advanced NSCLC
    • Extensive-stage SCLC
    • Mesothelioma
  • Consolidation in unresectable locally advanced NSCLC after chemoradiation
  • Neoadjuvant or adjuvant therapy in stage 2-3 NSCLC
Webinar outline

• Key Principles of Immune Mediated Adverse Events (irAE)
  ▪ Mechanisms
  ▪ Onset and Recognition
  ▪ Management
Immunotherapy after ChemoRT: How often can I start durvalumab within 14 days of completion?

1. <10%
2. 20%
3. 50%
4. >50%
Immune Related AEs (irAEs)

• Subset of patients develop irAEs
• Wide range of manifestation
  • Co-localize around “barrier” (gut, lungs, skin) or endocrine tissues
  • Up to 85% of patients treated with CTLA-4
  • 24-37% of patients treated with anti-PD-L1 or anti-PD-1
• Variable timing
  • Skin often earlier
  • Gut and endocrinopathies later
• Dual blockade of CTLA-4 and PD-1 pathway leads to both increased frequency and severity of irAEs
Postulated Mechanisms of irAEs

1. Pre-existing susceptibility to autoimmunity
2. Aberrant presentation of “self” by the tumor
3. Increasing level of inflammatory cytokines
4. Enhanced complement-mediated inflammation

Postow, NEJM 2018
Burke, Jour of Exper Med, 2020
Spectrum of Organs Affected by ICIs
Most common- thyroid, skin, and colitis
Kinetics of irAEs

Pooled analysis of 23 Clinical Trials/8436 Patients
-Tang, Cancer Res Treat 2021
irAEs and Efficacy of ICIs

• Conflicting but intriguing data
• Challenges in adjudication, attribution, and immortal time bias
• Diagnostic challenges
• Impact of treatment with immunosuppression
Using ICI Agents in Clinic

• Medical history
  • Specific questions on organ function-ie, shortness of breath on exertion, bowel function, previous history of autoimmune disease?

• Physical Examination
  • Vitals signs (with oximetry), weight, other significant findings

• Laboratory investigations
  • CBC, CMP, LFTs, TSH, other endocrine function evaluation when appropriate
Common Terminology Criteria of Adverse Events (CTCAE)

<table>
<thead>
<tr>
<th>CTCAE grade</th>
<th>Clinical description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</td>
</tr>
<tr>
<td>2</td>
<td>Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental ADL</td>
</tr>
<tr>
<td>3</td>
<td>Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated, disabling; limiting self-care ADL</td>
</tr>
<tr>
<td>4</td>
<td>Life-threatening consequences; urgent intervention indicated</td>
</tr>
<tr>
<td>5</td>
<td>Dearth related to adverse event</td>
</tr>
</tbody>
</table>
### General Approach to Using IO in Clinic

<table>
<thead>
<tr>
<th>Grade</th>
<th>Management</th>
<th>Continuation of Drug?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1-LOW</td>
<td>Monitor closely</td>
<td>Continue (*watch pneumonitis if risk factors)</td>
</tr>
<tr>
<td>Grade 2-MODERATE</td>
<td>Symptomatic management</td>
<td>Delay dose</td>
</tr>
<tr>
<td></td>
<td>Monitor closely</td>
<td>Resume IO when AEs to grade ≤1 or baseline</td>
</tr>
<tr>
<td></td>
<td>Oral corticosteroids</td>
<td></td>
</tr>
<tr>
<td>Grade 3/4-HIGH</td>
<td>Administer high dose iv corticosteroids</td>
<td>Discontinue drug, usually permanently (skin, diarrhea can be exceptions)</td>
</tr>
<tr>
<td></td>
<td>Symptomatic management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitor closely</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Involve consultants</td>
<td></td>
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</table>

**STEROID TAPER IS USUALLY AT LEAST 4-6 WEEKS MINIMUM**
Types of Immunosuppressive Treatment

First line treatment: CORTICOSTERIODS

Steroid-refractory or steroid sparing:

- Infliximab
- Vedolizumab
- IVIG
- Mycophenolate mofetil
- Tocilizumab
- Etanercept
- Adalimumab
- Tacrolimus
- Azathioprine

Severe irAE

• Generally, all irAEs are treated with high dose steroids but:
  • Endocrine toxicities generally are simply treated with replacement of hormonal deficit in most situations except in specific situations
All presented with mild cough, flu like symptoms with low grade fever, desaturation only with ambulation
Polling Questions – Discussion Cont’d

No live questions – a review of answers

• Immunotherapy after ChemoRT:
  How often can I start durvalumab within 14 days of completion?
  • <10%
  • 20%
  • 50%
  • >50%
Autoimmune Diseases (AD) and ICIs

- 14-25% of patients diagnosed with lung cancer will have pre-existing AD
- In patients with no (>80%) or low dose immunosuppression, ICI use:\n  - 20-40% of patients with exacerbation of ADs
  - <15% of patients with permanent discontinuation
- In patients on pre-existing steroids, inferior outcomes, but may reflect co-morbidity

<table>
<thead>
<tr>
<th>Patients with Preexisting Autoimmune Disease and Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICIs May Be Considered</strong></td>
</tr>
<tr>
<td>1. Consult with appropriate specialists</td>
</tr>
<tr>
<td>2. Low level or no immunosuppression with good control of AD</td>
</tr>
<tr>
<td>3. Patient informed consent</td>
</tr>
</tbody>
</table>

1. Leonardi, JCO, 2018; Kennedy, INCCN, 2019
2. Arbour, JCO, 2019
Rechallenge after irAEs

• 11-16% of patients develop Gr 3-5 irAEs\(^1\)
• At rechallenge, incidence of Gr 3-4 irAE < than initial treatment (HR 0.44)\(^2\)
• At rechallenge, GI > endocrine irAE
• Rechallenge after Gr 4 irAE should always be undertaken with CAUTION

1. Pillai, Cancer, 2018
2. Xu, JTO Clin and Res Reports, 2022
# Innovation in irAEs

## Preclinical setting
- Improved preclinical irAE models
- Improved mechanisms of irAEs in preclinical models
- Identification of novel biomarkers of irAE

## irAE prevention
- Genetic biomarkers of irAE risk
- Microbial biomarkers of irAE risk
- Interventions to mitigate irAE risk e.g. microbial manipulation

## irAE diagnosis
- Biomarkers of irAEs
- Imaging of irAEs
- Improved diagnostic pathways e.g. Multidisciplinary IR-Tox team

## irAE treatment
- Prospective irAE clinical trials
- Refined treatment algorithms based on irAE mechanisms

Conroy, Nature Communications, 2022
irAEs-Conclusions

• Careful ongoing clinical assessment is necessary for early identification
• Can be life threatening when not identified early
• irAEs can occur at any time
• Toxicity does not equal response
• Consider all symptoms and signs as potential irAEs
• Refer to SITC organ-specific algorithms for management of irAEs
How to Submit Questions

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- Type your question in the Q&A box, then click “Send”
- Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)
Practical Management Pearls for Immunotherapy for the Treatment of Nonmelanoma Skin Cancer
October 3, 2022: 11:00 a.m.-12:00 p.m. ET

Case Studies in Immunotherapy for the Treatment of Nonmelanoma Skin Cancer
October 28, 2022: 3:30 p.m.-4:30 p.m. ET

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SEMINAR 4 – Targeted Systemic Delivery of Innate Immune Activators – Aug. 26, 2022: 11 a.m. – 1 p.m. ET

SEMINAR 5: Scientific Basis of B-cell Modulation for Anti-tumor Immunity and Reduction of ICI Toxicity – Sept. 15, 2022: 1 p.m. – 3 p.m. ET

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Module 2: Basic Cancer Immunotherapy Concepts
Module 3: Immune Checkpoint Blockade
Module 4: Managing Immune Checkpoint Inhibitor Adverse Events
Module 5: Other Approaches (Cytokines, Vaccines and Immune Cell Engagers)
Module 6: Oncolytic Viruses and Intralesional Therapy
Module 7: CAR T Cell and Cellular Therapy
Module 8: Implementing Cancer Immunotherapy in Clinical Practice

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- Address unique considerations for designing clinical trial protocols in cancer immunotherapy
- Work in small groups with experts in the field
- Learn about cancer immunotherapy clinical trial endpoints, biomarker development and validation and combination strategies

FEATURING EXPERT ORGANIZERS

- Elizabeth Garrett-Mayer, PhD – American Society of Clinical Oncology
- Isabella C. Glitza, MD, PhD – The University of Texas MD Anderson Cancer Center
- Michael Lotze, MD, FACS – Nurix Therapeutics
- Chris Takimoto, MD, PhD – IGM Biosciences

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