APTITUDE HEALTH®

EPICS

GLOBAL PERSPECTIVES IN LUNG CANCER 2021

February 8 and 10, 2021

FACULTY EXPERTS

Chair
Corey Langer, MD
University of Pennsylvania

Benjamin Besse, MD, PhD
Institute Gustave Roussy

Roy Herbst, MD, PhD
Yale Cancer Center

Marina Chiara Garassino, MD
Istituto Nazionale dei Tumori

Naiyer Rizvi, MD
Columbia University
Irving Medical Center

Solange Peters, MD, PhD
University Hospital of Lausanne

Mark Socinski, MD
AdventHealth Cancer
Institute

David Spigel, MD
Sarah Cannon
Research Institute

AGENDA (FEB 8): IMMUNOTHERAPY

EPICS

Time (EDT)	Topic	Speaker/Moderator
10.00 AM – 10.05 AM	Welcome, Introductions, and Meeting Objectives	Corey Langer, MD
10.05 AM – 10.20 AM	Immunotherapy in Stage IV NSCLC	Roy Herbst, MD, PhD
10.20 AM – 11.00 AM	Discussion	
11.00 AM – 11.10 AM	Immunotherapy in Stage I–III Lung Cancer	Mark Socinski, MD
11.10 AM – 11.55 AM	Discussion	
11.55 AM – 12.05 PM	Immune-Based and Other New Approaches in SCLC	David Spigel, MD
12.05 PM – 12.25 PM	Discussion	
12.25 PM – 12.30 PM	Closing Remarks and Adjourn	Corey Langer, MD

AGENDA (FEB 10): TARGETED THERAPY

EPICS

Time (EDT)	Topic	Speaker/Moderator
1.00 PM – 1.05 PM	Welcome, Introductions, and Meeting Objectives	Corey Langer, MD
1.05 PM – 1.25 PM	*EGFR* Mutation-Positive NSCLC (Resectable and Metastatic)	Benjamin Besse, MD, PhD
1.25 PM – 1.45 PM	Discussion	
1.45 PM – 1.55 PM	Targeting Other Gene Mutations (*KRAS, HER2, MET [BRAF]*)	Marina Garassino, MD
1.55 PM – 2.25 PM	Discussion	
2.25 PM – 2.35 PM	Targeting Gene Fusions (*ALK, ROS1, NTRK [RET]*)	Solange Peters, MD, PhD
2.35 PM – 2.55 PM	Discussion	
2.55 PM – 3.00 PM	Closing Remarks and Adjourn	Corey Langer, MD

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

> OA01.03 – Clinical Benefits of First-Line (1L) Cemiplimab Monotherapy by PD-L1

Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.65 months

	CPS 1/2+	TC	HR	95% CI
OS (overall) (N = 309)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	18%	8%		
OS (post-transplant) (n = 92)				
Median	Not reached	10.25 months	0.51	0.28–0.90
3-year	34%	23%		
OS by age subgroup				
60–69 years	9.59 months	6.87 months	0.73	0.54–0.99
70–75 years	8.87 months	5.62 months	0.52	0.34–0.77

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HR, hazard ratio; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

- FP13.03 – IMpower110: Updated OS Analysis of Atezolizumab vs Platinum-Based Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

	CPS-3EH	PAQ	HR	95% CI
OS (overall) (N = 309)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	18%	8%		
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PD-L1, programmed cell death protein 1 ligand 1.

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

- FP13.04 – KEYNOTE-042 3-Year Survival Update: 1L Pembrolizumab vs Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

	CPS ≥20	PAQ	HR	95% CI
OS (overall) (N = 308)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	18%	8%		
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Median	Not reached	10.25 months	0.51	0.28–0.90
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TPS, tumor proportion score.

PROGRAM OVERVIEW: ABSTRACTS
IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

> FP13.01 – 5-Year Survival Update From KEYNOTE-010: Pembrolizumab Versus Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.83 months

	CPS-EBV	PAS	HR	95% CI
OS (overall) (N = 308)				
Median	9.33 months	5.85 months	0.70	0.55-0.91
3-year	39%	8%		
OS (post-transplant) (n = 92)				
Median	Not reached	10.25 months	0.51	0.28-0.90
3-year	56%	23%		
OS by age subgroup				
60-69 years	9.59 months	6.87 months	0.73	0.54-0.99
70-75 years	8.87 months	3.62 months	0.52	0.34-0.77

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

> FP13.02 – Pembrolizumab + Pemetrexed-Platinum vs Pemetrexed-Platinum for Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.65 months

	CPS-EBV	PAS	HR	95% CI
OS (overall) (N = 308)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	18%	8%		
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ITT, intent to treat.

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

- PS01.09 – Pembrolizumab Plus Ipilimumab vs Pembrolizumab Plus Placebo as 1L Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

OS (overall) (N = 309)				
Median	9.33 months	5.95 months	0.70	0.55–0.91
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DOR, duration of response; irAE, immune-related adverse event.

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

- P77.02 – Efficacy of Tiragolumab + Atezolizumab in PD-L1 IHC and TIGIT

Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.65 months

OS (overall) (N = 309)				
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IHC, immunohistochemistry; PVR, poliovirus receptor; TIGIT, T-cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domains.

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE IV NSCLC

EPICS

- OA01.07 – A Phase II Study of the Oral Selective AXL Inhibitor Bemcentinib with Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

OS (overall) (N = 309)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	18%	8%		
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ALT, alanine aminotransferase; AST, aspartate aminotransferase; cAXL, composite AXL.

IMMUNOTHERAPY IN STAGE IV NSCLC – DISCUSSION (1/4)

EPICS

- The experts think the failure of the KEYNOTE-598 trial (first-line pembrolizumab-

IMMUNOTHERAPY IN STAGE IV NSCLC – DISCUSSION (2/4)

EPICS

> The experts mentioned potential predictive factors for immunotherapy beyond

IMMUNOTHERAPY IN STAGE IV NSCLC – DISCUSSION (3/4)

EPICS

- While long-term follow-up of IMpower110 (exploratory analysis in the high–PD-L1

IMMUNOTHERAPY IN STAGE IV NSCLC – DISCUSSION (4/4)

EPICS

- The experts think combining antiangiogenic agents with immunotherapy is a

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE I–III NSCLC

EPICS

> PS01.05 – Surgical and Clinical Outcomes With Neoadjuvant Atezolizumab in

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE I–III NSCLC

EPICS

> P21.05 – Overall Survival by PD-L1 Status in Stage III NSCLC Following

PROGRAM OVERVIEW: ABSTRACTS IMMUNOTHERAPY IN STAGE I–III NSCLC

EPICS

> OA02.03 – Pembrolizumab Plus Platinum Chemotherapy and Radiotherapy in

IMMUNOTHERAPY IN STAGE I–III NSCLC – DISCUSSION (1/4)

EPICS

Resectable Disease

IMMUNOTHERAPY IN STAGE I–III NSCLC – DISCUSSION (2/4)

EPICS

Unresectable Stage III Disease

IMMUNOTHERAPY IN STAGE I–III NSCLC – DISCUSSION (3/4)

EPICS

Unresectable Stage III Disease

IMMUNOTHERAPY IN STAGE I–III NSCLC – DISCUSSION (4/4)

EPICS

Unresectable Stage III Disease

PROGRAM OVERVIEW: ABSTRACTS
IMMUNE-BASED AND OTHER NEW APPROACHES IN SCLC

EPICS

> OA11.03 – A Phase 1 Study of AMG 757, Half-Life Extended Bispecific T-Cell

PROGRAM OVERVIEW: ABSTRACTS
IMMUNE-BASED AND OTHER NEW APPROACHES IN SCLC

EPICS

> OA11.04 – Lurbinectedin With Irinotecan in Relapsed Small Cell Lung Cancer.

PROGRAM OVERVIEW: ABSTRACTS
IMMUNE-BASED AND OTHER NEW APPROACHES IN SCLC

EPICS

> OA11.06 – IMpower133: Exploratory Analysis of Maintenance Therapy in Patients

IMMUNE-BASED AND OTHER NEW APPROACHES IN SCLC – DISCUSSION (1/2)

EPICS

- The experts think lurbinectedin is an active agent and likely will remain available

IMMUNE-BASED AND OTHER NEW APPROACHES IN SCLC – DISCUSSION (2/2)

EPICS

> The IMpower133 and CASPIAN trials are seen by experts as having similar

PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> OA06.04 – Postoperative Chemotherapy Use and Outcomes from ADAURA: Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.65 months

	[illegible]	[illegible]	[illegible]	[illegible]
OS (overall) (N = 306)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
3-year	58%	8%		
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PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> FP14.02 – A Phase II Study of Osimertinib versus Combination of Osimertinib and

Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.83 months

OS (overall) (N = 309)				
Median	9.33 months	5.85 months	0.70	0.55–0.91
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QTc, corrected QT interval.

PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> OA03.04 – Efficacy and Safety of the Novel HER3 Directed Antibody Drug

PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> OA04.03 – Mobocertinib in NSCLC With EGFR Exon 20 Insertions: Results From Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al

- Median follow-up, 60.65 months

	CPX-351	7+3	HR	95% CI
OS (overall) (N = 309)				
Median	9.33 months	5.95 months	0.69	0.52–0.91
3-year	18%	8%		
OS (post-transplant) (n = 92)				
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OS by age subgroup				
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IRC, independent review committee; PPP, platinum-pretreated population.

PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

- MA11.04 – Updated Efficacy, Safety and Dosing Management of Poziotinib in Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

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PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> OA04.04 – Amivantamab in Post-platinum EGFR Exon 20 Insertion Mutant Non-

PROGRAM OVERVIEW: ABSTRACTS
EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC)

EPICS

> OA04.06 – Neratinib in Pretreated EGFR Exon 18-Mutant Non-Small Cell Lung

EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC) – DISCUSSION (1/3)

EPICS

Resectable Disease

- The experts generally consider osimertinib to be a standard part of adjuvant

EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC) – DISCUSSION (2/3)

EPICS

Metastatic Disease

> In patients whose disease becomes resistant to osimertinib, the experts favor

EGFR MUTATION-POSITIVE NSCLC (RESECTABLE AND METASTATIC) – DISCUSSION (3/3)

EPICS

Metastatic Disease

- The experts discussed current and future approaches for patients with *EGFR* exon

PROGRAM OVERVIEW: ABSTRACTS TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*])

EPICS

- PS01.07 – Registrational Phase 2 Trial of Sotorasib in KRAS p.G12C Mutant

PROGRAM OVERVIEW: ABSTRACTS TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*])

EPICS

- MA11.03 – Trastuzumab Deruxtecan in HER2-Mutated Metastatic Non-Small Cell

PROGRAM OVERVIEW: ABSTRACTS TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*])

EPICS

- OA04.05 – Trastuzumab Deruxtecan in HER2-Overexpressing Metastatic Non-

PROGRAM OVERVIEW: ABSTRACTS TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*])

EPICS

- MA11.05 – Tepotinib in Patients with MET exon 14 (METex14) Skipping Advanced Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

	[illegible]	[illegible]	[illegible]	[illegible]
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TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*]) – DISCUSSION (1/3)

EPICS

KRAS

> The experts are enthusiastic about the prospect of having a direct KRAS inhibitor

TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*]) – DISCUSSION (2/3)

EPICS

MET

- Both capmatinib and tepotinib are viewed by the experts as similar agents and

TARGETING OTHER GENE MUTATIONS (*KRAS, HER2, MET* [*BRAF*]) – DISCUSSION (3/3)

EPICS

HER2

> Regarding trastuzumab deruxtecan (T-DXd) and similar antibody-drug conjugates,

PROGRAM OVERVIEW: ABSTRACTS – TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES

EPICS

- MA11.08 – Patient-Reported Outcomes from the Randomized Phase 3 CROWN

PROGRAM OVERVIEW: ABSTRACTS – TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES

EPICS

- MA11.07 – Phase 1/2 TRIDENT-1 Study of Repotrectinib in Patients with ROS1+

PROGRAM OVERVIEW: ABSTRACTS – TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES

EPICS

- MA11.09 – Efficacy and Safety of Larotrectinib in Patients with Tropomyosin

PROGRAM OVERVIEW: ABSTRACTS – TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES

EPICS

- OA03.03 - Datopotamab Deruxtecan (Dato-DXd; DS-1062), a TROP2 ADC, in Adults with Newly Diagnosed High-Risk/Secondary Acute Myeloid Leukemia (AML): Outcomes By Age Subgroup and Among Responders. Lancet et al
  - Median follow-up, 60.65 months

	CPX-351	7+3	HR	95% CI
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TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES – DISCUSSION (1/2)

EPICS

ALK

> For patients with newly diagnosed, *ALK*-rearranged NSCLC, the experts think

TARGETING GENE FUSIONS (*ALK, ROS1, NTRK* [*RET*]) AND OTHER NOVEL APPROACHES – DISCUSSION (2/2)

EPICS

ROS1

> The high activity of entrectinib against brain metastases has made it the first-line

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