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Addressing Lung Cancer Biomarker Testing Through Project ECHO in Louisiana: Session 6 June 20, 2023

This project is generously supported by Amgen Oncology

Welcome to Session 6 of the Addressing Lung Cancer Biomarker Testing Through Project ECHO in Louisiana



Each ECHO session will be recorded and will be posted to echo.cancer.org



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LOUISIANA SESSION 6

Agenda Preview & Introductions





Feist-Weiller Cancer Center

Specialty: Surgical Oncology

Today's Agenda

01 Agenda Preview & Introductions (10 minutes)

02 Didactic Presentation: Lung Biomarker Testing Today & Tomorrow (20 minutes)

Didactic Q/A (5 minutes)

04 Case Presentation (5 minutes)

05 Case Presentation Recommendations & Discussion (10 minutes)

06 Post-ECHO Series Assessment (5 minutes)



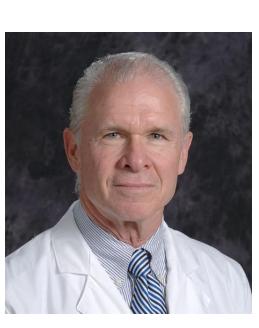
Meet our Louisiana Echo Hub Faculty Members



Robert Holladay, MD, FCCP Professor of Clinical Internal Medicine; Program Director, Interventional Pulmonary Fellowship Program Medicine Pulmonary Critical



David Chambers, MD Assistant Professor-of Clinical Internal Medicine, Associate Program Director of the Pulmonary and Critical Care Fellowship, Director of Lung Cancer Screening Medical Pulmonary



Robert White, MD, FACS Chairman and Professor of Surgery John C. McDonald, MD Endowed Chair of Surgery



Ira Surolia, MD Assistant Professor Feist Weiller Cancer Center



Kavitha Beedupalli, MD Associate Professor– Clinical Feist Weiller Cancer Center

Meet our Louisiana Echo Hub Faculty Members



Brian G. Fuller, MD Associate Professor Radiation Oncology Feist Weiller Cancer Center



Roberto Silva, MD Associate Professor of Pathology and Translational Pathobiology Pathology Department



Troy Richards, MD Clinical Assistant Professor of Radiology Radiation Oncology Department



Carlos Previgliano, MD Professor of Radiology, Clinical Specialist Thoracic / Cardiothoracic Radiology

Project Staff Rachel Langford RN, OCN Darren Guin, IT Analyst IV

Introductions: Meet our Louisiana Spoke Sites





Natchitoches Regional Medical Center







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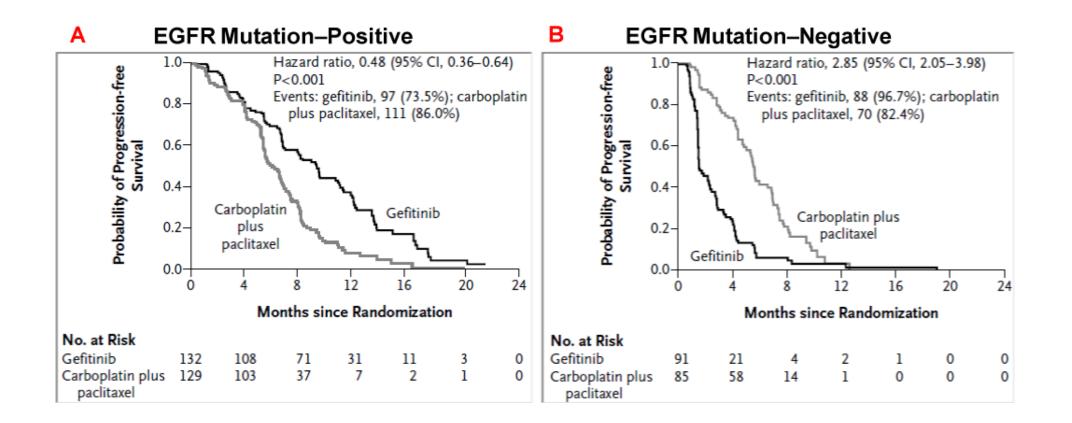


Pierre de Delva, MD

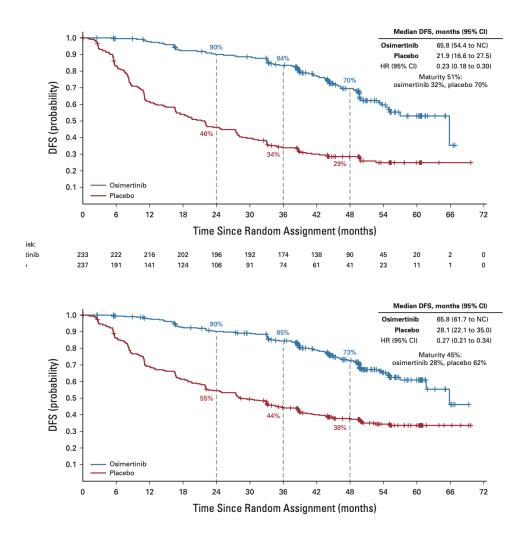
Chief of General Thoracic Surgery University of Mississippi Medical Center

Didactic Presentation: Lung Biomarker Testing Today & Tomorrow





Adura Trial- Adjuvant EGFR +



J Clin Oncol 41:1830-1840. © 2023 by American Society of Clinical Oncology

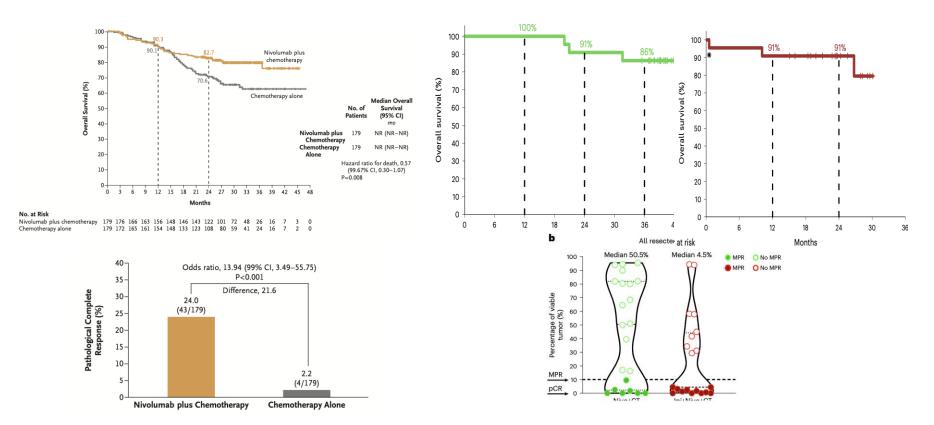
Neoadjuvant Chemoimmunotherapy

Checkmate 0816

N Engl J Med 386;21 May 26, 2022

Neostar

Nature Medicine | Volume 29 | March 2023 | 593–604



Old vs. New Treatment Options for Advanced Lung Cancer

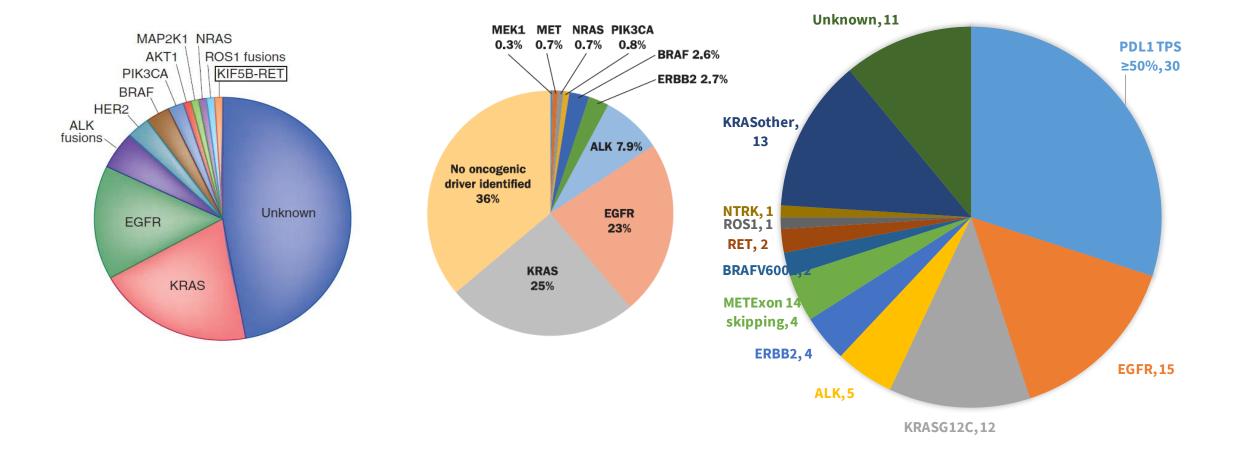
Traditional Chemotherapy

Biomarker Driven Chemotherapy/Immunotherapy





Treatment of Lung Cancer





NCCN Guidelines Version 3.2023 Non-Small Cell Lung Cancer

MOLECULAR AND BIOMARKER-DIRECTED THERAPY FOR ADVANCED OR METASTATIC DISEASE^{a,b}

EGFR Exon 19 Deletion or Exon 21 L858R

- First-line therapy ► Afatinib¹
- ► Erlotinib²
- Dacomitinib³
 Gefitinib^{4,5}
- ▸ Osimertinib⁶
- Erlotinib + ramucirumab⁷
- Erlotinib + bevacizumab^c (nonsquamous)⁸
- Subsequent therapy
 > Osimertinib⁹

EGFR S768I, L861Q, and/or G719X

- First-line therapy
- ► Afatinib^{1,10}
- ► Erlotinib²
- Dacomitinib³
- ▶ Gefitinib^{4,5}
- ► Osimertinib^{6,11}
- Subsequent therapy
- Osimertinib⁹

EGFR Exon 20 Insertion Mutation

- Subsequent therapy
 Amivantamab-vmjw¹²
- ► Mobocertinib¹³

KRAS G12C Mutation

- Subsequent therapy
 Sotorasib¹⁴
- ► Adagrasib¹⁵

- **ALK Rearrangement**
- First-line therapy
- ► Alectinib^{16,17}
- Brigatinib¹⁸
 Ceritinib¹⁹
- ► Crizotinib^{16,20}
- ► Lorlatinib²¹
- Subsequent therapy
 Alectinib^{22,23}
- Brigatinib²⁴
 Ceritinib²⁵
 Lorlatinib²⁶

ROS1 Rearrangement

- First-line therapy
- ► Ceritinib^{27,28}
- Crizotinib²⁹
- ▶ Entrectinib³⁰
- Subsequent therapy
- ▸ Lorlatinib³¹
- ► Entrectinib³⁰

BRAF V600E Mutation

- First-line therapy
- ► Dabrafenib/trametinib³²
- ► Dabrafenib³²
- Vemurafenib
- Subsequent therapy
- ► Dabrafenib/trametinib^{33,34}

NTRK1/2/3 Gene Fusion

- First-line/Subsequent therapy
 Larotrectinib³⁵
- ► Entrectinib³⁶

MET Exon 14 Skipping Mutation

- First-line therapy/Subsequent therapy
 Capmatinib³⁷
- ► Crizotinib³⁸
- ▶ Tepotinib³⁹

RET Rearrangement

- First-line therapy/Subsequent therapy
 Selpercatinib⁴⁰
- Pralsetinib⁴¹
- ► Cabozantinib^{42,43}

ERBB2 (HER2) Mutation

- Subsequent therapy
- Fam-trastuzumab
- deruxtecan-nxki⁴⁴
- ► Ado-trastuzumab emtansine⁴⁵

PD-L1 ≥50% First-line Therapy

PD-L1 ≥1-49% First-line Therapy



NCCN Guidelines Version 3.2023
 Non-Small Cell Lung Cancer

MOLECULAR AND BIOMARKER-DIRECTED THERAPY FOR ADVANCED OR METASTATIC DISEASE^{a,b}

PD-L1 ≥1%–49% First-line Therapy

ADENOCARCINOMA, LARGE CELL, NSCLC NOS

Preferred

- (Carboplatin or cisplatin) + pemetrexed + pembrolizumab (category 1)^{48,49} Other Recommended
- Carboplatin + paclitaxel + bevacizumab^{c,d} + atezolizumab (category 1)⁵²
- Carboplatin + albumin-bound paclitaxel + atezolizumab⁵³
- Nivolumab + ipilimumab + pemetrexed + (carboplatin or cisplatin) (category 1)⁵⁴
- Nivolumab + ipilimumab (category 1)⁵⁷
- Cemiplimab-rwlc + paclitaxel + (carboplatin or cisplatin) (category 1)⁵⁵
- Cemiplimab-rwlc + pemetrexed + (carboplatin or cisplatin) (category 1)⁵⁵
- Tremelimumab-actl + durvalumab + carboplatin + albumin-bound paclitaxel (category 1)⁵⁶
- Tremelimumab-actl + durvalumab + (carboplatin or cisplatin) + pemetrexed (category 1)⁵⁶

Useful in Certain Circumstances

Pembrolizumab (category 2B)^{e,46,47}

SQUAMOUS CELL CARCINOMA

Preferred

- Carboplatin + (paclitaxel or albumin-bound paclitaxel) + pembrolizumab (category 1)⁵⁸ Other Recommended
- Nivolumab + ipilimuab + paclitaxel + carboplatin (category 1)⁵³
- Nivolumab + ipilimumab (category 1)⁵⁷
- Cemiplimab-rwlc + paclitaxel + (carboplatin or cisplatin) (category 1)⁵⁵
- Tremelimumab-actl + durvalumab + carboplatin + albumin-bound paclitaxel
- Tremelimumab-actl + durvalumab + (carboplatin or cisplatin) + gemcitabine⁵⁶ Useful in Certain Circumstances
- Pembrolizumab (category 2B)^{e,46,47}

PD-L1 ≥50% First-line Therapy

Continuation Maintenance



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MOLECULAR AND BIOMARKER-DIRECTED THERAPY FOR ADVANCED OR METASTATIC DISEASE^b

PD-L1 ≥50% Continuation Maintenance

ADENOCARCINOMA, LARGE CELL, NSCLC NOS

- Pembrolizumab (category 1)^f
- Pembrolizumab + pemetrexed (category 1)^g
- Atezolizumab and bevacizumab^{c,d} (category 1)^h
- Atezolizumabⁱ
- Nivolumab + ipilimumab (category 1)^j
- Cemiplimab-rwlc (category 1)^k
- Cemiplimab-rwlc^l ± pemetrexed^m (category 1)
- Durvalumabⁿ ± pemetrexed^o

SQUAMOUS CELL CARCINOMA

- Pembrolizumab (category 1)^{f,p}
- Atezolizumabⁱ
- Nivolumab + ipilimumab (category 1)^j
- Cemiplimab-rwlc (category 1)^{k,l}
- Durvalumabⁿ

PD-L1 ≥1%–49% Continuation Maintenance

ADENOCARCINOMA, LARGE CELL, NSCLC NOS

- Pembrolizumab (category 2B)^f
- Pembrolizumab + pemetrexed (category 1)^g
- Atezolizumab and bevacizumab^{c,d} (category 1)^h
- Atezolizumabⁱ
- Nivolumab + ipilimumab (category 1)^j
- Cemiplimab-rwlc^l ± pemetrexed^m (category 1)
- Durvalumabⁿ ± pemetrexed^o

SQUAMOUS CELL CARCINOMA

- Pembrolizumab^{f,p}
- Nivolumab + ipilimumab (category 1)^j
- Cemiplimab-rwlc (category 1)
- Durvalumabⁿ

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2023 Non-Small Cell Lung Cancer

CONCURRENT CHEMORADIATION REGIMENS

Concurrent Chemoradiation Regimens[€]

Preferred (nonsquamous)

- Carboplatin AUC 5 on day 1, pemetrexed 500 mg/m² on day 1 every 21 days for 4 cycles; concurrent thoracic RT^{1,*,†,‡}
- Cisplatin 75 mg/m² on day 1, pemetrexed 500 mg/m² on day 1 every 21 days for 3 cycles; concurrent thoracic RT^{2,3,*,†,‡}

± additional 4 cycles of pemetrexed 500 mg/m^{2†,§}

- Paclitaxel 45–50 mg/m² weekly; carboplatin AUC 2, concurrent thoracic RT^{4,*,†,‡} ± additional 2 cycles every 21 days of paclitaxel 200 mg/m² and carboplatin AUC 6^{7,§}
- Cisplatin 50 mg/m² on days 1, 8, 29, and 36; etoposide 50 mg/m² days 1–5 and 29–33; concurrent thoracic RT^{5,6,*,†,‡}

Preferred (squamous)

- Paclitaxel 45–50 mg/m² weekly; carboplatin AUC 2, concurrent thoracic RT^{6,*,†,‡} ± additional 2 cycles every 21 days of paclitaxel 200 mg/m² and carboplatin AUC 6^{T,§}
- Cisplatin 50 mg/m² on days 1, 8, 29, and 36; etoposide 50 mg/m² days 1–5 and 29–33; concurrent thoracic RT^{5,6,*,†,‡}

Consolidation Immunotherapy for Patients with Unresectable Stage II/III NSCLC, PS 0–1, and No Disease Progression After Definitive Concurrent Chemoradiation

Durvalumab 10 mg/kg IV every 2 weeks or 1500 mg every 4 weeks for up to 12 months (patients with a body weight of ≥30 kg)^{7,8} (category 1 for stage III; category 2A for stage II)



National
Comprehensive
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Network®NCCN Guidelines Version 3.2023Non-Small Cell Lung Cancer

PERIOPERATIVE SYSTEMIC THERAPY

Neoadjuvant Systemic Therapy

- All patients should be evaluated for preoperative therapy, with strong consideration for nivolumab + chemotherapy for those patients with tumors ≥4 cm or node positive and no contraindications to immune checkpoint inhibitors.* Otherwise refer to the Neoadjuvant Systemic Therapy for Patients Not Candidates for Immune Checkpoint Inhibitors.
- Test for PD-L1 status, *EGFR* mutations, and *ALK* rearrangements (stages IB–IIIA, IIIB [T3,N2]). <u>Principles of Molecular and Biomarker Analysis (NSCL-H)</u>
- After surgical evaluation, patients likely to receive adjuvant chemotherapy may be treated with induction systemic therapy as an alternative.

Neoadjuvant Systemic Therapy in Patients Candidates for Immune Checkpoint Inhibitors

- Nivolumab 360 mg and platinum-doublet chemotherapy every 3 weeks for 3 cycles¹
- Platinum-doublet chemotherapy options include:
 - ♦ Carboplatin AUC 5 or AUC 6 day 1, paclitaxel 175 mg/m² or 200 mg/m² day 1 (any histology)
 - ◊ Cisplatin 75 mg/m² day 1, pemetrexed 500 mg/m² day 1 (nonsquamous histology)
 - ◊ Cisplatin 75 mg/m² day 1, gemcitabine 1000 mg/m² or 1250 mg/m² days 1 and 8 (squamous histology)
 - ◊ Cisplatin 75 mg/m² day 1, paclitaxel 175 mg/m² or 200 mg/m² day 1 (any histology)
- Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy
- ♦ Carboplatin AUC 5 or AUC 6 day 1, pemetrexed 500 mg/m² day 1 (nonsquamous histology)
- ♦ Carboplatin AUC 5 or AUC 6 day 1, gemcitabine 1000 mg/m² or 1250 mg/m² days 1 and 8 (squamous histology)

Neoadjuvant Systemic Therapy for Patients Not Candidates for Immune Checkpoint Inhibitors

Preferred (nonsquamous)

- Cisplatin 75 mg/m² day 1, pemetrexed 500 mg/m² day 1 every 21 days for 4 cycles²
- Preferred (squamous)
- Cisplatin 75 mg/m² day 1, gemcitabine 1250 mg/m² days 1 and 8, every 21 days for 4 cycles³
- Cisplatin 75 mg/m² day 1, docetaxel 75 mg/m² day 1 every 21 days for 4 cycles⁴

Other Recommended

- Cisplatin 50 mg/m² days 1 and 8; vinorelbine 25 mg/m² days 1, 8, 15, and 22, every 28 days for 4 cycles⁵
- Cisplatin 100 mg/m² day 1, vinorelbine 30 mg/m² days 1, 8, 15, and 22, every 28 days for 4 cycles^{6,7}
- Cisplatin 75–80 mg/m² day 1, vinorelbine 25–30 mg/m² days 1 and 8, every 21 days for 4 cycles
- Cisplatin 100 mg/m² day 1, etoposide 100 mg/m² days 1–3, every 28 days for 4 cycles⁶
- Useful in Certain Circumstances
- Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy
- ▶ Carboplatin AUC 6 day 1, paclitaxel 200 mg/m² day 1, every 21 days for 4 cycles⁸
- Carboplatin AUC 5 day 1, gemcitabine 1000 mg/m² days 1 and 8, every 21 days for 4 cycles⁹ (squamous histology)
- ► Carboplatin AUC 5 day 1, pemetrexed 500 mg/m² day 1 every 21 days for 4 cycles¹⁰ (nonsquamous histology)
- All chemotherapy regimens listed above can be used for sequential chemotherapy/RT.

Adjuvant Systemic Therapy

National Comprehensive NCCN Cancer

Network[®]

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 Non-Small Cell Lung Cancer

PERIOPERATIVE SYSTEMIC THERAPY

Adjuvant Systemic Therapy

• Test for PD-L1 status, *EGFR* mutations, and *ALK* rearrangements (stages IB–IIIA, IIIB [T3,N2]). <u>Principles of Molecular and Biomarker Analysis (NSCL-H)</u>.

Preferred (nonsquamous)

- Cisplatin 75 mg/m² day 1, pemetrexed 500 mg/m² day 1 every 21 days for 4 cycles²
- Preferred (squamous)
- Cisplatin 75 mg/m² day 1, gemcitabine 1250 mg/m² days 1 and 8, every 21 days for 4 cycles³
- Cisplatin 75 mg/m² day 1, docetaxel 75 mg/m² day 1 every 21 days for 4 cycles⁴

Other Recommended

- Cisplatin 50 mg/m² days 1 and 8; vinorelbine 25 mg/m² days 1, 8, 15, and 22, every 28 days for 4 cycles⁵
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- Cisplatin 100 mg/m² day 1, etoposide 100 mg/m² days 1–3, every 28 days for 4 cycles⁶

Useful in Certain Circumstances

- Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy
- ► Carboplatin AUC 6 day 1, paclitaxel 200 mg/m² day 1, every 21 days for 4 cycles⁸
- ► Carboplatin AUC 5 day 1, gemcitabine 1000 mg/m² days 1 and 8, every 21 days for 4 cycles⁹
- ► Carboplatin AUC 5 day 1, pemetrexed 500 mg/m² day 1 every 21 days for 4 cycles¹⁰ (nonsquamous histology)

All chemotherapy regimens listed above can be used for sequential chemotherapy/RT.

Systemic Therapy Following Previous Adjuvant Systemic Therapy

- Osimertinib 80 mg daily¹¹
- Osimertinib for patients with completely resected stage IB–IIIA or stage IIIB (T3, N2) NSCLC and positive for EGFR (exon 19 deletion, exon 21 L858R) mutations who received previous adjuvant chemotherapy or are ineligible to receive platinum-based chemotherapy.
- Atezolizumab 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks for up to 1 year¹²
- Atezolizumab for patients with completely resected stage IIB–IIIA, stage IIIB (T3, N2), or high-risk stage IIA NSCLC with PD-L1 ≥1% and negative for EGFR exon 19 deletion or exon 21 L858R mutations or ALK rearrangements who received previous adjuvant chemotherapy and with no contraindications to immune checkpoint inhibitors.*
- Pembrolizumab 200 mg every 3 weeks or 400 mg every 6 weeks for up to 1 year¹³
- Pembrolizumab for patients with completely resected stage IIB–IIIA, stage IIIB (T3, N2), or high-risk stage IIA NSCLC and negative for EGFR exon 19 deletion or exon 21 L858R mutations or ALK rearrangements who received previous adjuvant chemotherapy and with no contraindications to immune checkpoint inhibitors.*

Neoadjuvant Systemic Therapy



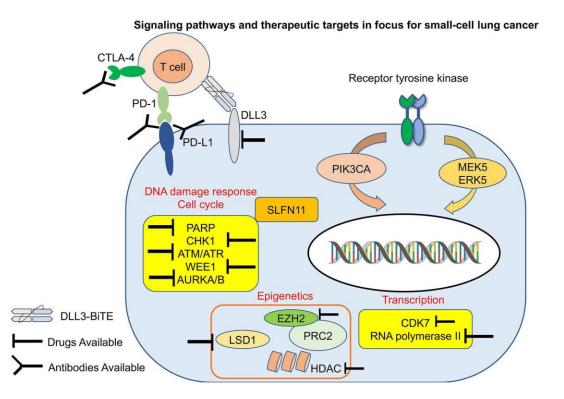
Where are we today in biomarker testing for lung cancer?

- Tremendous expansion of treatment options with rapid discovery of new targets, development of effective therapeutic agents and providing hope to many more patients with lung cancer
- However, serious challenges remain:
 - The pace of discovery and implementation has made it hard for most oncologist and lung cancer providers to keep up
 - As more discoveries are made, many unanswered questions remain, which clinical research is struggling to answers in a timely fashion
 - Disparities in consistent delivery of biomarker driven care due to access to sophisticated oncology programs, insurance coverage/approval, treatment cost and patient/provider education

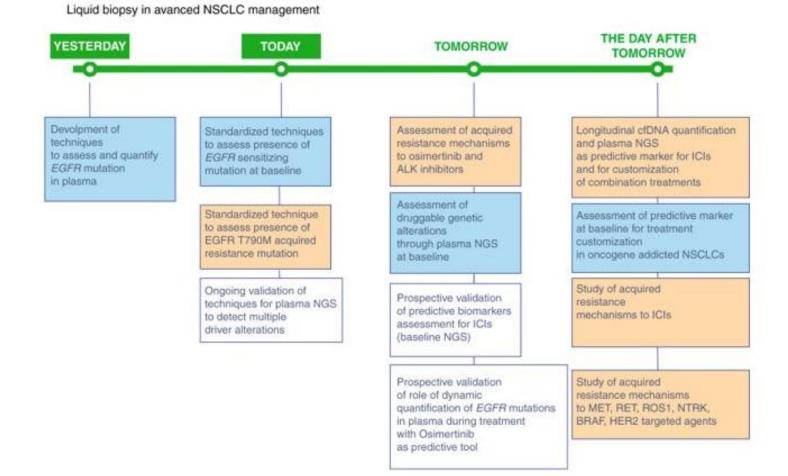


Biomarker Driven Care in Small Cell and NET

- SCLC historically a graveyard for drug development
- Multiple targets signaling pathways have been discovered
- Trials in biomarker driven care are starting to show some modest results

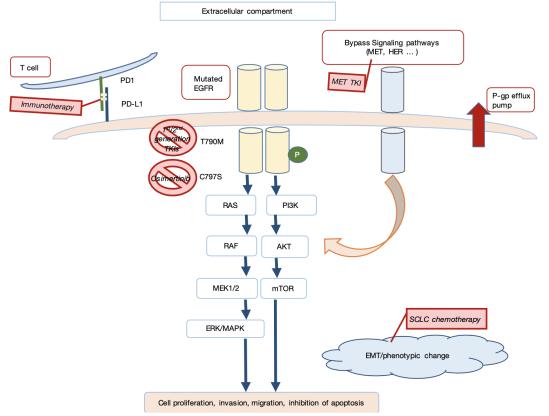


Liquid Biopsy for biomarker testing, screening and monitoring



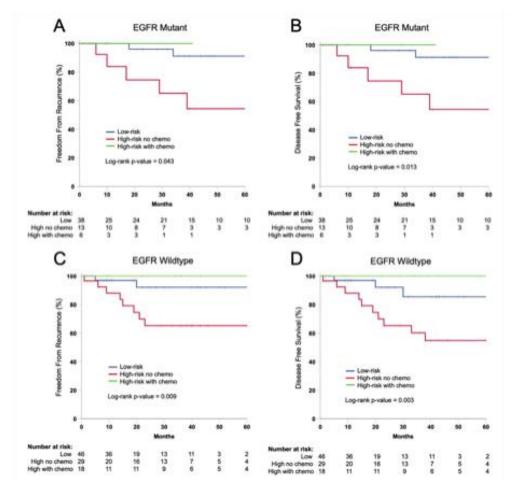
Biomarker Driven Resistance and Outcome Prediction

- Acquired resistance to targeted and immunotherapy is a rapidly expanding field of diagnostics and therapeutics
 - Resistant to EGFR mutant NSCLC to Osimertinib and treatment with mobocertinum and amivantamab
 - Resistance to immunotherapy by EGFR and ALK mutant NSCLC
 - Targeting PD1/PDL1 and CTLA4



Biomarker Driven Outcome Prediction

- Biomarker signals demonstrates risk of recurrence and mortality in the NSCLC and can drive therapeutic decisions
 - Ex. 14 gene panel and adjuvant chemotherapy in Stage 1a NSCLC



Clinical Lung Cancer November 2021

Biomarker Driven Pharmacology/Toxicity

- Biomarkers can predict appropriate dosing and toxicity
 - Frameshift Neoantigens Peptides can predict Immunotherapy toxicities

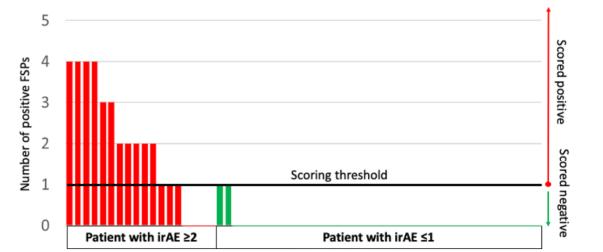
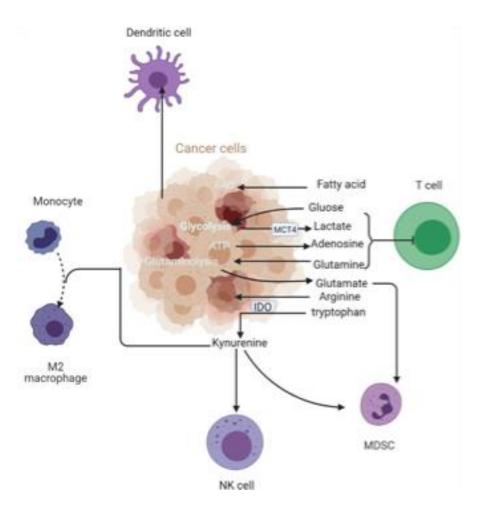


Fig. 5 Bar graph displays ordered, positive contrast scores for irAE prediction. A set of 11 irAE-specific FSPs were statistically selected to build a model for irAE prediction. Patients with 1 or more positive FSPs (left Y axis) are predicted to have irAE \geq G 2. Red bar: patient with observed irAE \geq G 2. Green bar: patient with observed irAE = G 0 or G 1. Black line: cut-off score for irAE \geq G 2 prediction. Predictions are shown on right Y-axis

Shen et al. Journal of Translational Medicine (2023) 21:338

Modulation of the tumor microenvironment (TME)

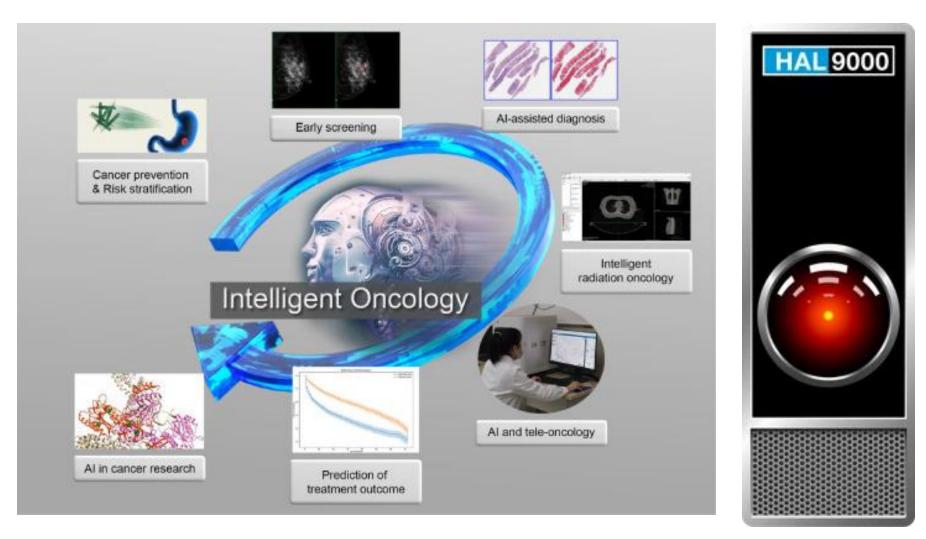
- Assessment of the TME can predict response to treatment
- Radiotherapy, electroporation, cytokines and oncoviruses demonstrates the ability to prime the tumor for Immunotherapy

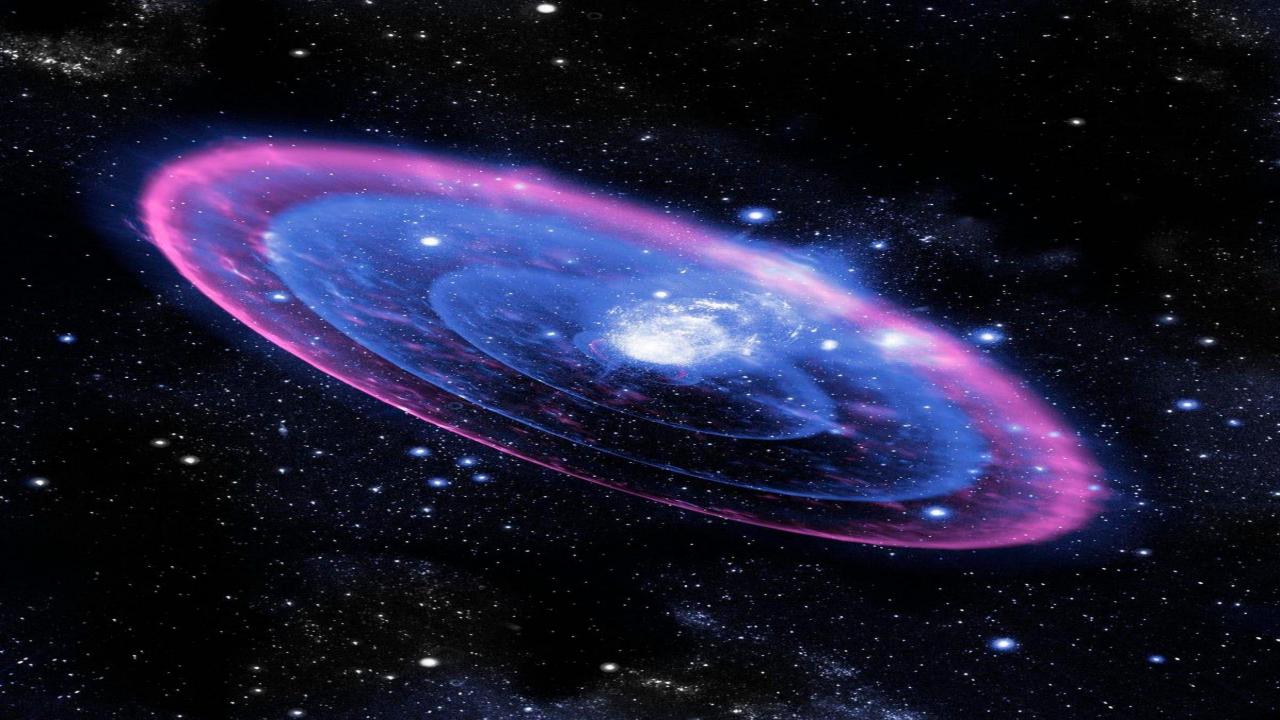


Biomarker and non anatomic staging

- 9th Edition TNM Staging due January 2024.
 - Staging will likely stay focused on TNM factors
- Non anatomical factors, particularly biomarkers are part of the survey and likely be part of a future staging scheme

AI assisted oncology









Together Everyone Achieves More

Didactic Q & A



Case Presentation: Ochsner LSU Health Feist-Weiller Cancer Center



Robert Holladay, MD, FCCP

Professor of Clinical Internal Medicine; Program Director, Interventional Pulmonary Fellowship Program Medicine Pulmonary Critical

Case Summary by Dr. Holladay

Case #1

- 76 yo woman with a PMH of HTN, type 2 DM and previous Hepatitis B infection presented to the hospital with complaints of fatigue and some "dizziness". Noted to have a small left sided pleural effusion and a LUL lung nodule. Initial thoracentesis was performed which was positive for adenocarcinoma.
- Stage 4 T1b, N0, M1a. Pleural fluid was not sufficient for tissue for biomarker testing.
- Had bronchoscopy to evaluate the LUL lung nodule. Was performed with robotic navigation. On site cytology review noted to be positive for adenocarcinoma. Pathology was sent for biomarker testing noted to be positive for EGFR with NGS testing.
- Patient has been started on standard chemotherapy with carboplatin and premetrexed. Osimertinib added once NGS results noted positive for EGFR. Tolerating the treatment currently.

Case Summary by Dr. Holladay

Case #2

- 47 yo woman with PMH of obesity and anxiety who presented with a persistent cough and dyspnea. CT chest showed findings of RUL lung mass and associated mediastinal adenopathy. Had bronchoscopy with EBUS which was positive at station 4R lymph node for adenocarcinoma.
- Specimen had biomarker testing by NGS which was positive for EML4-ALK.
- PET scan showed activity in lung lesions and also in the left ilium.
- Biopsy of iliac lesion noted to be positive for adenocarcinoma
- Stage 4 T4, N2, M1b.
- Started on therapy with alectinib.
- Dosage adjusted for problems with fatigue and lower extremity edema

Case Summary by Dr. Holladay

Case #2 Continued

- PET imaging after being on targeted therapy shows improvement in chest and bone findings.
- Started on denosumab for metastatic bone disease at six months after diagnosis of lung cancer
- Repeat imaging at 15 months from presentation shows continued improvement in RUL lung mass and mediastinal adenopathy. No evidence of new bone metastasis.

Case Presentation Discussion

Discussion/Feedback from our Faculty



Wrap-Up & Post-ECHO Series Assessment

Reminder: Post-ECHO Series Assessment Survey



We need your help to continue improving this ECHO Series and appreciate your feedback.

Please check your email inbox and junk folders for an email from *"redcap@vumc.org"* with a Post-ECHO Survey link.



You will also receive a Six-Month Follow-Up Survey in late November/early December.



Materials and Resources will be available soon on the <u>ACS ECHO Website</u>



Questions: Contact <u>korey.hofmann@cancer.org</u> and <u>leigh.davis@cancer.org</u>





Thank you to Amgen for their generous support!



Oncology

Thank you to Dr. Sarah Thayer for your leadership.

Thank you to Oschner LSU Health Feist- Weiller Cancer Center for their partnership.

