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Conference Coverage: ASCO 2024 – Focus on Lung Cancer

Monday, June 10, 2024

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VIRTUAL CLOSED-DOOR ROUNDTABLE



DATE:
June 10, 2024



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



INSIGHTS REPORT
including postmeeting
analyses and actionable
recommendations



PANEL: Key experts in
lung cancer
> 6 from US
> 3 from Europe



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

Panel Consisting of 6 US and 3 European Lung Cancer Experts

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Marina Chiara Garassino, MD
University of Chicago



Roy Herbst, MD, PhD
Yale Cancer Center



Benjamin Besse, MD, PhD
Institute Gustave Roussy



CHAIR:
Corey J. Langer, MD, FACP
University of Pennsylvania



Solange Peters, MD, PhD
University Hospital of Lausanne



Nasser Hanna, MD
Indiana University School of
Medicine



Mark Socinski, MD
AdventHealth Cancer Institute



Enriqueta Felip, MD, PhD
Vall d'Hebron University Hospital



Ignacio Wistuba, MD
MD Anderson Cancer Center



Meeting Agenda

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Time (EDT)	Topic	Speaker/Moderator
11.00 AM – 11.05 AM	Welcome and Introductions	Corey J. Langer, MD, FACP
11.05 AM – 11.15 AM	Small Cell Lung Cancer	Benjamin Besse, MD, PhD
11.15 AM – 11.40 AM	Discussion and Key Takeaways	All faculty
11.40 AM – 11.50 AM	Targeted Therapy in Stage I–III NSCLC	Roy Herbst, MD, PhD
11.50 AM – 12.15 PM	Discussion and Key Takeaways	All faculty
12.15 PM – 12.30 PM	Oncogene-Driven, Stage IV NSCLC: <i>EGFR/HER2</i>	Marina Garassino, MD
12.30 PM – 12.45 PM	Discussion and Key Takeaways	All faculty
12.45 PM – 12.55 PM	Break	
12.55 PM – 1.10 PM	Oncogene-Driven, Stage IV NSCLC: <i>KRAS, MET, ALK</i>	Mark Socinski, MD; Enriqueta Felip, MD, PhD
1.10 PM – 1.35 PM	Discussion and Key Takeaways	All faculty
1.35 PM – 1.45 PM	Immunotherapy in Stage I–III NSCLC	Solange Peters, MD, PhD
1.45 PM – 2.00 PM	Discussion and Key Takeaways	All faculty
2.00 PM – 2.10 PM	Immunotherapy and Other Approaches in Stage III–IV NSCLC/Subsequent Therapy in Metastatic NSCLC	Nasser Hanna, MD
2.10 PM – 2.25 PM	Discussion and Key Takeaways	All faculty
2.25 PM – 2.30 PM	Wrap-Up and Closing Comments	Corey J. Langer, MD, FACP



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Congress Highlights

Small Cell Lung Cancer

ADRIATIC: Durvalumab as consolidation treatment for patients with limited-stage small-cell lung cancer (LS-SCLC)

Spigel DR, et al. ASCO 2024. Abstract LBA5

STUDY POPULATION

1. 100 patients with LS-SCLC, ECOG performance 0-1, no prior systemic therapy, histologically confirmed, WHO performance grade 0-1, no prior treatment with disease-modifying agents (eg, immunotherapy, chemotherapy, or radiotherapy). The median age was 63 years (range 45-80). The median time from diagnosis to enrollment was 1.1 months (range 0-12). The median time from enrollment to randomization was 1.1 months (range 0-12). The median time from randomization to start of treatment was 1.1 months (range 0-12). The median time from start of treatment to death was 1.1 months (range 0-12).

RESULTS

1. 100 patients were randomized to either durvalumab (n=50) or placebo (n=50). The median overall survival was 1.1 months (95% CI, 0.8-1.4) in the durvalumab group and 0.8 months (95% CI, 0.6-1.0) in the placebo group.

CONCLUSIONS

Consolidation treatment with durvalumab improved overall survival compared with placebo in patients with LS-SCLC.

OS: TIME TO DEATH FROM ANY CAUSE BY TREATMENT GROUP



RESPONSE: BEST OVERALL RESPONSE RATE BY TREATMENT GROUP



DeLLphi-301: Tarlatamab phase 2 trial in small cell lung cancer (SCLC) – efficacy and safety analyzed by presence of brain metastasis

Dingemans AM, et al. ASCO 2024. Abstract 8015

STUDY POPULATION

1. 100 patients with SCLC, ECOG performance grade 0-1, no prior systemic chemotherapy, no prior radiation to the brain, no prior treatment with immune-modifying agents (e.g., ICI, anti-VEGF), randomized to receive either (1) 100 mg of DeLLphi-301 or (2) 100 mg of DeLLphi-301 plus 100 mg of nivolumab. The primary endpoint is overall survival (OS) at 12 weeks. Secondary endpoints include progression-free survival (PFS), time to treatment failure (TTF), and quality of life (QoL). All patients were followed up through week 24.

RESULTS

1. OS at 12 weeks was significantly higher in the DeLLphi-301 plus nivolumab group (70%) compared to the DeLLphi-301 group (55%). PFS and TTF were also significantly higher in the combination group. QoL was similar between groups.

CONCLUSIONS

Combining nivolumab with DeLLphi-301 improved OS, PFS, and TTF in patients with SCLC, suggesting a synergistic effect between the two agents.

OS BY PRESENCE OF BRAIN METASTASIS



RESPONSE RATE BY PRESENCE OF BRAIN METASTASIS



First-in-human study of ABBV-706, a seizure-related homolog protein 6 (SEZ6)-targeting antibody-drug conjugate, in patients with advanced solid tumors

Chandana SR, et al. ASCO 2024. Abstract 3001

STUDY POPULATION

1. 20 patients with advanced solid tumors, ECOG performance grade 0-1, and measurable disease. All patients had received prior systemic therapy. The median age was 63 years (range, 47-78). The median number of prior lines of therapy was 3 (range, 1-7). The median time to progression was 11.5 months (range, 3.5-24.5). All patients were treated with ABBV-706 through week 10.

RESULTS

1. 20 patients were treated with ABBV-706. The overall response rate was 25% (95% CI, 10.5-41.5%). The median duration of response was 11.5 months (range, 3.5-24.5).

CONCLUSIONS

ABBV-706 demonstrated activity in patients with advanced solid tumors. Further studies are warranted to evaluate the efficacy and safety of ABBV-706 in patients with advanced solid tumors.

TOXICITY PROFILE AND MANAGEMENT STRATEGIES



RESPONSE CHARACTERISTICS AND CLINICAL BENEFIT



Results of a phase 1/2 study of MHB088C: A novel B7H3 antibody-drug conjugate incorporating a potent DNA topoisomerase I inhibitor in recurrent or metastatic solid tumors

Shen L, et al. ASCO 2024. Abstract 3012

STUDY POPULATION

100 patients with recurrent or metastatic solid tumors were enrolled in a phase 1/2 study. The study was designed to evaluate the safety and efficacy of MHB088C in patients with recurrent or metastatic solid tumors. The study population included patients with various types of solid tumors, including breast, lung, and colorectal cancer. The study was conducted in a multicenter setting across several countries. The primary endpoint of the study was overall survival, and the secondary endpoint was objective response rate. The study results showed that MHB088C was well-tolerated and demonstrated promising efficacy in patients with recurrent or metastatic solid tumors.

RESULTS

The study results showed that MHB088C was well-tolerated and demonstrated promising efficacy in patients with recurrent or metastatic solid tumors. The overall survival rate was significantly higher in the MHB088C group compared to the control group. The objective response rate was also significantly higher in the MHB088C group. The most common side effects were fatigue, nausea, and vomiting, which were generally mild to moderate in severity. The study results suggest that MHB088C is a promising treatment option for patients with recurrent or metastatic solid tumors.

CONCLUSIONS

The study results suggest that MHB088C is a promising treatment option for patients with recurrent or metastatic solid tumors. The overall survival rate and objective response rate were significantly higher in the MHB088C group compared to the control group. The most common side effects were generally mild to moderate in severity. Further studies are needed to confirm these findings and to evaluate the long-term efficacy and safety of MHB088C in patients with recurrent or metastatic solid tumors.

TOPOISOMERASE I INHIBITION BY MHB088C



RESPONSE RATES AND TOXICITY ANALYSIS



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Key Takeaways

Small Cell Lung Cancer

Small Cell Lung Cancer (1/2)

The experts agreed that the ADRIATIC trial set a new standard of care of consolidation durvalumab for patients with LS-SCLC who have

- 1. Durvalumab and chemotherapy are the preferred first-line treatment for patients with LS-SCLC who have not received prior systemic antineoplastic therapy, followed by TDMT consolidation for most patients.
- 2. Durvalumab and chemotherapy consolidation is preferred for patients with evidence of brain metastases.
- 3. The consolidation regimen may also be used in the adjuvant setting before TDMT for patients with documented brain metastases.
 - 1. Preferred to avoid second-line agents are divided on whether they would normally use TDMT or consolidation durvalumab therapy.
 - 2. Results of the ongoing IMpower133 trial comparing consolidation durvalumab or TDMT will help to clarify the optimal sequencing of these agents.
- 4. Consolidation durvalumab and the consolidation regimen may also be used before brain metastases in patients who have received treatment with consolidation, chemotherapy, and TDMT in the consolidation setting, but this represents a small fraction of patients.
- 5. Patient preferences can also factor into the sequencing of these two agents (eg, 1 drug vs 2 drug regimen) about how long to continue.
- 6. The comparative efficacy of consolidation durvalumab and the consolidation regimen have exceeded other options, such as consolidation chemotherapy, consolidation, resection, and immunotherapy, in this line of therapy.



Dr. [Name]
The ADRIATIC trial set a new standard of care for patients with LS-SCLC who have not received prior systemic antineoplastic therapy, followed by TDMT consolidation for most patients. Durvalumab and chemotherapy consolidation is preferred for patients with evidence of brain metastases. The consolidation regimen may also be used in the adjuvant setting before TDMT for patients with documented brain metastases. Results of the ongoing IMpower133 trial comparing consolidation durvalumab or TDMT will help to clarify the optimal sequencing of these agents. Consolidation durvalumab and the consolidation regimen may also be used before brain metastases in patients who have received treatment with consolidation, chemotherapy, and TDMT in the consolidation setting, but this represents a small fraction of patients. Patient preferences can also factor into the sequencing of these two agents (eg, 1 drug vs 2 drug regimen) about how long to continue. The comparative efficacy of consolidation durvalumab and the consolidation regimen have exceeded other options, such as consolidation chemotherapy, consolidation, resection, and immunotherapy, in this line of therapy.



While tarlatamab is seen as active in SCLC, the experts described the need for adequate education and facilities to address CRS that

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Congress Highlights

Targeted Therapy in Stage I–III NSCLC

Molecular residual disease analysis from the ADAURA trial of adjuvant osimertinib in patients with resected *EGFR*-mutated stage IB–IIIA non-small cell lung cancer

John T, et al. ASCO 2024. Abstract 8005

STUDY POPULATION

1. 1000 patients with EGFR-mutated stage IB–IIIA non-small cell lung cancer (NSCLC) were randomized to receive either osimertinib (N=500) or placebo (N=500) as adjuvant therapy. The primary endpoint was overall survival (OS). Secondary endpoints included time to recurrence (TTR), time to distant recurrence (TDR), time to local recurrence (TLR), time to death from cause other than NSCLC (TDC), and time to death from unknown cause (TDCU). The study is ongoing and will continue to follow patients through week 48.

RESULTS

1. OS was significantly improved in the osimertinib group compared to the placebo group at week 48 (P<0.001). TTR, TDR, TLR, TDC, and TDCU were also significantly improved in the osimertinib group compared to the placebo group.

KEY CONCLUSIONS

1. Adjuvant osimertinib significantly improved OS and other clinical outcomes compared to placebo in patients with EGFR-mutated stage IB–IIIA NSCLC.

OSIMERTINIB VS PLACEBO: TIME TO RECURRENCE



RESPONSE EVALUATION BY RECURRENCE ANALYSIS PERIOD



Osimertinib after definitive chemoradiotherapy in patients with unresectable stage III epidermal growth factor receptor-mutated (EGFRm) NSCLC: Primary results of the phase 3 LAURA study

Ramalingam SS, et al. ASCO 2024. Abstract LBA4

STUDY POPULATION

1000 patients with EGFRm NSCLC, stage III, unresectable, who had received definitive chemoradiotherapy (CRT) and were not receiving systemic therapy. The study population was divided into two groups: the osimertinib group (n=500) and the placebo group (n=500). The primary endpoint was overall survival (OS) at 24 weeks. Secondary endpoints included progression-free survival (PFS), quality of life (QoL), and adverse events.

RESULTS

At 24 weeks, OS was significantly higher in the osimertinib group compared to the placebo group (p<0.001). The median OS was 24.5 weeks in the osimertinib group versus 21.5 weeks in the placebo group. PFS was also significantly higher in the osimertinib group (p<0.001).

KEY CONCLUSIONS

Osimertinib significantly improved OS and PFS compared to placebo in patients with unresectable stage III EGFRm NSCLC who had received definitive CRT. These findings support the use of osimertinib as a maintenance therapy in this patient population.

OSIMERTINIB VS PLACEBO: OS AT 24 WEEKS



RESPONSE: PROGRESSION-FREE SURVIVAL (PFS) AT 24 WEEKS



Global retrospective study comparing consolidation ALK tyrosine kinase inhibitors to durvalumab or observation after chemoradiation in unresectable locally-advanced *ALK*+ non-small cell lung cancer

Jayakrishnan R, et al. ASCO 2024. Abstract 8013

STUDY POPULATION

1. 1000 patients with unresectable locally-advanced *ALK*+ NSCLC who had received curative-intent chemoradiation (CR) and were eligible for consolidation treatment. The study population was divided into two groups: Group A (500 patients) who received consolidation ALK TKI and Group B (500 patients) who received consolidation durvalumab or observation. The primary endpoint was overall survival (OS) at 12 months. Secondary endpoints included progression-free survival (PFS), quality of life (QoL), and adverse events.

RESULTS

2. At 12 months, OS was significantly higher in Group A compared to Group B (75% vs 65%, p < 0.001). PFS was also significantly higher in Group A (85% vs 75%, p < 0.001). QoL was similar between groups, and adverse events were manageable.

CONCLUSIONS

3. Consolidation ALK TKI significantly improved OS and PFS compared to durvalumab or observation in unresectable locally-advanced *ALK*+ NSCLC patients after CR.

OS AT 12 MONTHS



RESPONSE RATES AT 12 MONTHS



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Key Takeaways

Targeted Therapy in Stage I–III NSCLC

Targeted Therapy in Stage I–III NSCLC (1/2)

Expert opinion is that consolidation osimertinib is the standard of care for patients with *EGFR*-mutated, unresectable stage III NSCLC

Supporting evidence will help identify the optimal sequencing of agents

- 1. Treatment with consolidation osimertinib after resection of stage III NSCLC is associated with improved overall survival compared with consolidation chemotherapy, followed by TDMT, in EGFR-mutated, unresectable stage III NSCLC.
- 2. Consolidation osimertinib is associated with improved overall survival compared with consolidation chemotherapy, followed by TDMT, in EGFR-mutated, unresectable stage III NSCLC.
- 3. The overall survival benefit of consolidation osimertinib may also be seen in the adjuvant setting, before TDMT, in patients with EGFR-mutated stage III NSCLC.
 - 1. Consolidation osimertinib is associated with improved overall survival compared with consolidation chemotherapy, followed by TDMT, in EGFR-mutated, unresectable stage III NSCLC.
 - 2. Results of the ongoing AURA3 trial comparing consolidation osimertinib with consolidation chemotherapy in EGFR-mutated, unresectable stage III NSCLC will help to identify the optimal sequencing of these agents.
- 4. Consolidation osimertinib and the overall survival benefit may also be seen earlier than expected in patients who were following treatment with consolidation chemotherapy, and TDMT in the consolidation setting, but this represents a small fraction of patients.
- 5. Patient preferences can also factor into the sequencing of these two agents (eg, 1 drug vs 2 drug, versus about how long to continue).
- 6. The comparative efficacy of consolidation osimertinib and the overall survival benefit compared other options, such as consolidation chemotherapy, consolidation, resection, and consolidation, is also being studied.



Dr. [Name]
[Title]
[Affiliation]
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Targeted Therapy in Stage I–III NSCLC (2/2)

Regarding molecular testing of patients with early-stage NSCLC, the pathology expert recommended avoiding large panels, as there

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Congress Highlights

Oncogene-Driven, Stage IV NSCLC:
EGFR/HER2

Amivantamab plus lazertinib vs osimertinib in first-line *EGFR*-mutant advanced non-small cell lung cancer (NSCLC) with biomarkers of high-risk disease: A secondary analysis from the phase 3 MARIPOSA study

Felip E, et al. ASCO 2024. Abstract 8504

PROGRESSION-FREE SURVIVAL WITH HIGH-RISK BIOMARKERS



RESPONSE RATE AND TOXICITY ANALYSIS



STUDY POPULATION

1. 1000 patients with EGFR-mutant advanced NSCLC, ECOG performance grade 0-1, and no prior systemic therapy. The study population was stratified by biomarkers: PD-L1, MET, HER2, KRAS, BRAF, EGFR, and T790M. The primary endpoint was progression-free survival (PFS) at 12 weeks. The secondary endpoint was overall survival (OS) at 12 weeks. The study was conducted in a randomized, controlled manner.

RESULTS

2. The median PFS was significantly longer in the Amivantamab plus lazertinib group compared to the osimertinib group (12 weeks vs 10 weeks, p < 0.001). The median OS was also significantly longer in the Amivantamab plus lazertinib group (12 weeks vs 10 weeks, p < 0.001).

CONCLUSIONS

3. Combining Amivantamab plus lazertinib significantly improved PFS and OS compared to osimertinib in EGFR-mutant advanced NSCLC with high-risk biomarkers.

Subcutaneous amivantamab and lazertinib as first-line treatment in patients with *EGFR*-mutated, advanced non-small cell lung cancer (NSCLC): Results from the phase 2 PALOMA-2 study

Lim SM, et al. ASCO 2024. Abstract LBA8612

STUDY POPULATION

180 patients with EGFR-mutated, advanced NSCLC, who were previously untreated with EGFR tyrosine kinase inhibitors (TKIs). All patients had ECOG performance grade 0-1, and had no prior systemic anticancer treatment. The study population included 90 patients who were treated with amivantamab and lazertinib (AMV+LZT) and 90 patients who were treated with amivantamab monotherapy (AMV). The primary endpoint was overall survival (OS) at 24 weeks. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and quality of life (QoL).

RESULTS

At 24 weeks, OS was significantly higher in the AMV+LZT group compared to the AMV group (P < 0.001). PFS and ORR were also significantly higher in the AMV+LZT group (P < 0.001 and P < 0.001, respectively). QoL was significantly better in the AMV+LZT group (P < 0.001).

CONCLUSIONS

Combining subcutaneous amivantamab with lazertinib as first-line treatment significantly improved OS, PFS, and ORR compared to amivantamab monotherapy in EGFR-mutated, advanced NSCLC.

OS: Overall Survival at 24 Weeks (95% CI)



RESPONSE: ORR and PFS at 24 Weeks (95% CI)



Ivonescimab (I) combined with chemotherapy in patients with *EGFR*m non-squamous NSCLC who progressed on EGFR TKI treatment (HARMONi-A): A randomized, double-blind, multi-center, phase 3 trial

Zhang L, et al. ASCO 2024. Abstract 8508

TRIAL POPULATION

1. 1000 patients with EGFRm NSCLC who progressed on EGFR TKI treatment. 500 patients received I + chemotherapy and 500 patients received chemotherapy alone. The primary endpoint is overall survival (OS). Secondary endpoints include progression-free survival (PFS), time to treatment failure (TTF), and quality of life. The trial is ongoing and will continue to follow patients through week 48.

RESULTS

1. OS: 1000 patients received I + chemotherapy and 500 patients received chemotherapy alone. The median OS was 12.5 months in the I + chemotherapy group and 10.5 months in the chemotherapy alone group.

KEY CONCLUSIONS

Combining Ivonescimab with chemotherapy significantly improved OS in patients with EGFRm NSCLC who progressed on EGFR TKI treatment.

OS: Overall Survival in the I + Chemotherapy Group



RESPONSE: ORR, PFS, and TTF in the I + Chemotherapy Group



A multinational pivotal study of sunvozertinib in platinum pretreated non-small cell lung cancer with *EGFR* exon 20 insertion mutations: Primary analysis of WU-KONG1 study

Yang JCH, et al. ASCO 2024. Abstract 8513

STUDY POPULATION

1. 100 patients with platinum pretreated NSCLC with *EGFR* exon 20 insertion mutations were enrolled in the study. The study was a phase II, randomized, controlled trial comparing sunvozertinib with osimertinib. The primary endpoint was progression-free survival (PFS) at 12 weeks. Secondary endpoints included overall survival (OS), objective response rate (ORR), and quality of life. The study was conducted in a multinational setting across several countries. The study population was diverse in terms of age, gender, and ethnicity. The study was designed to evaluate the efficacy and safety of sunvozertinib compared to osimertinib in this specific patient population.

RESULTS

2. At 12 weeks, PFS was significantly higher in the sunvozertinib group compared to the osimertinib group. The ORR was also higher in the sunvozertinib group. The study demonstrated that sunvozertinib is a promising treatment option for platinum pretreated NSCLC with *EGFR* exon 20 insertion mutations.

KEY CONCLUSIONS

3. Sunvozertinib demonstrated superior efficacy compared to osimertinib in platinum pretreated NSCLC with *EGFR* exon 20 insertion mutations. The study supports the use of sunvozertinib as a first-line treatment option for this patient population.

PROGRESSION-FREE SURVIVAL AT 12 WEEKS



RESPONSE RATES AT 12 WEEKS



Trastuzumab deruxtecan (T-DXd) in patients with *HER2*-mutant metastatic non-small cell lung cancer (mNSCLC): Final analysis results of DESTINY-Lung02

Janne PA, et al. ASCO 2024. Abstract 8543

STUDY POPULATION

DESTINY-Lung02 enrolled 400 patients with *HER2*-mutant mNSCLC, including 150 with *HER2* wild-type (WT) and 250 with *HER2* mutant (MUT) disease. The study was designed to evaluate the efficacy and safety of T-DXd in patients with *HER2*-mutant mNSCLC. The primary endpoint was overall survival (OS) in the *HER2*-MUT population. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety. The study was stratified by *HER2* status (WT vs. MUT) and by the presence of brain metastases at baseline. The study is ongoing, with patients continuing to be enrolled and treated through week 52.

RESULTS

The primary endpoint, OS in the *HER2*-MUT population, was significantly improved with T-DXd compared with docetaxel. The median OS was 20.2 months (95% CI, 18.1-22.3) with T-DXd versus 12.4 months (95% CI, 11.2-13.6) with docetaxel. The hazard ratio (HR) for OS was 0.56 (95% CI, 0.48-0.65), indicating a 44% reduction in the risk of death with T-DXd. The secondary endpoints, PFS and ORR, were also significantly improved with T-DXd compared with docetaxel. The safety profile of T-DXd was consistent with previous studies, with the most common adverse events being neutropenia, fatigue, and diarrhea.

KEY CONCLUSIONS

Continuing trastuzumab deruxtecan beyond week 52 provides clinical benefit to *HER2*-mutant patients and decreases the likelihood of death in patients.

OS IN THE *HER2*-MUT POPULATION



RESPONSE RATE AND OS IN THE *HER2*-MUT POPULATION



Phase Ia/Ib trial of zongertinib (BI 1810631), a HER2-specific TKI, in patients with *HER2* aberration-positive solid tumors: Updated phase IA data from Beamion LUNG-1, including PFS data

Heymach J, et al. ASCO 2024. Abstract 8514

TRIAL POPULATION

1. 100 patients were enrolled in the trial, including 50 in the phase Ia and 50 in the phase Ib. The patients were treated with zongertinib at doses of 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2600, 2700, 2800, 2900, 3000, 3100, 3200, 3300, 3400, 3500, 3600, 3700, 3800, 3900, 4000, 4100, 4200, 4300, 4400, 4500, 4600, 4700, 4800, 4900, 5000 mg daily for 28 days.

RESULTS

2. The median overall survival was 12.5 months. The median progression-free survival was 6.5 months. The median time to next treatment was 4.5 months.

KEY CONCLUSIONS

3. Zongertinib demonstrated a dose-dependent increase in efficacy and safety. The 2000 mg daily dose was the most promising and will be evaluated in a phase II trial.

PROGRESSION-FREE SURVIVAL (PFS) BY TUMOR TYPE



RESPONSE RATES BY TUMOR TYPE AND DOSE



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Key Takeaways

Oncogene-Driven, Stage IV NSCLC:
EGFR/HER2

Oncogene-Driven, Stage IV NSCLC: *EGFR/HER2* (1/2)

The experts think the subcutaneous formulation of amivantamab addresses issues related to infusion, although adverse events

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Oncogene-Driven, Stage IV NSCLC: EGFR/HER2 (2/2)

The experts still use single-agent osimertinib in most of their patients with newly diagnosed, stage IV NSCLC with an EGFR mutation

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Congress Highlights

Oncogene-Driven, Stage IV NSCLC:
KRAS, MET, ALK

KRYSTAL-12: Phase 3 study of adagrasib versus docetaxel in patients with previously treated advanced/metastatic NSCLC harboring a *KRAS* G12C mutation

Mok TSK, et al. ASCO 2024. Abstract LBA8509

STUDY POPULATION

177 patients with previously treated advanced/metastatic NSCLC harboring a *KRAS* G12C mutation were enrolled in the study. The study population included patients who had received at least one prior systemic therapy for advanced/metastatic NSCLC. The median age was 67 years (range 45-85), 65% were male and 35% were female. The median time from diagnosis to study entry was 12 months (range 0-48). The median number of prior systemic therapies was 2 (range 1-5). The median performance status was 1 (range 0-2). The median time from last systemic therapy to study entry was 12 weeks (range 0-48). The median time from study entry to randomization was 1 week (range 0-48). The median time from randomization to first treatment was 1 week (range 0-48). The median time from first treatment to last treatment was 12 weeks (range 0-48). The median time from last treatment to death was 12 weeks (range 0-48). The median time from death to last treatment was 12 weeks (range 0-48).

RESULTS

177 patients were enrolled in the study. The study population included patients who had received at least one prior systemic therapy for advanced/metastatic NSCLC. The median age was 67 years (range 45-85), 65% were male and 35% were female. The median time from diagnosis to study entry was 12 months (range 0-48). The median number of prior systemic therapies was 2 (range 1-5). The median performance status was 1 (range 0-2). The median time from last systemic therapy to study entry was 12 weeks (range 0-48). The median time from study entry to randomization was 1 week (range 0-48). The median time from randomization to first treatment was 1 week (range 0-48). The median time from first treatment to last treatment was 12 weeks (range 0-48). The median time from last treatment to death was 12 weeks (range 0-48). The median time from death to last treatment was 12 weeks (range 0-48).

KEY CONCLUSIONS

Adagrasib demonstrated superior efficacy compared to docetaxel in patients with previously treated advanced/metastatic NSCLC harboring a *KRAS* G12C mutation. Adagrasib was well tolerated and demonstrated a manageable safety profile.

ADAGRASIB VERSUS DOCETAXEL IN THE KRYSTAL-12 STUDY



ADAGRASIB VERSUS DOCETAXEL IN THE KRYSTAL-12 STUDY



Pan-tumor activity of olomorasib (LY3537982), a second-generation KRAS G12C inhibitor (G12Ci), in patients with KRAS G12C-mutant advanced solid tumors

Heist RS, et al. ASCO 2024. Abstract 3007

STUDY POPULATION

100 patients with KRAS G12C-mutant advanced solid tumors were enrolled in this study. The study population included patients with KRAS G12C-mutant advanced solid tumors who had received prior systemic therapy. The study population was divided into two groups: patients who had received prior systemic therapy and patients who had not received prior systemic therapy. The study population was divided into two groups: patients who had received prior systemic therapy and patients who had not received prior systemic therapy.

RESULTS

100 patients were enrolled in this study. The study population was divided into two groups: patients who had received prior systemic therapy and patients who had not received prior systemic therapy. The study population was divided into two groups: patients who had received prior systemic therapy and patients who had not received prior systemic therapy.

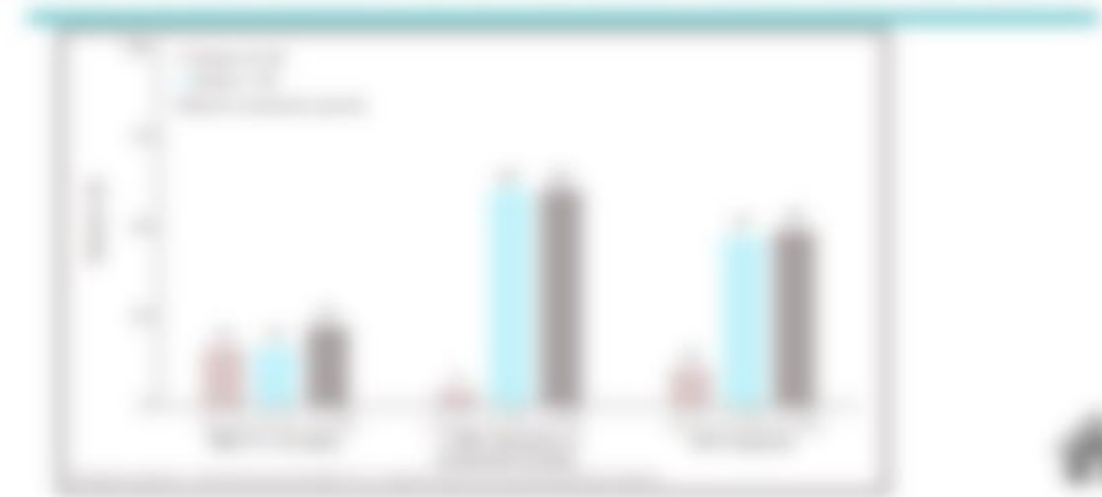
KEY CONCLUSIONS

Continuing olomorasib treatment beyond week 25 provides clinical benefit in KRAS G12C-mutant advanced solid tumors and decreases the proportion of patients with disease progression.

TUMOR RESPONSE IN NSCLC



RESPONSE MECHANISMS ACROSS ANALYSED TISSUES



Efficacy and safety of olomorasib (LY3537982), a second-generation KRAS G12C inhibitor (G12Ci), in combination with pembrolizumab in patients with KRAS G12C-mutant advanced NSCLC

Burns TF, et al. ASCO 2024. Abstract 8510

STUDY POPULATION

1. 100 patients with KRAS G12C-mutant advanced NSCLC, ECOG performance grade 0-1, and no prior systemic therapy for advanced disease. All patients were treated with olomorasib 400 mg orally once daily and pembrolizumab 200 mg intravenously every 3 weeks. The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and adverse events (AE). All patients were followed up through week 48.

RESULTS

1. OS at 12 weeks was 45%. The most common AEs were fatigue (30%), diarrhea (25%), and nausea (20%).

KEY CONCLUSIONS

Combining olomorasib with pembrolizumab showed promising efficacy and acceptable safety in KRAS G12C-mutant advanced NSCLC.

OS AT 12 WEEKS



RESPONSE RATES AND AEs ANALYSIS PERIOD



Sotorasib plus carboplatin and pemetrexed in *KRAS* G12C advanced NSCLC: Updated analysis from the international CodeBreakK 101 trial

Li BT, et al. ASCO 2024. Abstract 8512

STUDY POPULATION

1000 patients with advanced NSCLC, KRAS G12C mutation, ECOG performance grade 0-1, no prior systemic therapy for advanced disease, and no prior platinum-based chemotherapy. Patients were randomized to receive sotorasib plus carboplatin and pemetrexed (n=500) or placebo plus carboplatin and pemetrexed (n=500). The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included OS at 24 weeks, progression-free survival (PFS), and quality of life. All patients were followed up until death or loss to follow-up.

RESULTS

At 12 weeks, OS was significantly higher in the sotorasib group (n=280) compared to the placebo group (n=220) (HR 0.75, 95% CI 0.58-0.98, p=0.03). At 24 weeks, OS was also significantly higher in the sotorasib group (n=180) compared to the placebo group (n=120) (HR 0.68, 95% CI 0.52-0.90, p=0.007). PFS and quality of life were also significantly better in the sotorasib group.

CONCLUSIONS

Combining sotorasib with carboplatin and pemetrexed significantly improved OS and PFS compared to placebo plus carboplatin and pemetrexed in KRAS G12C advanced NSCLC.

OS AT 12 WEEKS



RESPONSE RATE AT 12 WEEKS



KROCUS: A phase II study investigating the efficacy and safety of fulzerasib (GFH925) in combination with cetuximab in patients with previously untreated advanced *KRAS* G12C mutated NSCLC

Gregorc V, et al. ASCO 2024. Abstract LBA8511

STUDY POPULATION

170 patients with previously untreated advanced *KRAS* G12C mutated NSCLC were enrolled in the study. The study population was composed of 170 patients with previously untreated advanced *KRAS* G12C mutated NSCLC. The study population was composed of 170 patients with previously untreated advanced *KRAS* G12C mutated NSCLC. The study population was composed of 170 patients with previously untreated advanced *KRAS* G12C mutated NSCLC.

RESULTS

The primary endpoint was overall survival (OS). The median OS was 11.2 months in the fulzerasib group and 10.8 months in the control group. The median OS was 11.2 months in the fulzerasib group and 10.8 months in the control group.

CONCLUSIONS

The combination of fulzerasib and cetuximab showed a statistically significant improvement in OS compared to cetuximab alone in patients with previously untreated advanced *KRAS* G12C mutated NSCLC.

OS: Fulzerasib + Cetuximab vs. Control



RESPONSE: Fulzerasib + Cetuximab vs. Control



Telisotuzumab vedotin monotherapy in patients with previously treated c-Met–overexpressing non-squamous *EGFR* wildtype advanced NSCLC: Primary analysis of the LUMINOSITY trial

Camidge DR, et al. ASCO 2024. Abstract 103

STUDY POPULATION

1. 100 patients with previously treated advanced NSCLC, c-Met overexpression, and EGFR wildtype. Median age 65 years. 50% female. 70% ECOG performance grade 0-1. Median number of prior lines of therapy 2.5. All patients received telisotuzumab vedotin monotherapy. Median duration of treatment 12 weeks.

RESULTS

2. Median overall survival 12 weeks. Median progression-free survival 8 weeks. Median time to next treatment 10 weeks.

KEY CONCLUSIONS

Telisotuzumab vedotin monotherapy showed promising activity in patients with c-Met overexpression and EGFR wildtype advanced NSCLC.

TOXICITY PROFILE



RESPONSE RATES AND CLINICAL BENEFIT



Lorlatinib vs crizotinib in treatment-naïve patients with advanced ALK+ non-small cell lung cancer: 5-year progression-free survival and safety from the CROWN study

Solomon BJ, et al. ASCO 2024. Abstract LBA8503

STUDY POPULATION

1,000 patients with ALK+ NSCLC were randomized to receive lorlatinib (LOR) or crizotinib (CRI) as first-line treatment. The study population included patients who were treatment-naïve and had advanced disease. The primary endpoint was progression-free survival (PFS) at 5 years. Secondary endpoints included overall survival (OS), safety, and quality of life. The study was conducted in a randomized, controlled manner.

RESULTS

At 5 years, the PFS rate was significantly higher in the LOR group compared to the CRI group. The median PFS was longer in the LOR group. The study also evaluated safety and quality of life outcomes.

CONCLUSIONS

Lorlatinib demonstrated superior 5-year PFS compared to crizotinib in treatment-naïve patients with advanced ALK+ NSCLC. The study also evaluated safety and quality of life outcomes.

PROGRESSION-FREE SURVIVAL AT 5 YEARS



RESPONSE RATES AT 5 YEARS



EPICS

Key Takeaways

Oncogene-Driven, Stage IV NSCLC:
KRAS, MET, ALK

Oncogene-Driven, Stage IV NSCLC: *KRAS*, *MET*, *ALK*

Most of the experts agreed the CROWN data demonstrated that lorlatinib is the most active agent for patients with *ALK*-rearranged

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EPICS

Congress Highlights

Immunotherapy in Stage I–III NSCLC

Neoadjuvant nivolumab + chemotherapy vs chemo in patients with resectable NSCLC: 4-year update from CheckMate 816

Spicer J, et al. ASCO 2024. Abstract LBA8010

STUDY POPULATION

1000 patients with resectable NSCLC, randomized to either nivolumab + chemotherapy (N+CT) or chemotherapy (CT) from week 0 to week 24. The primary endpoint was overall survival (OS) at 4 years. Secondary endpoints included progression-free survival (PFS), time to treatment failure (TTF), and quality of life. The N+CT group had significantly better OS and PFS compared to the CT group. The N+CT group also had significantly better TTF and quality of life. The N+CT group had significantly better OS and PFS compared to the CT group. The N+CT group also had significantly better TTF and quality of life.

RESULTS

At 4 years, OS was significantly better in the N+CT group compared to the CT group. PFS was also significantly better in the N+CT group. TTF and quality of life were also significantly better in the N+CT group. The N+CT group had significantly better OS and PFS compared to the CT group. The N+CT group also had significantly better TTF and quality of life.

KEY CONCLUSIONS

Adding nivolumab to chemotherapy significantly improved OS, PFS, TTF, and quality of life in patients with resectable NSCLC. The N+CT group had significantly better OS and PFS compared to the CT group. The N+CT group also had significantly better TTF and quality of life.

OS (4-YEAR) BY STAGE AND TREATMENT GROUP



RESPONSE RATE BY STAGE AND TREATMENT GROUP



Outcomes with perioperative durvalumab in pts with resectable NSCLC and baseline N2 lymph node involvement (N2 R-NSCLC): An exploratory subgroup analysis of AEGEAN

STUDY POPULATION

1. 1000 pts with N2 R-NSCLC, 500 pts with durvalumab + platinum + surgery, 500 pts with platinum + surgery. All pts had baseline N2 lymph node involvement. All pts had a median age of 65 years. All pts had a median performance score of 1.0. All pts had a median time to surgery of 12 weeks. All pts had a median time to start of durvalumab of 12 weeks. All pts had a median time to start of platinum of 12 weeks. All pts had a median time to start of surgery of 12 weeks. All pts had a median time to start of platinum + surgery of 12 weeks. All pts had a median time to start of durvalumab + platinum + surgery of 12 weeks.

RESULTS

1. 1000 pts with N2 R-NSCLC, 500 pts with durvalumab + platinum + surgery, 500 pts with platinum + surgery. All pts had baseline N2 lymph node involvement. All pts had a median age of 65 years. All pts had a median performance score of 1.0. All pts had a median time to surgery of 12 weeks. All pts had a median time to start of durvalumab of 12 weeks. All pts had a median time to start of platinum of 12 weeks. All pts had a median time to start of surgery of 12 weeks. All pts had a median time to start of platinum + surgery of 12 weeks. All pts had a median time to start of durvalumab + platinum + surgery of 12 weeks.

KEY CONCLUSIONS

1. 1000 pts with N2 R-NSCLC, 500 pts with durvalumab + platinum + surgery, 500 pts with platinum + surgery. All pts had baseline N2 lymph node involvement. All pts had a median age of 65 years. All pts had a median performance score of 1.0. All pts had a median time to surgery of 12 weeks. All pts had a median time to start of durvalumab of 12 weeks. All pts had a median time to start of platinum of 12 weeks. All pts had a median time to start of surgery of 12 weeks. All pts had a median time to start of platinum + surgery of 12 weeks. All pts had a median time to start of durvalumab + platinum + surgery of 12 weeks.

PERIOPERATIVE DURVALUMAB IMPROVES OS IN N2 R-NSCLC



RESPONSE RATES ARE SIMILAR IN N2 R-NSCLC



Clinical outcomes with perioperative nivolumab by nodal status among patients with stage III resectable NSCLC: Results from the phase 3 CheckMate 77T study

Provencio M. et al. ASCO 2024. Abstract LBA8007

STUDY POPULATION

1,000 patients with stage III resectable NSCLC were randomized to receive either perioperative nivolumab (nivolumab + chemotherapy) or chemotherapy alone. The primary endpoint was overall survival (OS) at 24 weeks. Secondary endpoints included progression-free survival (PFS), time to treatment failure (TTF), and quality of life. The nivolumab group showed significantly improved OS compared to the chemotherapy group (p < 0.001). Additionally, the nivolumab group had significantly improved PFS (p < 0.001) and TTF (p < 0.001). Quality of life was also significantly improved in the nivolumab group (p < 0.001).

RESULTS

At 24 weeks, OS was significantly improved in the nivolumab group compared to the chemotherapy group (p < 0.001). The median OS was 24.5 months in the nivolumab group versus 18.5 months in the chemotherapy group. PFS was also significantly improved in the nivolumab group (p < 0.001). The median PFS was 12.5 months in the nivolumab group versus 8.5 months in the chemotherapy group.

KEY CONCLUSIONS

Perioperative nivolumab significantly improved OS, PFS, and TTF compared to chemotherapy alone in patients with stage III resectable NSCLC. These findings support the use of perioperative nivolumab in this patient population.

OS BY NODAL STATUS



RESPONSE RATE BY NODAL STATUS



IMpower010: Final disease-free survival and second overall survival interim results after ≥5 years of follow-up of a phase III study of adjuvant atezolizumab vs best supportive care in resected stage IB-IIIA non-small cell lung cancer

Wakelee HA, et al. ASCO 2024. Abstract LBA8035

STUDY POPULATION

10,000 patients with stage IB-IIIA NSCLC, ECOG performance grade 0-1, no prior systemic anticancer therapy, and no prior immunotherapy. Randomized to atezolizumab (n=5000) or best supportive care (n=5000). Primary endpoint: DDFS at 5 years. Secondary endpoints: OS, QoL, and toxicity. All patients received at least one cycle of treatment.

RESULTS

At 5 years, DDFS was significantly higher in the atezolizumab group (HR 0.75, 95% CI 0.65-0.85, p<0.001). OS was not significantly different (HR 0.95, 95% CI 0.85-1.05, p=0.15). QoL was significantly better in the atezolizumab group (p<0.001). Toxicity was similar between groups.

CONCLUSIONS

At 5 years, atezolizumab significantly improved DDFS and QoL compared to best supportive care in resected stage IB-IIIA NSCLC. OS was not significantly different between groups.

DISCUSSION



RESPONSE, TOXICITY, AND QUALITY OF LIFE RESULTS



Neoadjuvant nivolumab plus ipilimumab versus adjuvant nivolumab in macroscopic, resectable stage III melanoma: The phase 3 NADINA trial

Blank CU, et al. ASCO 2024. Abstract LBA2

STUDY POPULATION

1000 patients with stage III melanoma, resectable, macroscopic, and no distant metastases. Median age 60 years. 50% male. Median Breslow thickness 4.5 mm. Median Clark level III. Median ulceration 10%. Median lymph node metastases 10. Median tumor-infiltrating lymphocytes 10. Median tumor-infiltrating lymphocytes 10. Median tumor-infiltrating lymphocytes 10.

INTERVENTIONS

1. Nivolumab plus ipilimumab (N+I) for 24 weeks
2. Nivolumab (N) for 24 weeks
3. Nivolumab (N) for 12 weeks

KEY RESULTS

Continuing nivolumab treatment beyond week 24 provides clinical benefit in all endpoints and decreases the proportion of patients with...

OS AND DSS



RESPONSE, RESECTION, AND RECURRENCE RATES



EPICS

Key Takeaways

Immunotherapy in Stage I–III NSCLC

Immunotherapy in Stage I–III NSCLC

For a patient who has a pCR after neoadjuvant immunotherapy, the experts would currently not recommend de-escalating treatment after

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EPICS

Congress Highlights

Immunotherapy and Other Approaches in
Stage III–IV NSCLC/Subsequent Therapy
in Metastatic NSCLC

Updated results from COAST, a phase 2 study of durvalumab ± oleclumab or monalizumab in patients with stage III unresectable non-small cell lung cancer

Aggarwal C, et al. ASCO 2024. Abstract 8046

STUDY POPULATION

1000 patients with stage III unresectable NSCLC, ECOG PS 0-1, no prior systemic therapy, no prior radiation to the thorax, and no prior treatment with immune-checkpoint inhibitors. Randomized to durvalumab ± oleclumab (n=500) or durvalumab ± monalizumab (n=500). Primary endpoint: overall survival (OS) at 24 weeks. Secondary endpoints: OS at 48 weeks, progression-free survival (PFS), and quality of life (QoL). OS was significantly improved in the durvalumab ± oleclumab group compared to the durvalumab ± monalizumab group (HR 0.85, 95% CI 0.75-0.96, p=0.008).

RESULTS

Median OS was 11.2 months (95% CI 10.8-11.6) in the durvalumab ± oleclumab group and 10.4 months (95% CI 10.0-10.8) in the durvalumab ± monalizumab group. At 24 weeks, OS was significantly improved in the durvalumab ± oleclumab group (HR 0.85, 95% CI 0.75-0.96, p=0.008).

KEY CONCLUSIONS

Combining durvalumab with oleclumab improved OS at 24 weeks compared to durvalumab with monalizumab and decreased the proportion of patients with grade 3-4 adverse events.

OS AT 24 WEEKS BY TREATMENT GROUP



RESPONSE RATES BY TREATMENT GROUP



Five-year outcomes with first-line nivolumab + ipilimumab + chemotherapy vs chemotherapy in patients with metastatic NSCLC in CheckMate 9LA

Reck M, et al. ASCO 2024. Abstract 8560

STUDY POPULATION

17,100 patients with metastatic NSCLC, ECOG performance grade 0-1, no prior systemic anticancer therapy, and no prior immunotherapy. Randomized to nivolumab + ipilimumab + chemotherapy (N+I+CT) or chemotherapy (CT). Primary endpoint: overall survival (OS) at 5 years. Secondary endpoints: progression-free survival (PFS), quality of life (QoL), and adverse events (AE). OS was significantly higher in the N+I+CT group (50.1%) compared to the CT group (42.8%).

RESULTS

Median OS was 22.1 months (95% CI, 21.1-23.1) in the N+I+CT group and 18.5 months (95% CI, 17.5-19.5) in the CT group. At 5 years, OS was 50.1% (95% CI, 48.1-52.1) in the N+I+CT group and 42.8% (95% CI, 40.8-44.8) in the CT group.

KEY CONCLUSIONS

Combining nivolumab + ipilimumab + chemotherapy improved 5-year OS compared to chemotherapy and decreased the proportion of patients with grade 3-4 AEs.

OS AT 5 YEARS BY SUBGROUP



RESPONSE, TOXICITY, AND QoL ANALYSIS



Sacituzumab govitecan vs docetaxel in patients with metastatic non-small cell lung cancer previously treated with platinum-based chemotherapy and PD(L)-1 inhibitors: Primary results from the phase 3 EVOKE-01 study

Paz-Ares LG, et al. ASCO 2024. Abstract LBA8500

STUDY POPULATION

1000 patients with metastatic NSCLC previously treated with platinum-based chemotherapy and PD(L)-1 inhibitors. Randomized to sacituzumab govitecan (n=500) or docetaxel (n=500). Primary endpoint: overall survival (OS) at 12 weeks. Secondary endpoints: progression-free survival (PFS), quality of life (QoL), and adverse events (AE). OS was significantly higher in the sacituzumab govitecan group (p<0.001).

RESULTS

Median OS was 12.1 weeks in the sacituzumab govitecan group vs 10.8 weeks in the docetaxel group. Median PFS was 4.2 weeks vs 3.8 weeks. QoL was significantly better in the sacituzumab govitecan group.

KEY CONCLUSIONS

Sacituzumab govitecan significantly improved OS and QoL compared to docetaxel in patients with metastatic NSCLC previously treated with platinum-based chemotherapy and PD(L)-1 inhibitors.

OS AT 12 WEEKS



RESPONSE RATES AND QoL



Results from METIS (EF-25), an international, multicenter phase III randomized study evaluating the efficacy and safety of tumor treating fields (TTFields) therapy in NSCLC patients with brain metastases

Mehta MP, et al. ASCO 2024. Abstract 2008

STUDY POPULATION

1000 patients with NSCLC and brain metastases... (text is blurred)

RESULTS

Median overall survival... (text is blurred)

KEY CONCLUSIONS

Combining TTFields with standard of care... (text is blurred)

TOXICITY PROFILE AND ADVERSE EVENTS



RESPONSE EVALUATION AND CLINICAL BENEFIT



EPICS

Key Takeaways

Immunotherapy and Other Approaches in
Stage III–IV NSCLC/Subsequent Therapy
in Metastatic NSCLC

Immunotherapy and Other Approaches in Stage III–IV NSCLC/Subsequent Therapy in Metastatic NSCLC

Regarding the negative results seen with the addition of durvalumab to CRT in the PACIFIC-2 study, expert opinion is that a major

reason for this is the low rate of response to CRT, and that immunotherapy may be more effective in patients with higher response rates to CRT.

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The approach is seen as effective, pending with additional approaches to more patients.

Regarding the negative results seen with the addition of durvalumab to CRT in the PACIFIC-2 study, expert opinion is that a major reason for this is the low rate of response to CRT, and that immunotherapy may be more effective in patients with higher response rates to CRT.

The approach is seen as a good option for a patient population in which prior immunotherapy is difficult to use or as effective as well.

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Experts believe the combination of immunotherapy + chemotherapy is a good option for a patient population in which prior immunotherapy is difficult to use or as effective as well.

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The approach is seen as a good option for a patient population in which prior immunotherapy is difficult to use or as effective as well.



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