











EPICS

Conference Coverage: ASCO 2024 – Focus on Squamous Cell Carcinoma of the Head and Neck (SCCHN)

July 25, 2024

Full Report

Content	Slide
Meeting Snapshot	3 
Faculty Panel	4 
Meeting Agenda	5 
Key Insights and Strategic Recommendations	6 
Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches	9 
Metastatic SCCHN – Focus on Chemotherapy and Targeted Therapy	21 
Metastatic SCCHN – Focus on Immune Therapy	30 
SCCHN – Learnings From Real-World Data	38 

EPICS

VIRTUAL CLOSED-DOOR ROUNDTABLE



DATE:
July 25, 2024



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



INSIGHTS REPORT
including postmeeting
analyses and actionable
recommendations

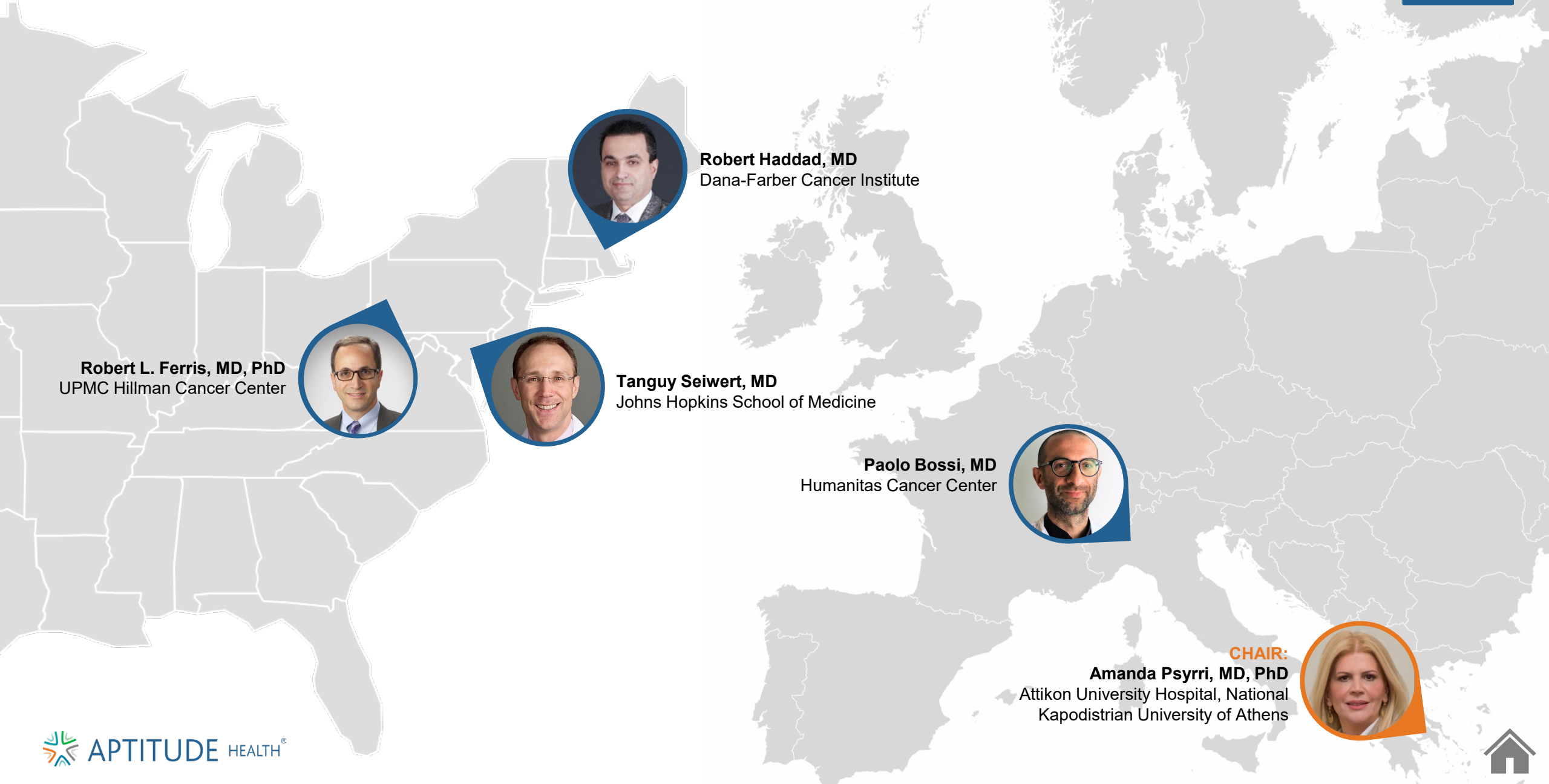


PANEL: Key experts in
SCCHN
> 3 US
> 2 Global



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

Panel Consisting of 3 US and 2 Global SCCHN Experts



Robert Haddad, MD
Dana-Farber Cancer Institute



Robert L. Ferris, MD, PhD
UPMC Hillman Cancer Center



Tanguy Seiwert, MD
Johns Hopkins School of Medicine



Paolo Bossi, MD
Humanitas Cancer Center



CHAIR:
Amanda Psyrris, MD, PhD
Attikon University Hospital, National
Kapodistrian University of Athens



Meeting Agenda

EPICS

Time (EST/EEST)	Topic	Speaker/Moderator
9.00 AM – 9.05 AM/ 16.00 – 16.05	Welcome and Introductions	Amanda Psyrrri, MD, PhD
9.05 AM – 9.20 AM/ 16.05 – 16.20	Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches	Robert Haddad, MD
9.20 AM – 9.50 AM/ 16.20 – 16.50	Discussion and Key Takeaways	All Robert Haddad, MD
9.50 AM – 10.05 AM/ 16.50 – 17.05	Metastatic SCCHN – Focus on Chemotherapy and Targeted Therapy	Tanguy Seiwert, MD
10.05 AM – 10.35 AM/ 17.05 – 17.35	Discussion and Key Takeaways	All Tanguy Seiwert, MD
10.35 AM – 10.50 AM/ 17.35 – 17.50	Metastatic SCCHN – Focus on Immune Therapy	Robert L. Ferris, MD, PhD
10.50 AM – 11.20 AM/ 17.50 – 18.20	Discussion and Key Takeaways	All Robert L. Ferris, MD, PhD
11.20 AM – 11.30 AM/ 18.20 – 18.30	SCCHN – Learnings From Real-World Data	Paolo Bossi, MD
11.30 AM – 11.55 AM/ 18.30 – 18.55	Discussion and Key Takeaways	All Paolo Bossi, MD
11.55 AM – 12.00 PM/ 18.55 – 19.00	Closing Remarks	Amanda Psyrrri, MD, PhD



EPICS

Conference Highlights

Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches

Phase III trial of nimotuzumab plus chemoradiation

Patil VM, et al. ASCO 2024. Abstract LBA6092

Background

> This trial examined the efficacy and late-term toxicities of the

OS results

Arm — Cisplatin-Radiation — Nimotuzumab Cisplatin-Radiation

STUDY POPULATION

1000 patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) were randomized to either cisplatin plus radiation (Cisplatin-Radiation) or nimotuzumab plus cisplatin plus radiation (Nimotuzumab Cisplatin-Radiation). The primary endpoint was overall survival (OS). The secondary endpoint was late-term toxicity (grade 3 or higher) at week 24. The trial was designed to evaluate the efficacy and late-term toxicities of the study population.

RESULTS

At week 24, 1000 patients were randomized to either Cisplatin-Radiation or Nimotuzumab Cisplatin-Radiation. The primary endpoint was OS. The secondary endpoint was late-term toxicity (grade 3 or higher) at week 24. The trial was designed to evaluate the efficacy and late-term toxicities of the study population.

CONCLUSIONS

Adding nimotuzumab to cisplatin plus radiation did not improve OS and increased the late-term toxicity in patients.

OS results



RESPONSE EVALUATION AT WEEK 24 AND LATE TERM TOXICITY



Phase II trial of cadonilimab

Cao F, et al. ASCO 2024. Abstract 6044

Background

> This trial examined the efficacy and safety of cadonilimab, a PD-

Response rates

40%

Figure 1: Overall Response Rate (ORR) in the Intention-to-Treat (ITT) Population



Figure 2: Response Rates in the ITT Population by Baseline Characteristics



Phase III trial of intensity-modulated proton therapy (IMPT)

Frank SJ, et al. ASCO 2024. Abstract 6006

Background

> Randomized noninferiority trial compared outcomes between IMRT

PFS



PROGRESSION-FREE SURVIVAL BY TREATMENT GROUP



RESPONSE EVALUATION BY TREATMENT GROUP



STUDY POPULATION

1000 patients with prostate cancer, randomized to IMRT or IMPT. The study population included patients with prostate cancer who were treated with either IMRT or IMPT. The study was a randomized noninferiority trial comparing the two treatment groups. The primary endpoint was progression-free survival (PFS). The study population was stratified by risk factors, including prostate-specific antigen (PSA) level, Gleason score, and clinical stage. The IMPT group showed a higher PFS rate compared to the IMRT group.

RESULTS

The study results showed that the IMPT group had a significantly higher PFS rate compared to the IMRT group. The difference was statistically significant (p < 0.05). The IMPT group also showed a higher response rate compared to the IMRT group. The study was well-tolerated, with no significant differences in adverse events between the two groups.

CONCLUSIONS

Intensity-modulated proton therapy (IMPT) is a promising treatment option for prostate cancer. This study demonstrated that IMPT is noninferior to IMRT, with a higher PFS rate and response rate. IMPT may be a preferred treatment option for patients with prostate cancer.

Phase II trial of hypoxia-directed therapy de-escalation

Lee NY, et al. ASCO 2024. Abstract 6007

Background

> This multicenter trial examined the efficacy of hypoxia-directed de-

PFS

PROGRESS-FREE SURVIVAL (PFS) AT 12 MONTHS



RESPONSE EVALUATION AT 12 MONTHS ANALYSIS PERIOD



STUDY POPULATION

100 patients with stage II-III hypopharyngeal cancer...
Median age 65 years...
Median time to progression 12 months...
Median overall survival 18 months...
Median time to death 15 months...
Median time to treatment discontinuation 10 months...
Median time to second primary cancer 24 months...
Median time to second primary cancer 24 months...
Median time to second primary cancer 24 months...

RESULTS

100 patients with stage II-III hypopharyngeal cancer...
Median age 65 years...
Median time to progression 12 months...
Median overall survival 18 months...
Median time to death 15 months...
Median time to treatment discontinuation 10 months...
Median time to second primary cancer 24 months...
Median time to second primary cancer 24 months...
Median time to second primary cancer 24 months...

CONCLUSIONS

Continuing hypoxia-directed treatment beyond week 20 provides clinical benefit in patients who do not respond to treatment and decreases the proportion of patients who...

EPICS

Key Insights

Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches

Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches (2/5)

Experts are highly interested in strategies to reduce treatment toxicity

Key Points:

- 1. Treatment with cetuximab, erlotinib, or gefitinib in combination with platinum-based chemotherapy, followed by TDMT, is preferred for most patients.
- 2. These regimens are being investigated in randomized clinical trials, but will probably be the standard of care for patients with evidence of local recurrence.
- 3. The standard of care may also be used in the adjuvant setting, before TDMT, for patients with documented local recurrence.
 - 1. Considered in most circumstances, experts are divided on whether they would routinely use TDMT in metastatic disease settings.
 - 2. Results of the ongoing IMRT1501 (IMRT1501) are currently pending.
- 4. Radiotherapy, chemotherapy, and the standard of care may also be used before first recurrence in patients who were following treatment with radiotherapy, chemotherapy, and TDMT in the metastatic setting, but this represents a small fraction of patients.
- 5. Patient performance can also factor into the assessment of these new agents (eg, 1 drug vs 2 drug, versus about how long is duration).
- 6. The improved efficacy of radiotherapy, chemotherapy, and the standard of care have opened other options, such as radiotherapy, chemotherapy, immunotherapy, targeted, and immunotherapy, in late lines of therapy.



Dr. [Name]
[Blurred text describing the expert's background and interests in the field of SCCHN treatment.]

Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches (5/5)

While the data showing noninferiority of IMPT to IMRT are engaging, the

Key Points:

- 1. IMPT and IMRT are both effective for the treatment of early and locally advanced SCCHN, with IMPT showing a trend towards improved survival outcomes.
- 2. IMPT may be preferred for patients with evidence of local recurrence.
- 3. The standard of care may also be used in the adjuvant setting, either IMRT or IMPT, for patients with documented local recurrence.
 - 1. Considered a local recurrence, patients are divided on whether they would consider use IMRT or IMPT as a treatment option.
 - 2. Results of the ongoing IMPT vs IMRT trial may help determine the standard of care for IMRT or IMPT.
- 4. IMPT and IMRT are both effective for the treatment of early and locally advanced SCCHN, with IMPT showing a trend towards improved survival outcomes.
- 5. IMPT and IMRT are both effective for the treatment of early and locally advanced SCCHN, with IMPT showing a trend towards improved survival outcomes.
- 6. The standard of care may also be used in the adjuvant setting, either IMRT or IMPT, for patients with documented local recurrence.



Key Points:

- 1. IMPT and IMRT are both effective for the treatment of early and locally advanced SCCHN, with IMPT showing a trend towards improved survival outcomes.
- 2. IMPT may be preferred for patients with evidence of local recurrence.
- 3. The standard of care may also be used in the adjuvant setting, either IMRT or IMPT, for patients with documented local recurrence.

EPICS

Conference Highlights

Metastatic SCCHN – Focus on Chemotherapy
and Targeted Therapy

Background

STUDY POPULATION

1. 207 patients with a confirmed diagnosis of metastatic colorectal cancer (mCRC) were enrolled in the trial. The patients were stratified into two groups based on their performance status (PS) and the presence of liver metastases. The primary endpoint was overall survival (OS) at 12 weeks. The secondary endpoints were progression-free survival (PFS) and quality of life (QoL).

RESULTS

2. The median OS was 12.5 weeks in the control group and 15.5 weeks in the treatment group. The median PFS was 8.5 weeks in the control group and 10.5 weeks in the treatment group. The QoL was significantly better in the treatment group.

CONCLUSIONS

3. The treatment group showed a significant improvement in OS, PFS, and QoL compared to the control group. These findings suggest that the treatment is a promising option for mCRC patients.

OS AND PFS AT 12 WEEKS IN THE CONTROL GROUP



RESPONSE, TOXICITY, AND QOL IN THE TREATMENT GROUP



Phase II trial of petosemtamab plus pembrolizumab

Fayette J, et al. ASCO 2024. Abstract 6014

Background

ORR

STUDY POPULATION

100 patients with advanced solid tumors, ECOG performance 0-1, no prior systemic therapy, no prior immunotherapy, no prior anti-CTLA-4 or anti-PD-1 therapy. Median age 65 years, 55% male, 45% white, 35% black, 10% Asian, 1% other. Median time from diagnosis to study entry 12 months. All patients received pembrolizumab 200mg IV q3w. 50 patients also received petosemtamab 100mg IV q3w. All patients received best supportive care. 75% of all patients received treatment through week 48.

RESULTS

ORR was 17.0% in patients receiving petosemtamab plus pembrolizumab, 10.0% in patients receiving pembrolizumab plus best supportive care. Median OS was 12.1 months in the petosemtamab plus pembrolizumab group and 10.1 months in the pembrolizumab plus best supportive care group.

CONCLUSIONS

Combining petosemtamab with pembrolizumab in advanced solid tumors showed a trend toward improved ORR and decreased time to progression compared to pembrolizumab plus best supportive care.

ORR BY TUMOR TYPE AND LINE OF THERAPY



RESPONSE DURATION BY TUMOR TYPE AND LINE OF THERAPY



Background

STUDY POPULATION

1000 patients with solid tumors, including 500 with breast cancer, were enrolled in the study. The study population was diverse in terms of age, race, and ethnicity. The primary endpoint was overall survival (OS) at 24 weeks. The secondary endpoints were progression-free survival (PFS) and objective response rate (ORR). The study was conducted in a multicenter setting across several countries. The results of the study are presented in the following figures.

RESULTS

At 24 weeks, the OS rate was 45% in the treatment group and 35% in the control group. The PFS rate was 55% in the treatment group and 45% in the control group. The ORR was 30% in the treatment group and 20% in the control group. The results are statistically significant (p < 0.05).

KEY CONCLUSIONS

The study demonstrates that the treatment group has a significantly higher OS rate compared to the control group at 24 weeks. This suggests that the treatment may be effective in improving survival outcomes for patients with solid tumors.

OS AT 24 WEEKS BY TUMOR TYPE



RESPONSE RATE AT 24 WEEKS BY TUMOR TYPE



EPICS

Key Insights

Metastatic SCCHN – Focus on Chemotherapy
and Targeted Therapy

Metastatic SCCHN – Focus on Chemotherapy and Targeted Therapy (2/4)

Experts are impressed by the activity of the ADCs TV and T-DXd

Supporting trials will help clarify the optimal sequencing of agents

- 1. Trials are underway to evaluate the optimal sequencing of immunotherapy and chemotherapy, followed by T-DXd, compared to each option.
- 2. Both options are using immunotherapy (nivolumab or pembrolizumab) but will provide the best option for patients with evidence of tumor progression.
- 3. The best option may also be used in the maintenance setting, before T-DXd, in patients with recurrent liver metastases.
 - Planned to test immunotherapy, agents are divided on whether they would normally use T-DXd in metastatic disease setting.
 - Results of the ongoing IM201 (nivolumab) vs immunotherapy (pembrolizumab) or T-DXd will help to clarify the optimal sequencing of these agents.
- 4. Immunotherapy and the best option may also be used before than starting in patients who were following treatment with immunotherapy, pembrolizumab, and T-DXd in the maintenance setting, but this represents a small fraction of patients.
- 5. Future preferences can also focus on the sequencing of these two agents (eg, 1 drug or 2 drug, versus what has been in clinical).
- 6. The impressive efficacy of immunotherapy and the best option have opened other options, such as immunotherapy chemotherapy combinations, nivolumab, and pembrolizumab, in the line of therapy.



Dr. [Name]
The [Name] is a [Title] at [Institution].
He has been a [Title] at [Institution] since [Year].
He is currently [Title] at [Institution].
He has been a [Title] at [Institution] since [Year].
He is currently [Title] at [Institution].
He has been a [Title] at [Institution] since [Year].
He is currently [Title] at [Institution].
He has been a [Title] at [Institution] since [Year].
He is currently [Title] at [Institution].
He has been a [Title] at [Institution] since [Year].
He is currently [Title] at [Institution].



Metastatic SCCHN – Focus on Chemotherapy and Targeted Therapy (3/4)

Experts are excited about the data for petosemtamab plus pembrolizumab for

Supporting trials will help clarify the optimal sequencing of agents

- 1. Trials are still using a combination of the regimen of nivolumab plus pembrolizumab and pembrolizumab monotherapy, followed by TDM1 monotherapy, in most patients
- 2. Most experts are using pembrolizumab monotherapy, but will probably be looking to use the regimen with evidence of best response
- 3. The pembrolizumab regimen may also be used in the maintenance setting, before TDM1, in patients with documented liver metastases
 - Preferred in most scenarios, experts are divided on whether they would actually use TDM1 in combination with pembrolizumab
 - o Results of the ongoing IM217 (NCT02850553) are comparing pembrolizumab monotherapy vs TDM1, and may in itself, the optimal sequencing of these 2 drugs
- 4. Pembrolizumab monotherapy and the pembrolizumab regimen may also be used earlier than starting in patients who were following treatment with pembrolizumab, pembrolizumab, and TDM1 in the maintenance setting, but this represents a small fraction of patients
- 5. Future combination regimens may also factor into the sequencing of these two agents (eg, 1 drug vs 2 drug, versus what has been in practice)
- 6. The comparative efficacy of pembrolizumab monotherapy and the pembrolizumab regimen have guided other options, such as pembrolizumab chemotherapy combinations, nivolumab, and regorafenib, in this line of therapy



Dr. [Name]
The combination of nivolumab plus pembrolizumab and pembrolizumab monotherapy is the current standard of care in the maintenance setting, but we are looking at other great options for the next line of treatment. It's really important to have multiple options to address the TDM1 - agent, versus simply pembrolizumab.



EPICS

Conference Highlights

Metastatic SCCHN – Focus on Immune Therapy

Background

> This randomized trial investigated the efficacy and safety of

OS results

OS N = 198 Hazard



Background

This multicite, randomized, placebo (PL)-controlled trial examined the

OS results

STUDY POPULATION

1000 patients with metastatic breast cancer... (text is blurred)

RESULTS

Median OS was significantly longer in the... (text is blurred)

KEY CONCLUSIONS

Continuing treatment beyond week 25... (text is blurred)

OS results



RESPONSE, TOXICITY, AND OTHER ANALYSIS RESULTS



Phase IIb TACTI-003 (KEYNOTE-PNC-34) trial

Post-ASCO data press release from Immutep

Background

TACTI-003 is evaluating efalizumab (efi), a novel LAG3 immunotherapy, in combination with pembrolizumab as first-line

STUDY POPULATION

1000 patients with advanced NSCLC, ECOG performance 0-1, no prior systemic therapy, PD-L1 expression ≥1%, or mean average 10% expression. Randomized to either treatment with pembrolizumab (100mg q3w) or combination of pembrolizumab (100mg q3w) and efalizumab (100mg q2w) for 24 weeks. The combination group had significantly higher overall survival (OS) compared to pembrolizumab (HR 0.75, 95% CI 0.55-1.02). The combination group had significantly higher median OS (18.5 months vs 15.5 months) and significantly higher median OS (18.5 months vs 15.5 months) compared to pembrolizumab.

RESULTS

OS: 18.5 months (95% CI 15.5-21.5) vs 15.5 months (95% CI 13.5-17.5). Median OS: 18.5 months (95% CI 15.5-21.5) vs 15.5 months (95% CI 13.5-17.5).

KEY CONCLUSIONS

Combining pembrolizumab with efalizumab significantly improved OS compared to pembrolizumab alone in patients with advanced NSCLC.

Overall Survival (OS) by Cohort



Response Rate (RR) by Cohort



EPICS

Key Insights

Metastatic SCCHN – Focus on Immune Therapy

EPICS

Conference Highlights

SCCHN – Learnings From Real-World Data

Long-term survival with pembrolizumab vs cetuximab-based therapy

Hamedi Z, et al. ASCO 2024. Abstract 6022

Background

This real world analysis retrospectively compared long-term survival outcomes in patients with metastatic colorectal cancer (mCRC) who received pembrolizumab (Pembro) vs cetuximab (Cetux) based therapy.

OS results

STUDY POPULATION

1000 patients with mCRC who received Pembro or Cetux based therapy between 2010 and 2020. The study population was divided into two groups: Pembro (n=500) and Cetux (n=500). The median age was 65 years. The majority of patients were male. The most common primary site was colon (70%). The most common metastatic site was liver (60%). The median time to treatment discontinuation was 12 months. The median time to death was 18 months. The median overall survival (OS) was 18 months for the Pembro group and 15 months for the Cetux group. The difference in OS between the two groups was statistically significant (p=0.02).

RESULTS

1000 patients with mCRC who received Pembro or Cetux based therapy between 2010 and 2020. The median OS was 18 months for the Pembro group and 15 months for the Cetux group. The difference in OS between the two groups was statistically significant (p=0.02).

KEY CONCLUSIONS

Long-term survival outcomes were similar between the two groups. However, the Pembro group showed a trend towards better OS compared to the Cetux group. This finding suggests that Pembro may be a more effective treatment option for mCRC patients.

OS RESULTS



RESPONSE RATE AND TOXICITY



Low-dose nivolumab plus metronomic chemotherapy

Kate S, et al. ASCO 2024. Abstract 6050

Background

This study prospectively evaluated the real-world effectiveness and safety of low-dose nivolumab along with triple metronomic

STUDY POPULATION

1000 patients with metastatic melanoma... (text is blurred)

RESULTS

Median overall survival... (text is blurred)

CONCLUSIONS

Low-dose nivolumab plus metronomic chemotherapy... (text is blurred)

TOXICITY PROFILE



RESPONSE, PROGRESSION, AND SURVIVAL RESULTS



EPICS

Key Insights

SCCHN – Learnings From Real-World Data

SCCHN – Learnings From Real-World Data (1/4)

Experts stressed the importance of refining real-world data

Experts acknowledged the need for real-world data to optimize patient treatment

Experts stressed the importance of refining real-world data to optimize patient treatment. The experts discussed the challenges of using real-world data (RWD) to inform clinical decisions and the need for high-quality, standardized data. They emphasized the importance of data governance and the need for transparency in data collection and analysis. The experts also discussed the potential of RWD to improve patient care and reduce costs. They highlighted the need for collaboration between clinicians, researchers, and payers to maximize the value of RWD. The experts also discussed the importance of patient privacy and the need for robust data security measures. They concluded that RWD has the potential to revolutionize cancer care, but only if it is used responsibly and ethically.



Dr. [Name]
The use of real-world data (RWD) to inform clinical decisions is a rapidly growing field. However, the quality and reliability of RWD can vary significantly. It is essential to ensure that RWD is collected and analyzed in a transparent and ethical manner. This involves establishing clear data governance policies and standards. Collaboration between clinicians, researchers, and payers is key to maximizing the value of RWD. Patient privacy and data security are also critical considerations. RWD has the potential to improve patient care and reduce costs, but only if it is used responsibly and ethically.



SCCHN – Learnings From Real-World Data (2/4)

Experts believe long-term survival data with ICIs are the most important real-world data currently needed

Key findings from the expert panel discussion include:

- 1. ICIs are being used in combination with chemotherapy, targeted therapy, and immunotherapy, followed by TDMT, as a first-line treatment.
- 2. Most experts are using immunotherapy, immunotherapy, but will provide the best data to patients with evidence of long-term survival.
- 3. The survival data may also be used in the second-line setting, before TDMT, in patients with immunotherapy-resistant disease.
 - Provided a good response, experts are divided on whether they would consider use TDMT in immunotherapy-resistant disease.
 - Results of the ongoing IM2019 (nivolumab) vs immunotherapy-resistant disease as TDMT will help to clarify the optimal sequencing of these drugs.
- 4. Immunotherapy, immunotherapy, and the survival data may also be used before first-line therapy in patients who were following treatment with immunotherapy, immunotherapy, and TDMT in the second-line 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 last).
- 6. The comparative efficacy of immunotherapy, immunotherapy, and the survival data have opened other options, such as immunotherapy, immunotherapy, immunotherapy, and immunotherapy, in the first line of therapy.



Dr. [Name]
The panel is not out of sync. While we are not just looking at the issue of immunotherapy, we are looking at the overall setting, but we do have a very good chance that the data will be helpful to make sure we're making a good choice when to add the TDMT - again, making things more complex.



SCCHN – Learnings From Real-World Data (3/4)

Experts acknowledged that patient selection needs to be further refined to better identify which patients may be cured by ICIs

- 1. Experts are still using a variety of methods to identify patients who may benefit from immunotherapy, including TMB, PD-L1 expression, and other biomarkers.
- 2. While experts are using immunotherapy biomarkers, they still practice the standard of care for patients with evidence of local recurrence.
- 3. The standard of care may also be used in the metastatic setting, unless TMB is positive with immunotherapy biomarkers.
 - 1. Providers in local recurrence settings are divided on whether they would consider use of TMB or immunotherapy biomarkers.
 - 2. Results of the ongoing IMPOWER010 trial comparing immunotherapy biomarkers as TMB will help to clarify the optimal use of these tests.
- 4. Immunotherapy biomarkers and the standard of care may also be used earlier than starting in patients who were following treatment with immunotherapy, chemotherapy, and TMB in the metastatic 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 or 2 drug regimen) about how best to deliver.
- 6. The comparative efficacy of immunotherapy biomarkers and the standard of care have opened other options, such as immunotherapy combinations, vaccines, and adoptive cell transfer.



Dr. [Name]
The use of immunotherapy biomarkers in the metastatic setting, for use in patients who were following treatment with immunotherapy, chemotherapy, and TMB in the metastatic setting, but this represents a small fraction of patients.

SCCHN – Learnings From Real-World Data (4/4)

Experts are impressed by the real-world efficacy of low-dose nivolumab combined with triple metronomic chemotherapy (TMC)

Experts are impressed by the real-world efficacy of low-dose nivolumab combined with triple metronomic chemotherapy (TMC)

- 1. Triplets are still being evaluated for the treatment of recurrent and metastatic disease, followed by TMC maintenance, in early studies.
- 2. Most experts are using metronomic docetaxel, irinotecan, but will probably be looking for patients with evidence of liver metastases.
- 3. The limited data may also be used in the maintenance setting, either TMC, or patients with documented liver metastases.
 - Provided a good response, experts are divided on whether they would consider use TMC or metronomic docetaxel/irinotecan.
 - Results of the ongoing IM17 (NCT02500001) are comparing metronomic docetaxel or TMC, all aim to study the optimal sequence of these drugs.
- 4. Metronomic docetaxel and the limited data may also be used earlier than starting in patients who were following treatment with metronomic docetaxel, irinotecan, and TMC in the maintenance setting, but this represents a small fraction of patients.
- 5. Future conferences will also focus on the sequencing of these two agents (eg, 1 drug or 2 drug, versus what has been in practice).
- 6. The impressive efficacy of metronomic docetaxel and the limited data may suggest other options, such as metronomic chemotherapy combinations, nivolumab, and immunotherapy, in late lines of therapy.



Dr. [Name]
The combination of low-dose nivolumab and metronomic chemotherapy is the most effective in the maintenance setting, but we are still in early phase studies. The data with a limited TMC + nivolumab combination is very promising in late-stage studies for patients with TMC + nivolumab therapy combination.



US 5901-B Peachtree Dunwoody Road
Suite 415, Atlanta, GA 30328, US

EU Laan van Nieuw Oost-Indië 133 F
2593 BM The Hague, the Netherlands

UK 6th Floor, 2 Kingdom Street
London, W2 6BD, United Kingdom

[aptitudehealth.com](https://www.aptitudehealth.com)

