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# Conference Coverage: ESMO 2023 – Focus on Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Tuesday, October 31, 2023

Full Report

# Report Contents

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# Meeting Snapshot

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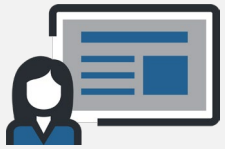
## VIRTUAL CLOSED-DOOR ROUNDTABLE

**DATE:**
October 31, 2023



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

**INSIGHTS REPORT** including postmeeting analyses and actionable recommendations

**PANEL:** Key experts in SCCHN

- 3 from US
- 3 from Europe

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

# Panel Consisting of 3 North American and 3 European Head and Neck Cancer Experts

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

**Ulrich Keilholz, MD, PhD**
Charité Comprehensive Cancer Center

**Tanguy Seiwert, MD**
Johns Hopkins School of Medicine

**Christophe Le Tourneau, MD, PhD**
Institut Curie

**Maura Gillison, MD, PhD**
MD Anderson Cancer Center

**CHAIR:**
**Amanda Psyrri, MD, PhD**
Attikon University Hospital

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# Meeting Agenda

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| Time (CET/EDT) | Topic | Speaker |
|---|---|---|
| 15.30 – 15.35/<br>10.30 AM – 10.35 AM | Welcome and Introductions | Amanda Psyrri, MD, PhD |
| 15.35 – 15.50/<br>10.35 AM – 10.50 AM | **Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches** | Robert L. Ferris, MD, PhD |
| 15.50 – 16.20/<br>10.50 AM – 11.20 AM | Discussion and Key Takeaways | Amanda Psyrri, MD, PhD |
| 16.20 – 16.35/<br>11.20 AM – 11.35 AM | **Metastatic SCCHN – Focus on Targeted Treatment Strategies** | Tanguy Seiwert, MD |
| 16.35 – 17.05/<br>11.35 AM – 12.05 PM | Discussion and Key Takeaways | Amanda Psyrri, MD, PhD |
| 17.05 – 17.20/<br>12.05 PM – 12.20 PM | **Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (IO, BsAbs, and Vaccines)** | Maura Gillison, MD, PhD |
| 17.20 – 17.30/<br>12.20 PM – 12.30 PM | **Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (Oncolytics, ADC, Others)** | Ulrich Keilholz, MD, PhD |
| 17.30 – 18.00/<br>12.30 PM – 1.00 PM | Discussion and Key Takeaways | Amanda Psyrri, MD, PhD |
| 18.00 – 18.15/<br>1.00 PM – 1.15 PM | **SCCHN – Learnings From Real-World Data** | Christophe Le Tourneau, MD, PhD |
| 18.15 – 18.30/<br>1.15 PM – 1.30 PM | Discussion and Key Takeaways | Amanda Psyrri, MD, PhD |
| 18.30/<br>1.30 PM | Meeting Close | Amanda Psyrri, MD, PhD |

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

Robert L. Ferris, MD, PhD

# Phase II SCCHN 15-132 trial

## Zandberg D, et al. 2023 ESMO 856MO

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- Evaluated the efficacy and safety of concurrent vs sequential




# Phase II ADJORL1 trial

## Guerlain J, et al. 2023 ESMO 855MO

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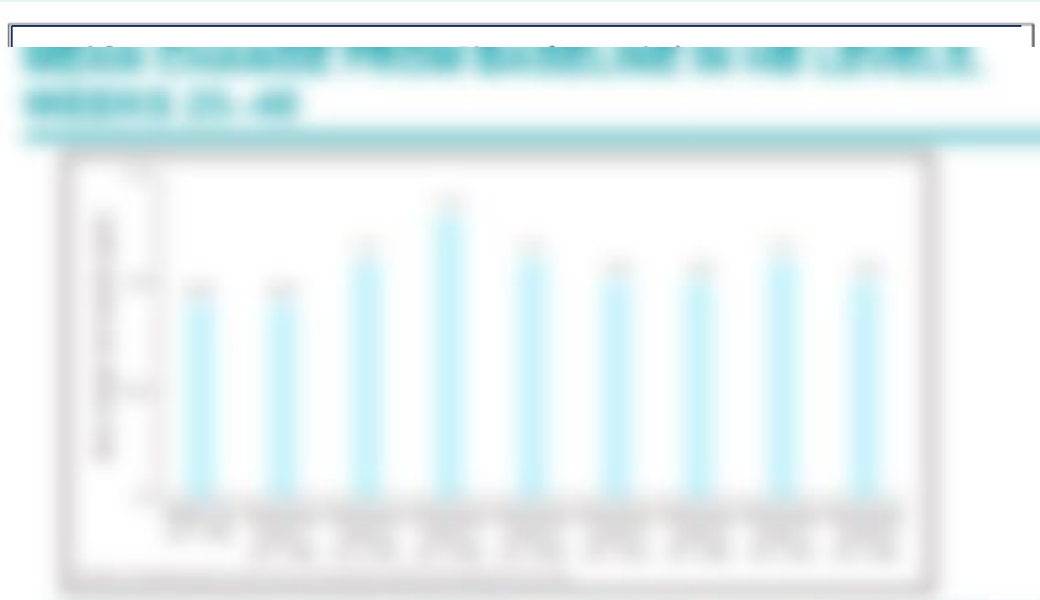
> Evaluated the efficacy and safety of adjuvant nivolumab after salvage



# MACH-EGFR

## Blanchard P, et al. 2023 ESMO 8570

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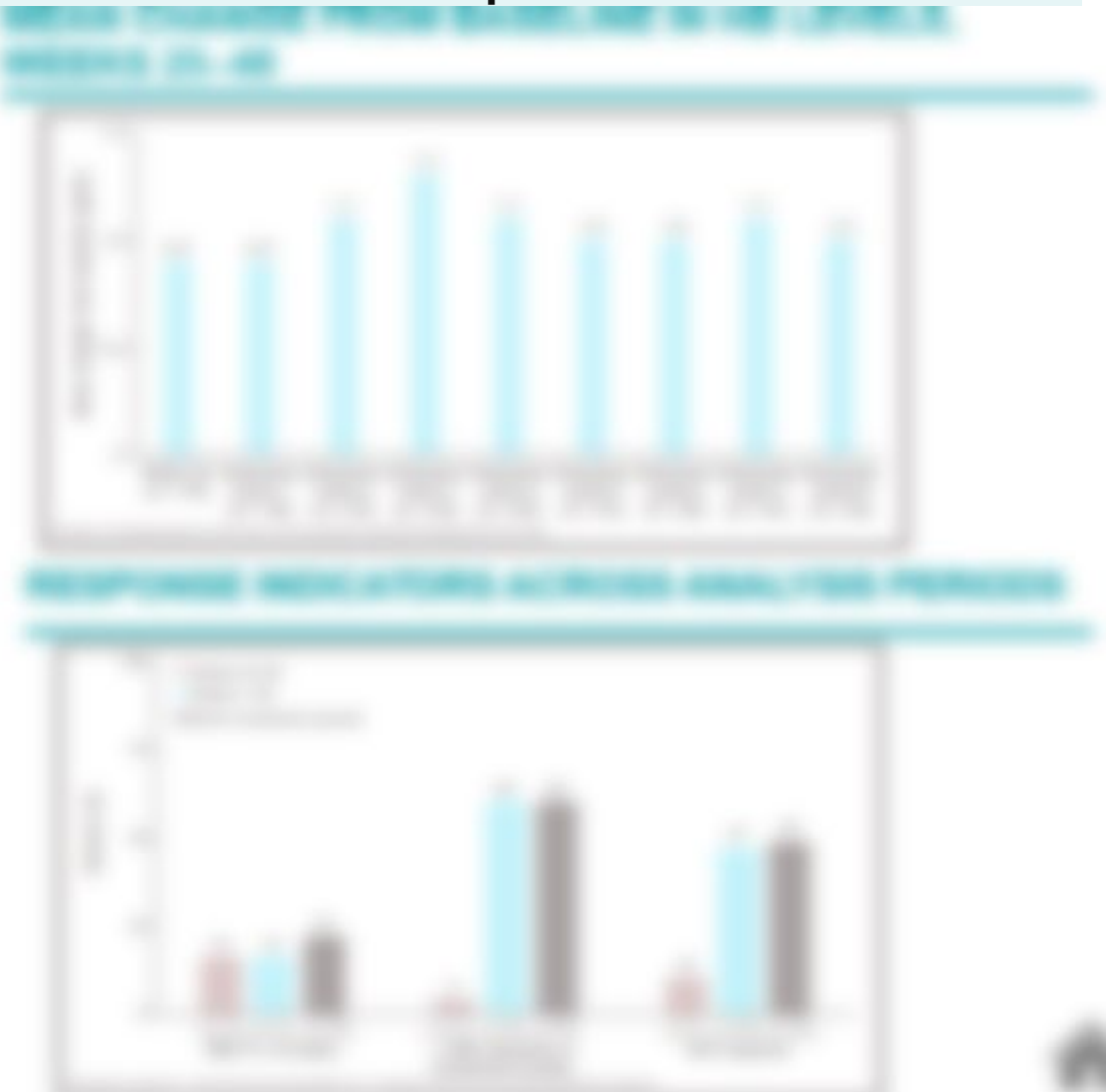
- Individual pt data meta-analysis of anti-EGFR monoclonal antibodies

**OS: Comparison 1**



# Post-treatment ctDNA is predictive of survival

## Honoré N, et al. 2023 ESMO 8580

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> Locally advanced SCCHNs have a high recurrence rate of



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# 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 (1/4)

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**Sequencing of radiotherapy and IO is important and consistent with findings in lung cancer**



1. ClinicalTrials.gov identifier: NCT02777385.

# Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches (2/4)

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**Adjuvant PD-1 inhibitor data appear promising, even with 6 months of treatment, and validation studies are warranted**



1. ClinicalTrials.gov identifier: NCT03406247.

# Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches (3/4)

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**EGFR targeting is worth further study in younger patients with HPV-negative SCCHN**

# Early and Locally Advanced SCCHN – Current Treatment Strategies and Novel Therapeutic Approaches (4/4)

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**ctDNA analyses consistently show prognostic value, but their role in guiding therapy is unclear**

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# Metastatic SCCHN – Focus on Targeted Treatment Strategies

Tanguy Seiwert, MD

# Phase II AIM-HN trial and phase II TROPiCS-03 trial

## Ho A, et al. 2023 ESMO LBA47
## Michel L, et al. 2023 ESMO 859MO

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**Phase II AIM-HN trial**

> Pivotal trial that showed clinical efficacy of tipifarnib in heavily pre-

**AIM-HN**

# Phase III INTERLINK-1 trial and CeTax study

## Fayette J, et al. 2023 ESMO 854O
## Herrera Gomez RG, et al. 2023 ESMO 942P

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**Phase III INTERLINK-1 trial**

> Evaluated the efficacy and safety of monalizumab + cetuximab in pts

**INTERLINK-1**

# Phase II GORTEC 2014-04 OMET trial

## Thariat J, et al. 2023 ESMO 853O

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> Evaluated the efficacy and safety of platinum-based chemotherapy combined with SBRT compared with exclusive SBRT for oligometastatic SCCHN for intra- or extracranial targets (N = 69)



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# Key Insights

Metastatic SCCHN – Focus on Targeted Treatment Strategies

# Metastatic SCCHN – Focus on Targeted Treatment Strategies (1/5)

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**Although tipifarnib has shown activity in SCCHN, the data are not yet sufficient to change current practice**

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1. ClinicalTrials.gov identifier: NCT03719690.

# Metastatic SCCHN – Focus on Targeted Treatment Strategies (2/5)

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**Although sacituzumab govitecan showed low activity in SCCHN, experts are enthusiastic that future studies of ADCs using other targets or payloads have the potential to show greater benefits in SCCHN**



1. ClinicalTrials.gov identifier: NCT03964727.

# Metastatic SCCHN – Focus on Targeted Treatment Strategies (3/5)

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**Despite the unfavorable outcomes observed, experts indicated that there are valuable lessons to be gleaned**



1. ClinicalTrials.gov identifier: NCT04590963; 2. ClinicalTrials.gov identifier: NCT03070366.

# Metastatic SCCHN – Focus on Targeted Treatment Strategies (4/5)

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**Paclitaxel + cetuximab appears to be an effective regimen for R/M SCCHN following progression on ICI in platinum-refractory disease**

# Metastatic SCCHN – Focus on Targeted Treatment Strategies (5/5)

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## Experts only use cetuximab in HPV-negative patients

**Cetuximab + chemotherapy is commonly used by the experts in IO-refractory,**

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# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (IO, BsAbs, and Vaccines)

Maura Gillison, MD, PhD

# BCA101 dose-expansion cohort

## Hanna G, et al. 2023 ESMO 922P

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> Evaluated dose-expansion results of the bifunctional EGFR/TGFβ



# Phase II UPSTREAM trial and phase II trial of IO102-IO103 vaccine

## Galot R, et al. 2023 ESMO 935P
## Reiss J, et al. 2023 ESMO 1038P

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**Phase II UPSTREAM trial**

UPSTREAM



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# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (Oncolytics, ADC, Others)

Ulrich Keilholz, MD, PhD

# Phase I/II trial of HB-200 arenavirus-based IO

## Nabell L, et al. 2023 ESMO 921P

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> This trial is evaluating the efficacy and safety of HB-200



# Phase I VCN-01 trial

## Jové M, et al. 2023 ESMO 937P

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- Reported survival outcomes in phase I trial combining VCN-01 and


# Phase II trial of MRG003

## Xue L, et al. 2023 ESMO 939P

EPICS

> MRG003 is a novel ADC composed of a humanized anti-EGFR

Figure2. Kaplan-Meier estimates of



# Phase II PEVOsq basket trial

## Le Tourneau C, et al. 2023 ESMO 923P

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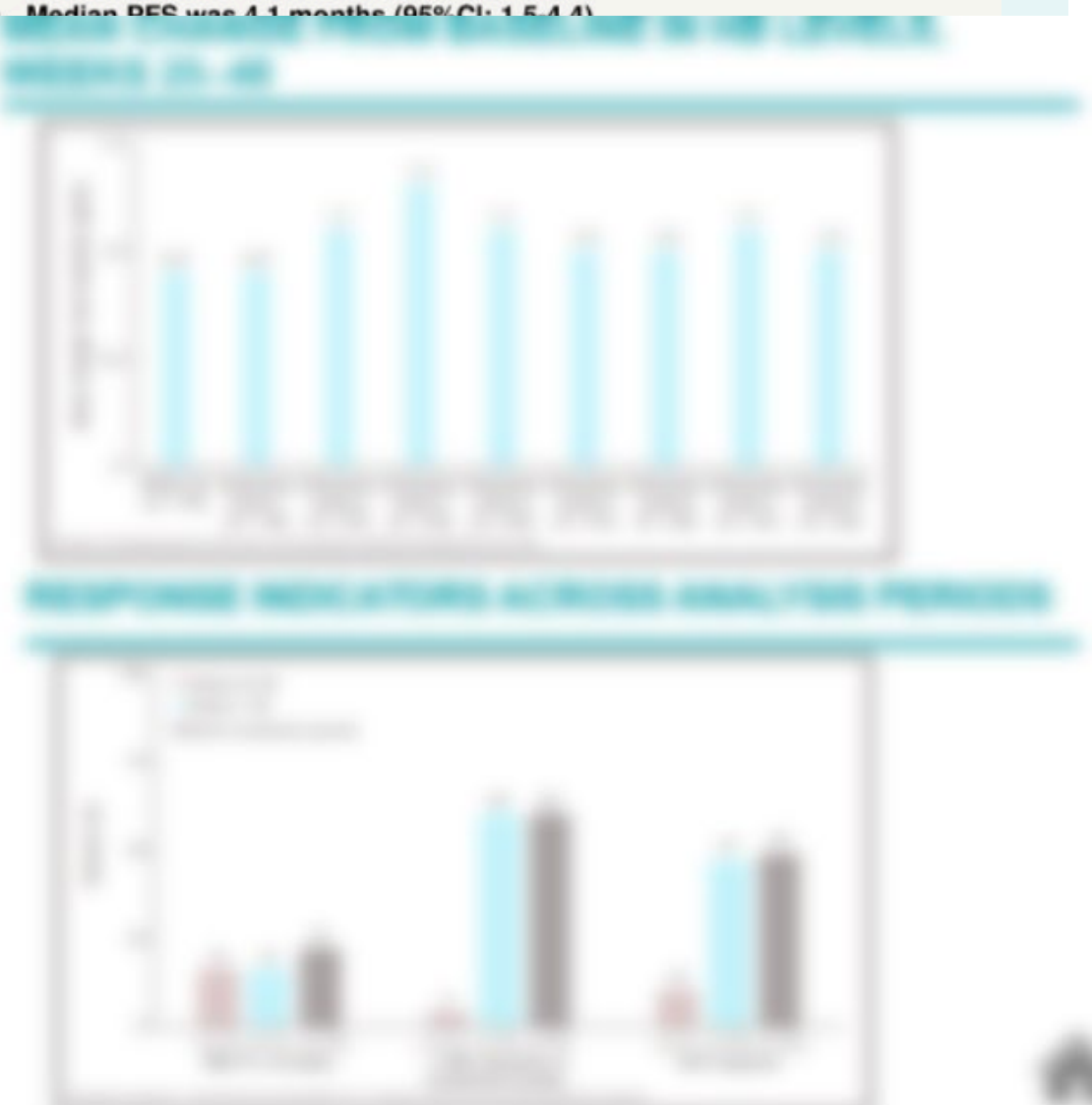
- PEVOsq is an open-label, nonrandomized, multicenter, basket



# Retrospective case analysis of ICI discontinuation

## Klinghammer K, et al. 2023 ESMO 925P

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> Retrospective case analysis of pts with SCCHN who experienced complete or very good partial remission under PD-1 inhibition (N = 53)



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# Key Insights

## Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations

# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (1/5)

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**Experts were not impressed with the data for BCA101 or for pembrolizumab combined with vorinostat**



1. ClinicalTrials.gov identifier: NCT04429542; 2. ClinicalTrials.gov identifier: NCT04357873.

# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (2/5)

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## Early data with the vaccine approaches were viewed with interest

- Although experts were hopeful regarding the efficacy of vaccine approaches, ongoing trials will help clarify the optimal sequencing of agents



1. ClinicalTrials.gov identifier: NCT05077709; 2. ClinicalTrials.gov identifier: NCT04180215.

# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (3/5)

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**ADCs also appear promising, but none of those tested thus far have been successful**

1. ClinicalTrials.gov identifier: NCT04868162.

# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (4/5)

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**Experts believe on the basis of anecdotal evidence that there are certain patients with SCCHN who experience rapid progression when they start anti–PD-(L)1 therapy**

# Metastatic SCCHN – Focus on Immune Checkpoint Therapy Combinations (5/5)

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**Experts believe TIGIT, LAG-3, and TIM-3 inhibitors are promising candidates for SCCHN**

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# SCCHN – Learnings From Real-World Data

Christophe Le Tourneau, MD, PhD

# Real-world survival outcomes and survival risk factors in elderly patients with locally advanced (la)SCCHN

## Saba NF, et al. 2023 ESMO 890P

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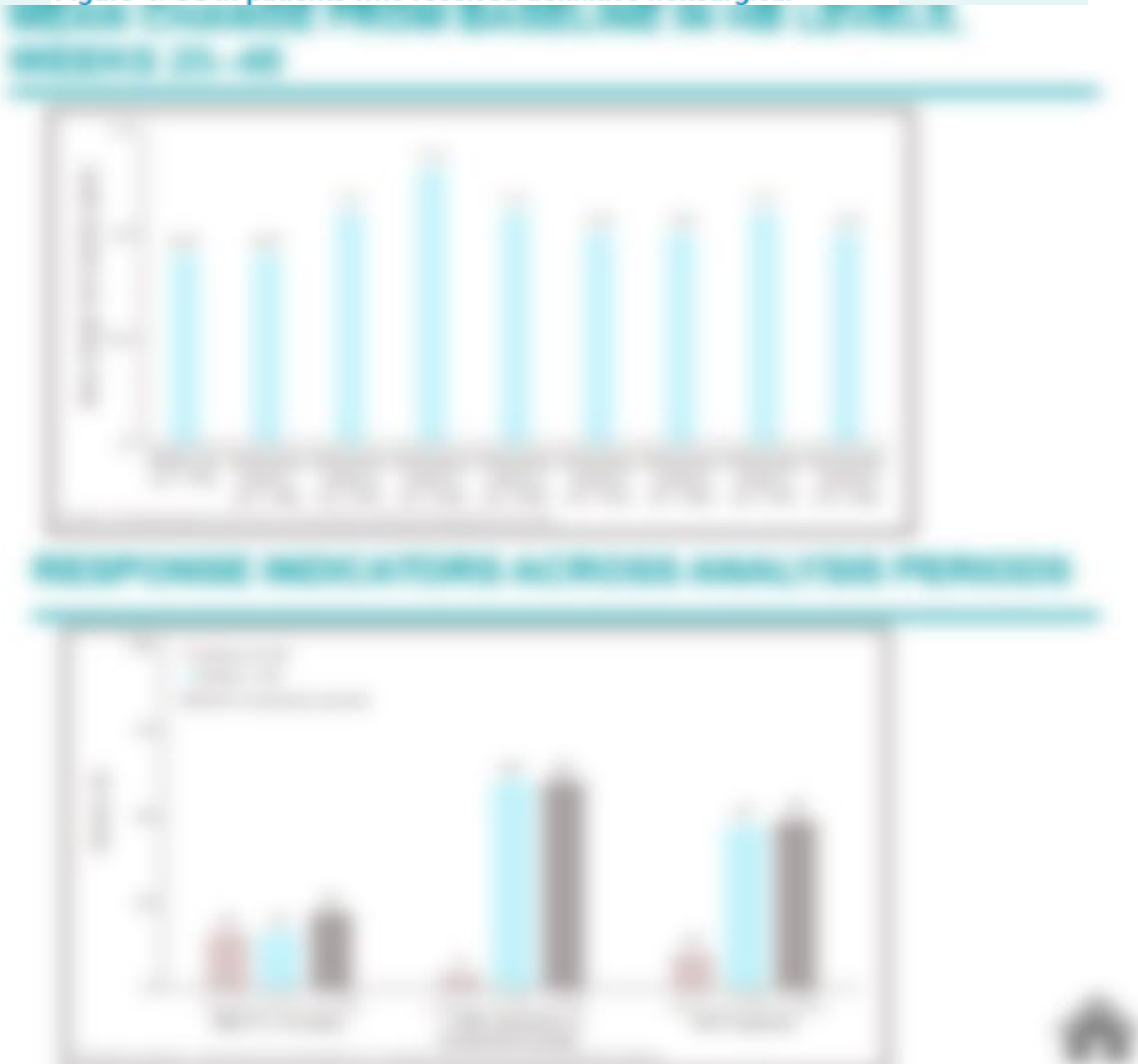
> Treatment options for laSCCHN include definitive nonsurgical

Figure 4. OS in patients who received definitive nonsurgical



# UK national real-world outcome data of 1L pembrolizumab treatment in SCCHN

## Vasiliadou I, et al. 2023 ESMO 926P

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# Updated results from the real-world HANNA study

## Kubuschok B et al. 2023 ESMO 927P

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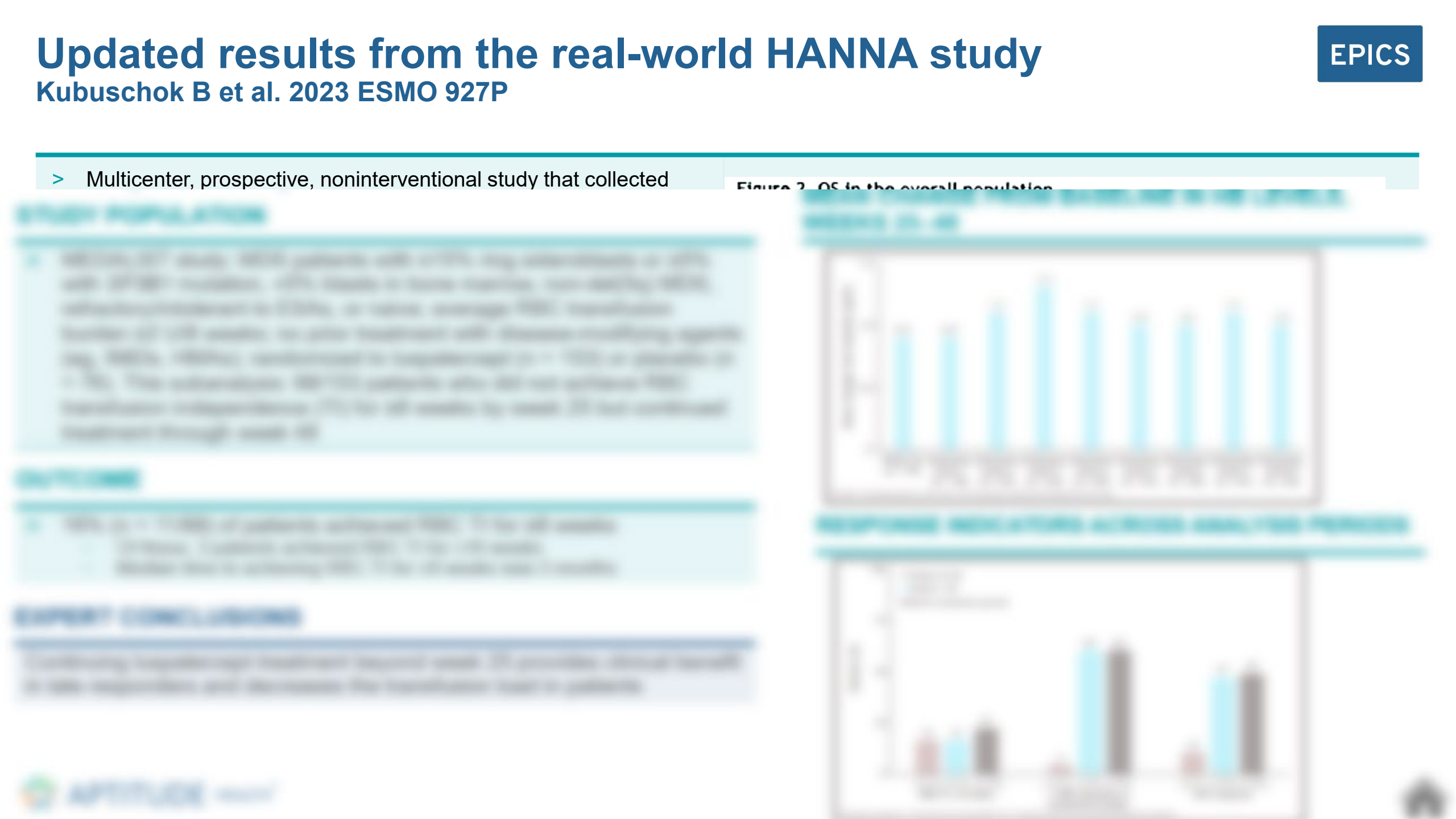
- Multicenter, prospective, noninterventional study that collected



# ProNiHN study

## Le Tourneau C, et al. 2023 ESMO 938P

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> Prospective, observational, and multicenter study of pts with

# A real-world data study with the TriNetX platform

## De La Varga LU, et al. 2023 ESMO 932P

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> Real-world data of OS of 3 cohorts of pts with R/M SCCHN:



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# Key Insights

SCCHN – Learnings From Real-World Data

# SCCHN – Learnings From Real-World Data (1/2)

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**Real-world data are appreciated and seen as reassuring when results are consistent with those of clinical trials**



1. ClinicalTrials.gov identifier: NCT04050761.

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

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**Experts speculated the reasons why some real-world studies reported better outcomes than clinical trials**

1. ClinicalTrials.gov identifier: NCT03114163.

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**US** 5901-C Peachtree Dunwoody Road NE
Suite 200, Atlanta, GA 30328, US

**EU** Wilhelmina van Pruisenweg 104
2595 AN The Hague, the Netherlands

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

**aptitudehealth.com**