Analysis of published literature on the relationship between patient overall survival and other patient outcomes (response rate and progression-free survival) in clinical trials of immuno-oncology treatments for head and neck squamous cell carcinoma (HNSCC)

This document provides a short summary of information about this study, which was a literature review and analysis presented at the 2020 European Society for Medical Oncology (ESMO) Congress (virtual format).

Full title of presentation: The Relationship Between Overall Survival (OS), Progression-Free Survival (PFS), and Objective Response Rate (ORR) in Immune Checkpoint Inhibitor Clinical Trials of Head and Neck Squamous Cell Carcinoma (HNSCC): A Systematic Review and Meta-analysis

Study number: 214479

Who sponsored the study: GlaxoSmithKline (GSK)

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Why was this study carried out?

Whether a new cancer treatment extends overall survival (OS) more than current treatments is an important measure in clinical trials but needs **long-term follow-up**, which may take years to complete.

To reduce delays in new treatments being available for patients, other less time-consuming outcomes that may predict the OS, such as objective response rate (ORR) and progression-free survival (PFS), are often measured in clinical trials and the results are used to speed up decisions for approval of these treatments.

- ORR is the proportion of patients whose tumor has shrunk or disappeared.
- PFS is the duration of time during and after treatment that a patient has cancer but does not get worse.

The current evidence for this varies among cancer types and treatment types.

This study looked at **whether ORR and PFS can predict OS improvement** in clinical trials of one of the newer types of treatment, immuno-oncology (I-O), in patients with advanced (recurrent or metastatic) HNSCC.

This would **help design future clinical trials** in this disease.

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About the study and analysis

This was a systematic (thorough or comprehensive) literature review (SLR) followed by a meta-analysis of the findings.

A meta-analysis is a research method that uses statistics to combine the results from multiple separate but similar studies to develop an estimate based on the pooled data.

The study process:

1 SLR

- Medical literature database search (2015–2020)
- Clinical trial registry search

2 Data assessment

Identification of **40 patient subpopulations** across:

2 3

5 phase II/III, randomized controlled trials of I-O treatments for recurrent or metastatic HNSCC

KEYNOTE-40 (pembrolizumab)
KEYNOTE-48 (pembrolizumab)
EAGLE (durvalumab, tremelumab)
CheckMate-141 (nivolumab)
CONDOR (durvalumab, tremelumab)

3 Meta-analysis

- Development and fitting of meta-analysis models using available evidence from the 5 trials for ORR, PFS and OS

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What were the results of the meta-analysis?

There was a strong correlation between ORR and median OS and between PFS and median OS.

A 10% absolute improvement in ORR, or 2-fold improvement of median PFS, would lead to a 1.22-fold improvement in median OS.

What were the main conclusions of the study researchers?

- **The findings support using ORR and PFS as measures to predict OS effect in early phases of future clinical trials evaluating I-O treatments in recurrent or metastatic HNSCC.**
- **ORR and PFS are being used as early assessment tools in an ongoing GSK Phase II/III trial in recurrent or metastatic HNSCC.**

Where can I find more information?

The GSK-sponsored Phase II/III clinical trial in recurrent or metastatic HNSCC is called INDUCE-3. The unique study numbers associated with this study are shown below with internet links to other information.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT04128696
GlaxoSmithKline (GSK)	www.gsk-clinicalstudyregister.com	209229

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