

A study of pembrolizumab (MK-3475) plus platinum and gemcitabine as first-line treatment of recurrent/ metastatic head and neck squamous cell carcinoma (PIPER)

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ABSTRACT

Introduction: A treatment combination of pembrolizumab plus platinum and 5-FU (PF) has increased the survival of recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). Although the combination of platinum and gemcitabine (PG) is commonly used for the treatment of R/M HNSCC, its use with pembrolizumab has not been tested. We hypothesize that the combination of pembrolizumab with PG would be comparable to pembrolizumab with PF, as first-line treatment in R/M HNSCC. **Methods:** In this open-label, phase 2 single-arm study of pembrolizumab plus PG as first-line treatment in subjects with R/M HNSCC, 63 evaluable subjects with no prior treatment in metastatic setting will be enrolled and given pembrolizumab 200 mg 3 weekly in combination with chemotherapy for up to 6 cycles of platinum (either cisplatin at 35 mg/m² IV on Day 1 and Day 8 or carboplatin at AUC 5 IV on Day 1 of each 3-week cycle) and gemcitabine at 1000 - 1250 mg/m² IV on Day 1 and 8 of 3-week cycle. The primary study endpoint will be the Objective Response Rate (ORR) using RECIST 1.1. The study applies a Simon two-stage design, where if at least 7 out of 26 evaluable patients achieved CR/PR in stage I, the study will proceed to stage II. **Current Status:** The study was initiated in September 2022 and actively recruiting to achieve the stage I interim analysis. To date, 9 patients have been enrolled.