# 10

## NEOADJUVANT AND ADJUVANT CEMIPLIMAB FOR HIGH-RISK LOCALLY ADVANCED OR RECURRENT CUTANEOUS SQUAMOUS CELL CARCINOMA: INITIAL RESULTS OF A SINGLE-INSTITUTION PHASE II STUDY

Michael Lowe[1 *], Nicki Schmitt[2], Keith Delman[1], Jennifer Gross[2], Monica Rizzo[1], Jeffery Switchenko[3], Emily Henkel[4], Doug Parker[4], Nabil Saba[5], David Lawson[5], Melinda Yushak[5]

[1]*Department of Surgery, Emory University, Atlanta, Georgia, USA*
[2]*Department of Otolaryngology, Emory University, Atlanta, Georgia, USA*
[3]*Department of Bioinformatics and Biostatistics, Emory University, Atlanta, Georgia, USA*
[4]*Department of Pathology, Emory University, Atlanta, Georgia, USA*
[5]*Department of Hematology and Medical Oncology, Emory University, Atlanta, Georgia, USA*

Corresponding Author: Michael Lowe Lowe mlowe3@emory.edu

---

**Background**: Cemiplimab was approved for treatment of unresectable locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC) based on the phase II EMPOWER-CSCC-1 trial, which demonstrated an objective response rate (ORR) of 47%. A non-randomized phase II study of 79 patients receiving four doses of neoadjuvant cemiplimab for resectable stage II-IV cSCC showed a pathologic complete response rate (pCR) of 51% and ORR of 68%. In a study designed in parallel to that study we hypothesized that three doses of neoadjuvant cemiplimab and mandated adjuvant cemiplimab would lead to high rates of pathologic response and reduce recurrence rates in patients with high-risk resectable cSCC.

**Methods**: Winship 4851-19 is a single arm phase II study of cemiplimab in the neoadjuvant and adjuvant setting for high-risk resectable cSCC (NCT04428671). Patients were given three doses of cemiplimab every three weeks followed by surgery. Adjuvant radiation was offered at the discretion of the investigators. Cemiplimab was given every three weeks to complete one year total of treatment or until recurrence or toxicity. Eligible patients had surgically resectable histologically proven high risk cSCC defined as: nodal disease with extracapsular extension or one node ≥ 20mm; in transit metastases; T4 head and neck primary tumor; or recurrent cSCC with concurrent ≥N2b nodal disease, size ≥4cm or bony invasion, or

poorly differentiated histology. Primary objective was to establish pathologic response rate. Secondary objective was to assess safety and feasibility of perioperative cemiplimab and efficacy as defined by recurrence-free and overall survival.

**Results**: Fourteen patients were enrolled; median age was 73 (range 53-87) and 13 (92.8%) were males. Thirteen patients (92.8%) had tumors on the head/scalp or cervical nodal disease; one patient had an axillary nodal recurrence. All patients received all planned preoperative therapy and successfully underwent curative intent surgery. 13 patients achieved R0 resection and one patient had R1 resection. Rates of complete, near-complete, and partial pathologic responses were 57.1%, 21.4%, and 14.3%, respectively, with major pathologic response rate of 78.5% and objective pathologic response rate of 92.8%. There were no grade 3 or higher adverse events in the neoadjuvant setting. One patient's surgery was delayed by two weeks due to COVID-19 infection. One patient's surgery was delayed by 4 weeks for new onset pulmonary embolism discovered on presurgical imaging; this patient received an additional neoadjuvant dose of cemiplimab and safely underwent surgery. Recurrence-free and overall survival data are immature and will be reported in the future.

**Conclusion**: Three doses of neoadjuvant cemiplimab leads to excellent pathologic responses for patients with locally advanced and recurrent cutaneous squamous cell carcinoma. This data confirms the safety profile and excellent pathologic responses to neoadjuvant immunotherapy and suggests comparable and possibly superior pathologic response rates with only three doses.