

# BC Cancer Protocol Summary for First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with Pembrolizumab

<b>Protocol Code</b>	<i>UHNAVPMBF</i>
<b>Tumour Group</b>	<i>Head and Neck</i>
<b>Contact Physician</b>	<i>Dr. Cheryl Ho</i>

## ELIGIBILITY:

Patients must have:

- Previously untreated recurrent or metastatic squamous cell carcinoma of the head and neck including primary unknown not amenable to local therapy with curative intent (surgery or radiation therapy with or without chemotherapy)
  - Prior neoadjuvant, radiosensitizing or adjuvant systemic therapy in the curative setting permitted if completed greater than 6 months prior
- **PD-L1 CPS score  $\geq 1\%$ , and**
- *BC Cancer Compassionate Access Program (CAP) approval*

Patient should have:

- ECOG 0-2
- Adequate hematologic, hepatic and renal function
- Access to a treatment centre with expertise to manage immune-mediated adverse reactions of pembrolizumab

## EXCLUSIONS:

- Nasopharyngeal carcinoma, or non-squamous histologies
- Recurrent disease within 6 months of curative neoadjuvant or adjuvant platinum-based therapy
- Symptomatic central nervous system metastases
- Cautions with concurrent autoimmune disease, known active hepatitis B, C or HIV,
- Use with caution in patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg prednisone/day or equivalent)

## TESTS:

- Baseline: CBC & differential, platelets, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol, chest x-ray
- Before each treatment: CBC & differential, platelets, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH
- If clinically indicated: chest x-ray, morning serum cortisol, lipase, glucose, serum or urine HCG (required for women of child bearing potential if pregnancy suspected), free T3 and free T4, serum ACTH levels, testosterone, estradiol, FSH, LH, ECG

- Weekly telephone nursing assessment for signs and symptoms of side effects while on treatment (Optional)

### PREMEDICATIONS:

- Antiemetics are not usually required
- If required, antiemetic protocol for low emetogenicity (see SCNAUSEA)
- If prior infusion reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV 30 minutes prior to treatment

### TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
pembrolizumab	2 mg/kg (maximum 200mg)	IV in 50 mL NS over 30 minutes Using a 0.2 micron in-line filter

- **Repeat every 3 weeks until disease progression, unacceptable toxicity, or a maximum of 35 cycles or 2 years of treatment**

### DOSE MODIFICATIONS:

No specific dose modifications. Toxicity managed by treatment delay and other measures (see SCIMMUNE protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy, [http://www.bccancer.bc.ca/chemotherapy-protocols-site/Documents/Supportive%20Care/SCIMMUNE\\_Protocol.pdf](http://www.bccancer.bc.ca/chemotherapy-protocols-site/Documents/Supportive%20Care/SCIMMUNE_Protocol.pdf)).

### PRECAUTIONS:

- 1. Serious immune-mediated reactions:** can be severe to fatal and usually occur during the treatment course, but may develop months after discontinuation of therapy. They may include enterocolitis, intestinal perforation or hemorrhage, hepatitis, dermatitis, neuropathy, endocrinopathy, pneumonitis, as well as toxicities in other organ systems. Early diagnosis and appropriate management are essential to minimize life-threatening complications (see SCIMMUNE protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy, [http://www.bccancer.bc.ca/chemotherapy-protocols-site/Documents/Supportive%20Care/SCIMMUNE\\_Protocol.pdf](http://www.bccancer.bc.ca/chemotherapy-protocols-site/Documents/Supportive%20Care/SCIMMUNE_Protocol.pdf)).
- 2. Infusion-related reactions:** isolated cases of severe infusion reactions have been reported. Discontinue pembrolizumab with severe reactions (Grade 3 or 4). Patients with mild or moderate infusion reactions may receive pembrolizumab with close monitoring and use of premedication.

**Contact Dr. Cheryl Ho or tumour group delegate at (604) 877-6000 or 1-800-523-2885 with any problems or questions regarding this treatment program.**

**REFERENCES:**

1. Burtness B, Harrington KJ, Greil R, et al. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *Lancet* 2019;394:1915-28.