BC Cancer Protocol Summary for the Treatment of Locally Advanced Basal Cell Carcinoma using Cemiplimab

Protocol Code	*USMLACEM*
Tumour Group	*Skin and Melanoma*
Contact Physician	*Dr. Vanessa Bernstein*

ELIGIBILITY:

Patients must have:

- Histologically confirmed, unresectable, invasive locally advanced basal cell carcinoma (BCC) that is not amenable to curative surgery or curative radiation therapy,
- Previously been treated with, or are intolerant of, a hedgehog pathway inhibitor (HHI) such as vismodegib, and
- BC Cancer "Compassionate Access Program" request approval prior to treatment

Patients should have:

- Good performance status
- Adequate hepatic and renal function
- Access to a treatment centre with expertise to manage immune-mediated adverse reactions of cemiplimab

Note:

- At time of subsequent disease progression, retreatment is allowed for an additional 16 cycles or 48 weeks if:
  - Patient completed 31 cycles or 93 weeks of cemiplimab therapy without progression, or
  - Patients stopped cemiplimab due to toxicity (not progression)
  - Additional CAP approval not required for retreatment

EXCLUSIONS:

Patients must not have:

- Active central nervous system metastases (unless asymptomatic and/or stable),
- Received prior anti-PD1 or anti-PDL-1 therapy, or
- Received prior treatment with idelalisib, regardless of indication

CAUTIONS:

- Concurrent autoimmune disease,
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent), or
- Active infection requiring treatment (at discretion of treating physician)

TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol, creatine kinase, appropriate imaging
- Baseline, if clinically indicated: BNP, troponin, ECG, echocardiogram
- Before each treatment: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, creatine kinase
- If clinically indicated: chest x-ray, morning serum cortisol, lipase, serum or urine HCG (required for woman of child bearing potential if pregnancy suspected), free T3 and free T4, serum ACTH levels, testosterone, estradiol, FSH, LH, random glucose, troponin, ECG
- Weekly telephone nursing assessment for signs and symptoms of side effects while on treatment (optional).

PREMEDICATIONS:

- Antiemetics are not usually required.
- Antiemetic protocol for low emetogenicity (see SCNAUSEA).
- If prior infusion reactions to cemiplimab: 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
cemiplimab	350 mg	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

- Repeat every 3 weeks up to a maximum of 31 cycles or 93 weeks treatment duration, symptomatic disease progression, or unacceptable toxicity, whichever occurs first.
- Retreatment may be allowed (refer to Eligibility section above).

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).

PRECAUTIONS:

- **Serious immune-mediated reactions**: these can be severe to fatal and usually occur during the treatment course. They may include enterocolitis, intestinal perforation or hemorrhage, hepatitis, dermatitis, neuropathy, endocrinopathy, 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).
- **Infusion-related reactions:** isolated cases of severe reaction have been reported. In case of a severe reaction, cemiplimab infusion should be discontinued and appropriate medical therapy administered. Patients with mild or moderate infusion reaction may receive cemiplimab with close monitoring, reduced rates of administration and use of premedication.

Contact Dr. Vanessa Bernstein or tumour group delegate at 250-519-5500 or 1-800-670-3322 with any problems or questions regarding this treatment program.

References:

1. Stratigos AJ, Sekulic A, Peris K, et. al. Cemiplimab in locally advanced basal cell carcinoma after hedgehog inhibitor therapy: an open-label, multi-centre, single-arm, phase 2 trial. Lancet Oncol. 2021 Jun;22(6):848-857.
2. Cemiplimab (Libtayo) CADTH Reimbursement Recommendation. Canadian Journal of Health Technologies, March 2022; 2(3).