BC Cancer Protocol Summary for the First-Line Treatment of Advanced Non-Small Cell Lung Cancer using Cemiplimab

Protocol Code	*LUAVCEMF*
Tumour Group	*Lung*
Contact Physician	*LU Systemic Therapy*

ELIGIBILITY:

Patients must have:

- Stage IIIB or IIIC non-small cell lung cancer (NSCLC) not amenable to curative intent therapy, or stage IV NSCLC, and
- No prior treatment in the advanced setting, and
- PD-L1 expression positive (TPS greater than or equal to 50%), confirmed by an accredited laboratory

Patients should have:

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

Note:

- Use of first-line cemiplimab precludes the use of nivolumab, pembrolizumab and atezolizumab as any subsequent line of therapy
- At time of subsequent progression, retreatment is permitted for an additional 1 year (17 cycles) if:
  - Patient completed 108 weeks (36 cycles) of therapy without progression, or
  - Patient stopped treatment due to toxicity (not progression)
  - CAP approval not required for retreatment

EXCLUSIONS:

Patients must not have:

- Presence of EGFR, ALK or ROS1 mutations
- Progression on or within 6 months of completing adjuvant or neoadjuvant treatment
- Active central nervous system metastases (unless asymptomatic and/or stable)

CAUTIONS:

- Concurrent autoimmune disease
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent)
- Received prior treatment with idelalisib, regardless of indication

TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol
- Baseline, if clinically indicated: BNP, troponin, creatine kinase, ECG, echocardiogram, chest x-ray
- Before each treatment: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH
- 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, creatine kinase, 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 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** until disease progression, unacceptable toxicity, or a maximum of 108 weeks (36 cycles), whichever comes 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:

1. **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).

2. **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 the LU Systemic Therapy physician at your regional cancer centre or LU Systemic Therapy Chair with any problems or questions regarding this treatment program.

REFERENCES:

1. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomized controlled trial. Lancet 2021; 397:592-604.
2. Cemiplimab (Libtayo) CADTH Reimbursement Recommendation. Canadian Journal of Health Technologies, June 2022; 2(6).