

Systemic Therapy Education Bulletin

BC Cancer News and updates from across the province for Systemic Therapy teams

Provincial Systemic Therapy Drug Programs Under Consideration



The Provincial Systemic Therapy Program (PSTP) is considering launching several new treatment programs at BC Cancer in the coming months (exact dates to be announced in the monthly Systemic Therapy Update once approved). The goal of this Education Bulletin is to support health care staff as they prepare for these new treatments and to ensure safe patient care during the administration, distribution and management of new and complex treatments. These new drug treatments may also be delivered to patients prior to formal listing through manufacturer patient support programs or clinical trials. Education Bulletins will be disseminated via email in advance of the expected formal launch date to facilitate awareness. They will also be posted on the Systemic Therapy website for easy access in future to all staff delivering systemic therapy around the Province. More details about the drugs, approved indications, and side effects can be found on the Cancer Drug Manual Drug Index website.

Adverse Events

Treatment Programs	Indication (Refer to protocol for more details)	Associated Adverse Events
Nivolumab plus Ipilimumab	First-line treatment of patients with advanced unresectable or metastatic melanoma	Possible adverse events (of any grade): Immune-mediated reactions: (see SCIMMUNE Resources) Infusion-related reactions Skin: Rash Pruritus Gastrointestinal: Piarrhea Nausea Endocrine: Hypothyroidism/hyperthyroidism Fatigue Pulmonary: Pheumonary: Pheumonary: Pheumonary: Prever Possible adverse events (of > grade 3) of combination therapy with Ipilimumab plus Nivolumab: Hepatic: Elevated alanine aminotransferase (ALT) and/or aspartate transaminase (AST) Gastrointestinal: Colitis Diarrhea

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Treatment	Indication	Associated Adverse Events
Programs	(Refer to protocol for more details)	
Nivolumab plus Ipilimumab	First-line treatment of patients with metastatic or advanced renal cell carcinoma	Refer to list of adverse events above for Nivolumab plus Ipilimumab for metastatic melanoma. Can you add a subheading for what is unique about the following since hepatic toxicities were also listed above? • Hepatic • Abnormal liver function tests (LFTs) • Renal • Elevated serum creatinine
Alectinib	First-line treatment of patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC)	Possible adverse events (of any grade):
Avelumab	Second-line treatment of patients with recurrent or metastatic Merkel cell carcinoma (MCC)	Possible adverse events (of any grade): • Immune-mediated reactions: (see <u>SCIMMUNE Resources</u>) • Infusion-related reactions • Fatigue • Nausea • Diarrhea *Adverse events of ≥ grade 3 with Avelumab are rare*

Treatment Regimens: Dosing and Administration Schedules

1. Nivolumab plus Ipilimumab: Metastatic Melanoma

Dosing and Schedule:

(Note: Dosing DIFFERS from Nivolumab & Ipilimumab dosing used in renal cell carcinoma)

Induction Phase

Nivolumab 1 mg/kg IV (maximum dose 240 mg) + Ipilimumab 3 mg/kg IV

o Every 3 weeks for a total of 4 doses

- Nivolumab given over 30 minutes using a 0.2- or 0.22-micron in-line filter
- Ipilimumab given over 90 minutes using a 0.2- or 0.22-micron in-line filter
 - If no infusion-related reactions after 2 treatments, may infuse subsequent doses over 30 minutes
- Use a separate infusion line and filter for EACH drug



Maintenance Phase

Nivolumab 3 mg/kg IV (maximum dose 240 mg)

o Every 2 weeks for maximum of 2 years

OR

Nivolumab 6 mg/kg IV (maximum dose 480 mg)

- o Every 4 weeks for maximum of 2 years
- Nivolumab given over 30 minutes using a 0.2 or 0.22 micron in-line filter

2. Nivolumab plus Ipilimumab: Metastatic Renal Cell Carcinoma

Dosing and Schedule:

(Note: Dosing DIFFERS from Nivolumab & Ipilimumab dosing used in metastatic melanoma)

Induction Phase

Nivolumab 3 mg/kg IV (maximum dose 240 mg) + Ipilimumab 1 mg/kg IV

- Every 3 weeks for a total of 4 doses
- Nivolumab given over 30 minutes using a 0.2- or 0.22-micron in-line filter
- Ipilimumab given over 90 minutes using a 0.2- or 0.22-micron in-line filter
 - If no infusion-related reactions after 2 treatments, may infuse subsequent doses over 30 minutes
- Use a separate infusion line and filter for EACH drug



Maintenance Phase

Nivolumab 3 mg/kg IV (maximum dose 240 mg)

Every 2 weeks until disease progression

OR

Nivolumab 6 mg/kg IV (maximum dose 480 mg)

- Every 4 weeks until disease progression
- Nivolumab given over 30 minutes using a 0.2 or 0.22 micron in-line filter

3. Alectinib: ALK-Positive NSCLC

Dosing and Schedule:

• Oral Alectinib 600 mg twice daily (to be taken with food) until disease progression

4. Avelumab: Metastatic Merkel Cell Carcinoma

Dosing and Schedule:

- Avelumab 10 mg/kg IV every 2 weeks until disease progression or unacceptable toxicity
 - o To be given over 60 minutes using a 0.2-micron in-line filter