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 goal of the Education Bulletin is to support health care staff as they prepare for 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. **Full details around the funded indications and eligibility criteria will be available in the Protocol Summaries and summarized in the Systemic Therapy Update newsletter once funding decisions have been finalized.** More details about the drugs, approved indications, and side effects can be found in the BC Cancer drug monographs, accessible from the Cancer Drug Manual Drug Index.

USMAVCEM

Treatment Programs	Indication: Under Review (Refer to protocol for more details)	Associated Adverse Events
Cemiplimab	Treatment of **Locally Advanced or Metastatic Cutaneous Squamous Cell Carcinoma**	Possible adverse events (**of any grade**): • Immune-mediated adverse reactions (see SCIMMUNE Resources) • Infusion-related reactions

Dosing and Administration Information

Premedications:

- **Antiemetic:** low emetogenic (see SCNAUSEA)
- **Infusion reaction*:** If prior reactions to cemiplimab:
  diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV

* Does not require physician coverage during delivery

Dosing and Schedule: Cycle length = 3 weeks

- **IV cemiplimab** 3 mg/kg (maximum 350 mg) administer over 30 minutes
  - Use a 0.2 micron in-line filter

Additional Protocol Information:

- Optional weekly telephone nursing assessment for signs and symptoms of side effects while on treatment.
- For further information on management of immune-mediated adverse reactions, see BC Cancer Protocol SCIMMUNE Management of Immune-Mediated Adverse Reactions to Checkpoint Inhibitors Immunotherapy.

SAAVTW

Treatment Programs	Indication: Under Review (Refer to protocol for more details)	Associated Adverse Events
Paclitaxel	Treatment of **Metastatic or Unresectable Angiosarcoma**	Possible adverse events (**of any grade**): • Myelosuppression • Infusion-related reactions • Nausea and vomiting • Peripheral sensory neuropathy • Arthralgia/myalgia • Alopecia • Mucositis

Dosing and Administration Information

Pre-medications:

- **Prior to paclitaxel:**
  - IV dexamethasone 10 mg
  - IV diphenhydramine 25 mg + IV famotidine 20 mg (Y-site compatible)

Dosing and Schedule: Cycle length = 4 weeks

- **IV paclitaxel** 80 mg/m^2 administer over 1 hour weekly for 3 weeks
  - Use non-DEHP bag and non-DEHP tubing with 0.2 micron or smaller in-line filter

Additional Protocol Information:

- **If no paclitaxel infusion reactions occur**:
  - No premedications may be needed for subsequent doses and may be omitted at physician's discretion.
- **If paclitaxel infusion reactions occur**:
  - Premedications for re-challenge include dexamethasone 20 mg PO given 12 hours and 6 hours prior to treatment, **plus** IV premedications given 30 minutes prior to paclitaxel: dexamethasone 10 mg, diphenhydramine 50 mg, and famotidine 20 mg.
- If extravasated paclitaxel causes pain and may cause tissue necrosis
  - Please refer to Policy III-20: Prevention and Management of Extravasation of Chemotherapy for more information
- Paclitaxel is a CYP 2C8 and CYP 3A4 substrate. Paclitaxel serum concentrations may be increased by inhibitors of these enzymes and decreased by inducers of these enzymes.

UMYBLDF

Treatment Programs	Indication: Under Review (Refer to protocol for more details)	Associated Adverse Events
Bortezomib Plus Lenalidomide Plus Dexamethasone	Treatment of Previously Untreated **Multiple Myeloma and Not Eligible for Stem Cell Transplant**	Possible adverse events (**of any grade**): • Myelosuppression • Nausea • Diarrhea • Epistaxis • Hemorrhage • Pneumonia • Peripheral sensory neuropathy • Musculoskeletal pain • Hypotension • Fatigue • Renal dysfunction • Hepatotoxicity • Pruritis • Rash • Hypothyroidism • Teratogenicity • Venous thrombosis/embolism • Dyspepsia • Insomnia • Increased blood sugar

Dosing and Administration Information

Pre-medications:

- Not required

Dosing and Schedule: Cycle length = 4 weeks

- **Subcutaneous bortezomib** 1.3 mg/m^2 administer into abdomen or thigh on days 1, 8, and 15 (*cycles 1 to 8 only)*
  - back of the arm can also be considered as a third option
- **Oral lenalidomide** 25 mg once daily on days 1 – 21
  - It is recommended to be taken in the evening
- **Oral dexamethasone** 40 mg once daily on days on days 1, 8, 15, and 22
  - It is recommended to be taken in the morning with breakfast

Additional Protocol Information:

- **Bortezomib drug Interactions:**
  - Bortezomib is a substrate for CYP 3A4, CYP 2C19, CYP 1A2, CYP 2D6, and CYP 2C9. Concomitant use of strong CYP 3A4 inducers is not recommended due to the potential for reduced efficacy of bortezomib.
- **Lenalidomide Special Precautions:**
  - do NOT give blood nor donate semen while taking lenalidomide and for 4 weeks after stopping
  - Pregnancy must be excluded in females of childbearing potential i.e., negative pregnancy test within 10-14 days prior and again within the 24 h immediately prior to the first dose. Testing should be repeated during treatment as required by the RevAid® Program.
  - Breastfeeding is not recommended due to the potential secretion into breast milk.

GOCISPBEV

Treatment Programs	Indication: Under Review (Refer to protocol for more details)	Associated Adverse Events
Paclitaxel Plus Cisplatin Plus Bevacizumab	Alternative Treatment of **Gynecological Malignancies** for patients with previous non-life threatening infusion-related reactions to carboplatin	Possible adverse events (**of any grade**): • Myelosuppression • Infusion-related reactions • Nausea and vomiting • Peripheral sensory neuropathy • Arthralgia/myalgia • Alopecia • Mucositis • Neurotoxicity • Nephrotoxicity • Tinnitus • Proteinuria • Hypertension • Poor wound healing

Dosing and Administration Information

Pre-medications:

- **Antiemetic:** high emetogenicity (see SCNAUSEA)
- **Prior to paclitaxel:**
  - IV dexamethasone 20 mg
  - IV diphenhydramine 50 mg + IV famotidine 20 mg (Y-site compatible)
- **Prior to cisplatin:**
  - 1 L NS administer over 1 hour

Dosing and Schedule: One cycle = 21 days

- **IV paclitaxel** 175 mg/m^2 infuse over 3 hours
  - Use non-DEHP bag and non-DEHP tubing with 0.2 micron or smaller in-line filter

  Plus
- **IV cisplatin** 75 mg/m^2 infuse over 1 hour

  Plus
- **IV bevacizumab**
  - For ovarian cancer: 7.5 mg/kg infuse over 15 minutes*
  - For cervical cancer: 15 mg/kg infuse over 30 minutes*

*** First Bevacizumab infusion over 60 minutes**

Additional Protocol Information:

- Blood pressure measurement pre-bevacizumab
- Blood pressure measurement post-bevacizumab for the first 3 cycles
- Urine dipstick analysis or laboratory urinalysis for protein should be performed at baseline and then prior to each cycle
- Paclitaxel causes pain and may cause tissue necrosis if extravasated
  - Please refer to Policy III-20: Prevention and Management of Extravasation of Chemotherapy for more information
- Paclitaxel is a CYP 2C8 and CYP 3A4 substrate. Paclitaxel serum concentrations may be increased by inhibitors of these enzymes and decreased by inducers of these enzymes.

UBRAVRBFLV

Treatment Programs	Indication: Under Review (Refer to protocol for more details)	Associated Adverse Events
Ribociclib Plus Fulvestrant	Treatment of **Advanced Breast Cancer**	Possible adverse events (**of any grade**): • Nausea and vomiting • Myelosuppression • Fatigue • Diarrhea • Loss of appetite • Skin rash • Mucositis • QT interval prolongation • Pulmonary embolism • Hepatotoxicity ○ Elevated ALT & AST • Abdominal/back pain • Bone pain • Headache

Dosing and Administration Information

Premedications:

- Not required

Dosing and Schedule: Cycle length = 28 days

- **Oral ribociclib** 600 mg once daily for 21 days, followed by 7-day rest
  plus
- **IM fulvestrant** 500 mg
  - Cycle 1: on days 1, 14, and 28
  - Cycle 2 +: every 28 days (± 3 days)

Additional Protocol Information:

- Ribociclib must be taken in the morning (QT prolongation risk may be increased when it is taken in the evening), with food or on an empty stomach.
- Crushing or chewing tablets may lead to increased ribociclib exposure.
- Grapefruit and grapefruit juice must be avoided for the duration of treatment.
- **For women needing chemically-induced menopause**
  - Buserelin 6.3 mg SC every 6 weeks for two treatments, then every 8 weeks
  - Goserelin 3.6 mg SC every 4 weeks
  - Leuprolide 7.5 mg IM every 4 weeks

Website Resources and Contact Information

CONTACT INFORMATION	EMAIL
To subscribe or update contact information, please contact:	
Provincial Systemic Therapy Program	ProvincialSystemicOffice@bccancer.bc.ca
Systemic Therapy Education Bulletin: http://www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/education-bulletin	
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