

Systemic Therapy Education Bulletin

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

Provincial Systemic Therapy Drug Programs Under Consideration

USMAJPEM

| Treatment | Indication: Under Review | Associated Adverse Events |
|---------------|--------------------------------------|--|
| Programs | (Refer to protocol for more details) | |
| Pembrolizumab | Adjuvant treatment of patients with | Possible adverse events (any grade): |
| | resected melanoma | Immune-mediated adverse reactions: (see <u>SCIMMUNE Resources</u>) |
| | | o Skin: |
| | | o Rash |
| | | o Pruritus |
| | | o Enterocolitis: |
| | | Diarrhea |
| | | Abdominal pain |
| | | o Endocrine: |
| | | Hypothyroidism/hyperthyroidism |
| | | Fatigue |
| | | o Pulmonary: |
| | | Pneumonitis |
| | | o Hepatic: |
| | | Elevated alanine aminotransferase (ALT) |
| | | o Renal |
| | | Increased serum creatinine |
| | | Infusion-related reactions |

Dosing and Administration Information

Pre-medications:

- Antiemetic: low emetogenicity
- Infusion reaction: <u>If prior reactions to pembrolizumab</u>: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV

Dosing and Schedule:

- IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks for 18 cycles (approximately 1 year), unless disease progression or unacceptable toxicity
 - o To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|----------|--|--|
| Cycle 1 | 55 | 110 |
| Cycle 2+ | 40 | 95 |

ULYPEM & ULYPEM6

| Treatment | Indication: Under Review | Associated Adverse Events |
|----------------------|--|---|
| Programs | (Refer to protocol for more details) | |
| <u>Pembrolizumab</u> | Treatment of patients with relapsed or refractory Hodgkin lymphoma | Possible adverse events (any grade): Please refer to associated adverse events for USMAJPEM. |

Dosing and Administration Information

Pre-medications:

- Antiemetic: low emetogenicity
- Infusion reaction: If prior reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV

Dosing and Schedule:

- IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks until disease progression, unacceptable toxicity or a maximum of 35 cycles or 2 years of treatment
 - o To be given over 30 minutes using a 0.2 micron in-line filter

OR

- IV pembrolizumab 4 mg/kg (max dose 400 mg) every 6 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - o To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|----------|--|--|
| Cycle 1 | 55 | 110 |
| Cycle 2+ | 40 | 95 |

UGUAVPEM & UGUAVPEM6

| Treatment | Indication: Under Review | Associated Adverse Events |
|----------------------|--|--|
| Programs | (Refer to protocol for more details) | |
| <u>Pembrolizumab</u> | Treatment of patients with locally advanced or metastatic urothelial carcinoma | Possible adverse events (any grade): Please refer to associated adverse events for USMAJPEM. |

Dosing and Administration Information

Pre-medications:

- Antiemetic: low emetogenicity
- Infusion reaction: If prior reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV

Dosing and Schedule:

- IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks until disease progression, unacceptable toxicity or a maximum of 35 cycles or 2 years of treatment
 - o To be given over 30 minutes using a 0.2 micron in-line filter

OR

- IV pembrolizumab 4 mg/kg (max dose 400 mg) every 6 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - o To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|----------|--|--|
| Cycle 1 | 55 | 110 |
| Cycle 2+ | 40 | 95 |

Combination Phase: ULUAVPCPMB

Maintenance Phase: LUAVPMBM or LUAVPMBM6

| Treatment | Indication: Under Review | Associated Adverse Events | |
|--------------------|--------------------------------------|---|--|
| Programs | (Refer to protocol for more details) | | |
| Pembrolizumab | Treatment of patients with advanced | Possible adverse events (any grade): | |
| Plus | squamous non-small cell lung cancer | Immune-mediated adverse reactions: (see <u>SCIMMUNE Resources</u>) | |
| <u>Paclitaxel</u> | (NSCLC) | o Skin: | |
| Plus | | o Rash | |
| <u>Carboplatin</u> | | o Pruritus | |
| | | o Enterocolitis: | |
| | | Diarrhea | |
| | | Abdominal pain | |
| | | o Endocrine: | |
| | | Hypothyroidism/hyperthyroidism | |
| | | Fatigue | |
| | | o Pulmonary: | |
| | | Pneumonitis | |
| | | o Hepatic: | |
| | | Elevated alanine aminotransferase (ALT) | |
| | | o Renal | |
| | | Increased serum creatinine | |
| | | Infusion-related reactions | |
| | | Anemia | |
| | | Neutropenia | |
| | | Nausea and vomiting | |
| | | Peripheral sensory neuropathy | |
| | | Arthralgia/myalgia | |
| | | Alopecia | |

Dosing and Administration Information

Premedications:

- If NO prior reaction to pembrolizumab:
 - O IV dexamethasone 20 mg prior to paclitaxel
 - IV diphenhydramine 50 mg + IV ranitidine 50 mg (compatible up to 3 hours when mixed in bag) prior to paclitaxel
- If prior reaction to pembrolizumab: Administer paclitaxel premedications prior to pembrolizumab
 - IV dexamethasone 20 mg prior to pembrolizumab
 - o IV diphenhydramine 50 mg + IV ranitidine 50 mg (compatible up to 3 hours when mixed in bag) prior to pembrolizumab
 - Oral acetaminophen 325 to 975 mg prior to pembrolizumab
- Antiemetic:
 - o high emetogenic (see SCNAUSEA)

Dosing and Schedule:

- Combination Phase repeat every 3 weeks x 4 cycles
 - o IV pembrolizumab 2 mg/kg (max dose 200 mg) + IV paclitaxel 200 mg/m² + IV carboplatin 6 (or 5) AUC
 - Pembrolizumab: infuse over 30 minutes using a 0.2 micron in-line filter
 - Paclitaxel: infuse over 3 hours using non-DEHP bag and non-DEHP tubing with 0.2 micron or smaller inline filter
 - Carboplatin: infuse over 30 minutes
- Maintenance Phase repeat every 3 OR 6 weeks
 - IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

OR

- IV pembrolizumab 4 mg/kg (max dose 400 mg) every 6 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

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| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|-------------|--|--|
| Cycle 1 | 85 | 385 |
| Cycle 2 – 4 | 65 | 370 |
| Cycle 5+ | 40 | 95 |

Combination Phase: ULUAVPGPMB

Maintenance Phase: LUAVPMBM or LUAVPMBM6

| Treatment | Indication: Under Review | Associated Adverse Events | |
|---------------|--------------------------------------|---|--|
| Programs | (Refer to protocol for more details) | | |
| Pembrolizumab | Treatment of patients with advanced | Possible adverse events (any grade): | |
| Plus | squamous non-small cell lung cancer | Immune-mediated adverse reactions: (see <u>SCIMMUNE Resources</u>) | |
| Gemcitabine | (NSCLC) | o Skin: | |
| Plus | | o Rash | |
| Cisplatin | | o Pruritus | |
| | | o Enterocolitis: | |
| | | Diarrhea | |
| | | Abdominal pain | |
| | | o Endocrine: | |
| | | Hypothyroidism/hyperthyroidism | |
| | | Fatigue | |
| | | o Pulmonary: | |
| | | Pneumonitis | |
| | | o Hepatic: | |
| | | Elevated alanine aminotransferase (ALT) | |
| | | o Renal | |
| | | Increased serum creatinine | |
| | | Infusion-related reactions | |
| | | Anemia | |
| | | Neutropenia | |
| | | Nausea and vomiting | |
| | | Flu- like illness | |
| | | Peripheral sensory neuropathy | |
| | | • Edema | |

Dosing and Administration Information

Premedications:

- Prior to cisplatin:
 - o 1000 mL NS over 1 hour
- Infusion reaction: If prior reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV
- Antiemetic:
 - o high emetogenic (see <u>SCNAUSEA</u>)

Dosing and Schedule:

- Combination Phase repeat every 3 weeks x 4 cycles
 - Day 1: IV pembrolizumab 2 mg/kg (max dose 200 mg) + IV gemcitabine 1250 mg/m² (or 1000 mg/m² if carboplatin is used) + IV cisplatin 75 mg/m²
 - Pembrolizumab: infuse over 30 minutes using a 0.2 micron in-line filter
 - Gemcitabine: infuse over 30 minutes
 - Cisplatin: infuse over 60 minutes
 - Day 8: IV gemcitabine 1250 mg/m² (or 1000 mg/m² if carboplatin is used)
 - Gemcitabine: infuse over 30 minutes
- Maintenance Phase repeat every 3 OR 6 weeks
 - IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

OR

- IV pembrolizumab 4 mg/kg (max dose 400 mg) every 6 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|-------------------|--|--|
| Cycle 1 Day 1 | 70 | 265 |
| Cycle 1 Day 8 | 40 | 85 |
| Cycle 2 - 4 Day 1 | 55 | 250 |
| Cycle 2 - 4 Day 8 | 40 | 85 |
| Cycle 5+ | 40 | 95 |

Combination Phase: ULUAVPPPMB

Maintenance Phase: LUAVPPMBM or LUAVPMBM or LUAVPMBM6

| Treatment | Indication: Under Review | Associated Adverse Events | |
|-------------------|---|---|--|
| Programs | (Refer to protocol for more details) | | |
| Pembrolizumab | Treatment of patients with advanced | Possible adverse events (any grade): | |
| Plus | non-squamous non-small cell lung cancer | Immune-mediated adverse reactions: (see <u>SCIMMUNE Resources</u>) | |
| <u>Pemetrexed</u> | (NSCLC) | o Skin: | |
| Plus | | o Rash | |
| <u>Cisplatin</u> | | o Pruritus | |
| | | o Enterocolitis: | |
| | | Diarrhea | |
| | | Abdominal pain | |
| | | o Endocrine: | |
| | | Hypothyroidism/hyperthyroidism | |
| | | Fatigue | |
| | | o Pulmonary: | |
| | | Pneumonitis | |
| | | o Hepatic: | |
| | | Elevated alanine aminotransferase (ALT) | |
| | | o Renal | |
| | | Increased serum creatinine | |
| | | Infusion-related reactions | |
| | | Neutropenia | |
| 1 | | Anemia | |
| 1 | | Nausea and vomiting | |
| i | | Loss of appetite | |

Dosing and Administration Information

Premedications:

- Vitamin Supplementation: starting at least 7 days prior to the first cycle, and to continue while on treatment, until 21 days after last pemetrexed dose
 - Folic acid 0.4 mg PO daily
 - O Vitamin B₁₂ 1000 mcg IM every 9 weeks
- Prophylaxis for skin rash:
 - o dexamethasone 4 mg PO twice a day for 3 days, starting the day before chemotherapy
- Prior to cisplatin:
 - \circ 1000 mL NS over 1 hour
- Infusion reaction: If prior reactions to pembrolizumab: diphenhydramine 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV
- Antiemetic:
 - high emetogenic (see <u>SCNAUSEA</u>)

Dosing and Schedule:

- Combination Phase repeat every 3 weeks x 4 cycles
 - O IV pembrolizumab 2 mg/kg (max dose 200 mg) + IV pemetrexed 500 mg/m² + IV cisplatin 75 mg/m²
 - Pembrolizumab: infuse over 30 minutes using a 0.2 micron in-line filter
 - Pemetrexed: infuse over 10 minutes
 - Cisplatin: infuse over 60 minutes
- Maintenance Phase
 - IV pembrolizumab 2 mg/kg (max dose 200 mg) + IV pemetrexed 500 mg/m² every 3 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - Pembrolizumab: infuse over 30 minutes using a 0.2 micron in-line filter
 - Pemetrexed: infuse over 10 minutes

OR (for patients intolerant to pemetrexed)

- IV pembrolizumab 2 mg/kg (max dose 200 mg) every 3 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

OR

- o **IV pembrolizumab** 4 mg/kg (max dose 400 mg) every 6 weeks until disease progression, unacceptable toxicity or a maximum of 2 years of treatment
 - To be given over 30 minutes using a 0.2 micron in-line filter

Additional Protocol Information:

Optional weekly nursing assessment

BC Cancer Recommended Nurse and Chair Time

| Cycle | Final Nurse Time (Rounded up to next 5min interval) | Final Chair Time (Rounded up to next 5min interval) |
|-------------|--|--|
| Cycle 1 | 70 | 240 |
| Cycle 2 – 4 | 55 | 225 |
| Cycle 5+ | 45 | 105 |

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 | |