BC CANCER
Provincial Health Services Authority

Systemic Therapy Education Bulletin

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

Biosimilar Oncology Drugs – Bevacizumab (Zirabev®)

The Provincial Systemic Therapy Program will soon begin introducing biosimilars into current practice.

Biologics are complex protein molecules produced by a living cell system. The natural variability in the production process of biologics does not allow for an identical replication of the protein structure of biologic drugs. Unlike generic drugs, which are chemically identical to an existing drug, *biosimilars* are similar to their reference product but are not identical.

Health Canada has developed comprehensive regulatory guidelines to ensure biosimilar drugs have comparable quality, safety, and efficacy as their corresponding reference biologic drugs. The goal of biosimilars is to establish similarity and to meet the same quality standards as the reference biologic drug product.

Information and resources on Biosimilar Drugs for **health care professionals** and **patients**, is available on the BC Cancer Website.

Health Canada has recently approved the first oncology biosimilar for bevacizumab. Thirteen treatment programs will be affected by the implementation of biosimilar bevacizumab. New patients starting on these treatment programs from November 1st onwards will receive the biosimilar for bevacizumab, Zirabev®. Existing patients will continue to receive the reference biologic for bevacizumab, Avastin®. For patients on the reference biologic, physicians may choose to switch patients to the biosimilar following discussion with their patients.

Bevacizumab, Zirabev®

Affected Treatment Programs	Indication (Refer to protocol for more details)
CNBEV	Palliative Therapy for **Recurrent Malignant Gliomas**
GIAVCAPB	Palliative Therapy of **Metastatic Colorectal Cancer**
GICIRB	Palliative Combination Chemotherapy for **Metastatic Colorectal Cancer**
GICOXB	Palliative Combination Chemotherapy for **Metastatic Colorectal Cancer**
GIFFIRB	Palliative Combination Chemotherapy for **Metastatic Colorectal Cancer**
GIFFOXB	Palliative Combination Chemotherapy for **Metastatic Colorectal Cancer**
GOCXCATB	Primary Treatment of **Metastatic or Recurrent Cancer of the Cervix**
UGOOVBEVG	Treatment of Platinum Resistant **Epithelial Ovarian Cancer**
UGOOVBEVLD	Treatment of Platinum Resistant **Epithelial Ovarian Cancer**
UGOOVBEVP	Treatment of Platinum Resistant **Epithelial Ovarian Cancer**
UGOOVBEVV	Treatment of Platinum Resistant **Epithelial Ovarian Cancer**
UGOOVCATB	Primary Treatment of **Invasive Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer** with High Risk Of Relapse
USATEMBEV	Therapy for **Advanced Solitary Fibrous Tumours and Hemangiopericytoma**

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. Exact details around the funded indication and patient eligibility will be available through the Systemic Therapy Update once a decision has been finalized on funding. More details about the drugs, approved indications, and side effects can be found on the Cancer Drug Manual Drug Index website.

USMAJNIV & USMAJNIV4

Treatment Programs	Indication (Refer to protocol for more details)	Associated Adverse Events

Nivolumab	Adjuvant treatment of patients with **resected melanoma**	Possible adverse events **(of any grade)**:
		• Immune-mediated reactions: (see SCIMMUNE Resources)
		  ○ Skin:
		  ○ Rash
		  ○ Pruritus
		  ○ Enterocolitis:
		  • Diarrhea
		  • Abdominal pain
		  ○ Endocrine:
		  • Hypothyroidism/hyperthyroidism
		  • Fatigue
		  ○ Pulmonary:
		  • Pneumonitis
		  ○ Hepatic:
		  • Elevated alanine aminotransferase (ALT)
		  ○ Renal
		  • Increased serum creatinine
		• Infusion-related reactions

Dosing and Administration Information

Pre-medications:

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

Dosing and Schedule:

- **IV nivolumab** 3 mg/kg (maximum dose 240 mg) every 2 weeks for one year
  - To be given over 30 minutes using a 0.2 or 0.22 micron in-line filter

OR

- **IV nivolumab** 6 mg/kg (maximum dose 480 mg) every 4 weeks for one year
  - To be given over 30 minutes using a 0.2 or 0.22 micron in-line filter

USMAJDT

Treatment Programs	Indication (Refer to protocol for more details)	Associated Adverse Events

Dabrafenib plus Trametinib	Adjuvant treatment of patients with **fully resected melanoma**	Possible adverse events (**of any grade**):
		• Pyrexia
		• Fatigue
		• Nausea
		• Headache
		• Chills
		• Diarrhea
		• Vomiting
		• Arthralgia
		• Cutaneous:
		  ○ Rash
		  ○ Dermatitis acneiform
		  ○ Palmar-plantar erythrodysesthesia
		• Cardiac:
		  ○ QT prolongation
		  ○ Decrease left ventricular ejection fraction (LVEF)
		• Ocular:
		  ○ Uveitis
		  ○ Retinal pigment epithelial detachment and retinal vein occlusion
		• Pulmonary:
		  ○ Pneumonitis

Dosing and Administration Information

Pre-medications:

- **Antiemetic:** low emetogenicity

Dosing and Schedule:
Oral dabrafenib 150 mg twice daily plus **oral trametinib** 2 mg once daily for one year .

ULUAVATE

Treatment Programs	Indication (Refer to protocol for more details)	Associated Adverse Events
Atezolizumab	Treatment of patients with **advanced Non-Small Cell Lung Cancer (NSCLC)**	Possible adverse events **(of any grade)**: • Immune-mediated reactions: (see SCIMMUNE Resources) • Infusion-related reactions • Pneumonitis • Colitis • Fatigue • Nausea • Decreased appetite • Asthenia

Dosing and Administration Information

Pre-medications:

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

Dosing and Schedule:

- **IV atezolizumab** 1200 mg every 3 weeks until disease progression or unacceptable toxicity
  - To be given over 1 hour*

* Subsequent infusions may be given over 30 minutes if the first infusion is well-tolerated

Website Resources and Contact Information

CONTACT INFORMATION	EMAIL
To subscribe or update contact information, please contact:	
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