

# **Systemic Therapy Update**

October 2019 | Vol. 22 | No. 10

# For Health Professionals Who Care For Cancer Patients

## **Inside This Issue:**

- Editor's Choice <u>New Programs</u>: Ribociclib in Advanced Breast Cancer (UBRAVRIBAI)
- Drug Updates Bevacizumab Biosimilars; <u>Drug Shortages</u>: Hydroxyurea, Resolved [Dexrazoxane]; Medical Patient Assistance Programs
- Benefit Drug List <u>New</u>: UBRAVRIBAI
- Cancer Drug Manual <u>Revised</u>: Filgrastim, Ribociclib
- Systemic Therapy Update Editorial Board Membership Updates
- List of New and Revised Protocols, Provincial Pre-Printed Orders and Patient Handouts – <u>New</u>: UBRAVRIBAI; <u>Revised</u>: UBRAJTTW, BRAVEVEX, UBRAVPALAI, GUBEP, UGUPABI, UGUPENZ, HNAVFUFA, HNNAVFUFA, ULKBLIN, ULKINOZ, LYCHOPRMTX, LYCODOXMR, LYIVACR, ULYVENETO, UMYCARLD, SAIME, SAVACM, SAVDCM
- Website Resources and Contact Information

# **EDITOR'S CHOICE**

## **New Programs**

Effective 01 October 2019, the BC Cancer Provincial Systemic Therapy Program has approved the following treatment program:

## Breast:

## Ribociclib and Aromatase Inhibitor With or Without LHRH Agonist in Advanced Breast Cancer

(UBRAVRIBAI) – The BC Cancer Breast Tumour Group is introducing ribociclib as an alternative agent to palbociclib for patients with advanced, hormone receptor-positive breast cancer. Ribociclib is an oral inhibitor of cyclin-dependent kinases associated with increased cellular proliferation and endocrine resistance in breast cancer. Funding for ribociclib is available for postmenopausal women and men in combination with an aromatase inhibitor (AI); women requiring chemically-induced menopause with an LHRH agonist are eligible. Note that patients are funded to receive treatment with one of ribociclib (UBRAVRIBAI), palbociclib (UBRAVPALAI), or everolimus plus exemestane (UBRAVEVEX), but not the sequential use of these regimens. BC Cancer Compassionate Access Program (CAP) approval is required.

Compared to endocrine therapy alone, addition of ribociclib is associated with significantly longer overall survival (OS) (OS at 42 months, 70.2% vs. 46.0%, p=0.00973).<sup>1</sup> The most common serious toxicities include neutropenia (77.3%), leukopenia (34.9%), and anemia (22.4%).<sup>2</sup> Grade 3 to 4 hepatobiliary toxicity (11%) and QT interval prolongation (1.8%) have been reported. Ribociclib should be used with caution in patients receiving or initiating concurrent therapy with other QT-prolonging medications.

#### References:

- 1. Im S-A, Lu Y-S, Bardia A, et al. Overall survival with ribociclib plus endocrine therapy in breast cancer. N Engl J Med 2019;381:307-316. DOI: 10.1056/NEJMoa1903765.
- Im S-A, Lu Y-S, Bardia A, et al. Overall survival with ribociclib plus endocrine therapy in breast cancer. N Engl J Med 2019;381:307-316. Supplementary Appendix. Available from: https://www.noim.org/doi/guppl/10.1056/NETMoo1902765/suppl\_file/noimoo1902765\_appendix.pdf
  - https://www.nejm.org/doi/suppl/10.1056/NEJMoa1903765/suppl\_file/nejmoa1903765\_appendix.pdf

# DRUG UPDATES

## **BEVACIZUMAB BIOSIMILARS**

Effective 01 November 2019, the BC Cancer Provincial Systemic Therapy Program will implement the use of biosimilar bevacizumab in all BC Cancer bevacizumab-containing protocols. Both biosimilars, Zirabev<sup>®</sup> and Mvasi<sup>®</sup>, are eligible for reimbursement. BC Cancer regional centres will stock Zirabev<sup>®</sup> as the designated biosimilar.

The following outlines key funding details:

- Patients starting on bevacizumab on or after November 1<sup>st</sup> will be funded for biosimilar bevacizumab only. Requests for the use of Avastin<sup>®</sup> on or after 01 November 2019 will require submission through the BC Cancer Compassionate Access Program (CAP).
- Patients who started treatment with the reference biologic, Avastin<sup>®</sup>, prior to November 1<sup>st</sup>, may continue to receive it for the duration of treatment. Clinicians may choose to switch patients currently receiving bevacizumab to the biosimilar, after discussion with the patient.
- Patients who have had a treatment interruption may continue to receive their original brand of bevacizumab if re-starting the same protocol.

More information about biosimilar drugs is available on the BC Cancer website, located in the <u>Biosimilar Drugs</u> section.

#### **DRUG SHORTAGES**

The following are updates of drug supply shortages in BC. Further details about the shortages and their recommended treatment alternatives can be found in the associated briefing notes and/or email communications previously circulated to BC Cancer and the Community Oncology Network (CON).

#### Hydroxyurea:

(Adapted from BC Cancer Briefing Note 12Sept2019)

The current shortage of hydroxyurea capsules is expected to last until November 2019. There are variable supplies remaining at BC Cancer centres and CON sites. The total quantity dispensed should be reduced to ensure that there is sufficient drug for all patients. Hydroxyurea is used in the treatment of various myeloid and lymphoid neoplasms, including polycythemia vera, essential thrombocythemia, myelofibrosis, and acute myeloid leukemia. Alternative treatment recommendations include peginterferon alfa-2a, ruxolitinib, and anagrelide, oral etoposide and 6-mercaptopurine.

## **Resolved:**

Dexrazoxane

# **MEDICAL PATIENT ASSISTANCE PROGRAMS**

The listing of oncology medical patient assistance programs offered by pharmaceutical companies has been updated and can be found at: <u>www.bccancer.bc.ca/mpap</u>.\*

\*Located on the BC Cancer Systemic Therapy website under Health Professionals > Systemic Therapy > Reimbursement & Forms

# **BENEFIT DRUG LIST**

## **New Programs**

Effective 01 October 2019, the following treatment program has been added to the BC Cancer <u>Benefit</u> <u>Drug List</u>:

Protocol Title	Protocol Code	Benefit Status
Therapy of Advanced Breast Cancer using Ribociclib and Aromatase Inhibitor With or Without LHRH Agonist	UBRAVRIBAI	Restricted

# CANCER DRUG MANUAL

## **REVISED MONOGRAPHS AND PATIENT HANDOUTS**

Highlights of key changes and/or updates to the Monographs, Patient Handouts and Chemotherapy Preparation and Stability Chart are listed below:

#### Filgrastim Monograph:

- Cautions deleted outdated information related to biosimilar formulations
- Supply and Storage updated wording related to biosimilar formulations

## **Ribociclib Monograph:**

Dosage Guidelines – added new protocol and bolded/italicized BC Cancer standard dosing

# SYSTEMIC THERAPY UPDATE EDITORIAL BOARD

## **MEMBERSHIP UPDATES**

**Dr. Sally Waignein** (Provincial Pharmacy Education Coordinator) will be stepping down as **Editor** of the **Systemic Therapy Update** due to her increasing responsibilities with the University of British Columbia. Sally joined the Editorial Board in 2011 and has served as the editor since 2012. While she will remain on the Editorial Board, she will transition her editor's responsibilities to **Dr. Anne Dar Santos** (Oncology Drug Information Specialist, Provincial Pharmacy). Anne joined the Editorial Board in May 2019 as Assistant Editor. Her new editorship role will compliment her involvement with the Cancer Drug Manual and its Editorial Board.

# LIST OF NEW AND REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

**BC Cancer Protocol Summaries, Provincial Pre-Printed Orders (PPPOs) and Patient Handouts** are revised periodically. New, revised or deleted protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatment requiring BC Cancer Compassionate Access Program approval are prefixed with the letter **U**.

New Protocols, PPPOs and Patient Handouts (Affected documents are checked)						
CODE	Protocol	РРРО	Patient Handout	Protocol Title		
UBRAVRIBAI	V	V		Therapy of Advanced Breast Cancer using Ribociclib and Aromatase Inhibitor With or Without LHRH Agonist		

Revised Protocols, PPPOs and Patient Handouts (Affected documents are checked)						
CODE	Protocol	РРРО	Patient Handout	Changes	Protocol Title	
UBRAJTTW	V			Treatment clarified	Adjuvant Therapy for Breast Cancer using Weekly Paclitaxel and Trastuzumab (HERCEPTIN)	
BRAVEVEX	V			Eligibility updated	Therapy for Advanced Breast Cancer using Everolimus and Exemestane	
UBRAVPALAI	V			Eligibility updated	Therapy of Advanced Breast Cancer using Palbociclib and Aromatase Inhibitor With or Without LHRH Agonist	
GUBEP	V	V		Etoposide infusion volume, duration and filter clarified	Curative Therapy for Germ Cell Cancer using Bleomycin, Etoposide and Cisplatin	
UGUPABI	V	V		Tests updated	Palliative Therapy for Metastatic Castration- Resistant Prostate Cancer using Abiraterone and Prednisone	
UGUPENZ	V	V		Institutional name and logo updated; Tests revised	Palliative Therapy for Metastatic Castration- Resistant Prostate Cancer using Enzalutamide	
HNAVFUFA	V	Ø		Minimum cycles removed; Eligibility and monitoring revised	Fluorouracil and Leucovorin for Recurrent Head and Neck Cancer (Squamous Cell Carcinoma)	
HNNAVFUFA	V	V		Minimum cycles removed; Eligibility and monitoring revised	Treatment of Recurrent or Metastatic Nasopharyngeal Cancer with Fluorouracil and Leucovorin	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)						
CODE	Protocol	РРРО	Patient Handout	Changes	Protocol Title	
ULKBLIN	Ø			Eligibility updated	Treatment of Philadelphia Chromosome- Negative Refractory or Relapsed Pre-B-Cell Acute Lymphoblastic Leukemia with Blinatumomab	
ULKINOZ				Eligibility, Exclusions, Supportive Medications, Precautions and References updated	Treatment of Relapsed or Refractory Pre-B Cell Acute Lymphoblastic Leukemia with Inotuzumat Ozogamicin	
LYCHOPRMTX	V			Hydration fluid revised	Central Nervous System Prophylaxis with High- Dose Methotrexate, CHOP and Rituximab in Diffuse Large B-Cell Lymphoma	
LYCODOXMR	Ø	Ø		Tests and signature requirement clarified	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX- M) and Rituximab	
LYIVACR	V	V		Tests and signature requirement clarified	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Ifosfamide, Mesna, Etoposide, Cytarabine (IVAC) and Rituximab	
ULYVENETO	Ø	V	V	Tests and treatment start date revised; PPPOs: Return appointments updated; Allopurinol prescription added	Treatment of Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma using Venetoclax	
UMYCARLD	Ø			Treatment duration clarified	Therapy of Multiple Myeloma using Carfilzomib, Lenalidomide with Dexamethasone	
SAIME	V			Dose Modifications clarified	Etoposide, Ifosfamide-Mesna (SAIME) for Use in Sarcomas	
SAVACM	V			Dose Modifications clarified	Treatment of Sarcomas with Pelvic Primaries or Chemotherapy-Induced Hematuria using Vincristine, Doxorubicin, Cyclophosphamide and Mesna	
SAVDCM	V			Dose Modifications clarified	Adjuvant Therapy for Rhabdomyosarcoma using Vincristine, Dactinomycin, Cyclophosphamide and Mesna	

# WEBSITE RESOURCES AND CONTACT INFORMATION

CONTACT INFORMATION	Рнопе	FAX	EMAIL
Systemic Therapy Update Editor	604-877-6000 x 672649		bulletin@bccancer.bc.ca
Provincial Systemic Therapy Program	604-877-6000 x 672247		mlin@bccancer.bc.ca
To update contact information of any CON sites, pleas	se contact:	bulletin@bccancer.bc.ca	
Oncology Drug Information	604-877-6275		druginfo@bccancer.bc.ca
Nurse Educators	604-877-6000 x 672638		nursinged@bccancer.bc.ca
Library/Cancer Information	604-675-8003 Toll Free 888-675-8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	604-877-6000 x 672247		mlin@bccancer.bc.ca
Provincial Professional Practice Nursing			BCCancerPPNAdmin@ehcnet.phsa.ca
OSCAR	888-355-0355	604-708-2051	oscar@bccancer.bc.ca
Compassionate Access Program (CAP)	604-877-6277	604-708-2026	cap bcca@bccancer.bc.ca
Pharmacy Oncology Certification	250-712-3900 x 686820		rxchemocert@bccancer.bc.ca
BC Cancer – Abbotsford	604-851-4710 Toll Free 877-547-3777		
BC Cancer – Kelowna	250-712-3900 Toll Free 888-563-7773		
BC Cancer – Prince George	250-645-7300 Toll Free 855-775-7300		
BC Cancer – Surrey	604-930-2098 Toll Free 800-523-2885		
BC Cancer – Vancouver	604-877-6000 Toll Free 800-663-3333		
BC Cancer – Victoria	250-519-5500 Toll Free 800-670-3322		

# EDITORIAL REVIEW BOARD

Anne Dar Santos, BScPharm, PharmD (Editor) Sally Waignein, BScPharm, PharmD Mario de Lemos, PharmD, MSc(Oncol) Caroline Lohrisch, MD Naren Bollipalli, BSc(Pharm)