BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using Gemcitabine

***Protocol Code**:* *BRAVGEM*
***Tumour Group**:* *Breast*
***Contact Physician**:* *Dr. Susan Ellard*

ELIGIBILITY:

- Progressive symptomatic breast cancer
- Fourth-line treatment of metastatic breast cancer after previous combination chemotherapy in patients who have an ECOG status of less than or equal to 2 and a life expectancy greater than three months; for patients with multiple responses to other standard breast cancer chemotherapy.
- Second line or third line therapy for metastatic breast cancer in patients for whom usual first and second line therapies may be contraindicated due to toxicity concerns, and who has an ECOG status of less than or equal to 2 and a life expectancy greater than three months.
- To continue beyond 8 cycles, a BCCA "Compassionate Access Program" request must be completed and approved.

TESTS:

- Baseline tests: CBC, including differential and platelets, creatinine, bilirubin
- Before each treatment: CBC, including differential and platelets
- If clinically indicated: creatinine, bilirubin
- Appropriate tumour markers and imaging studies should be repeated as necessary

PREMEDICATIONS:

- Antiemetic protocol for non-emetogenic chemotherapy (see SCNAUSEA).

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Gemcitabine	800 mg/m^2 once weekly x 3 weeks then 1 week rest (=4 week cycle)	IV in 250 mL NS over 30 minutes

Cycle	1				2				3				
Week	1	2	3	4	1	2	3	4	1	2	3	4	*etc*
Chemo	x	x	x		x	x	x		x	x	x		

Repeat every 28 days x 6 to 8 cycles. Responding patient may be continued on treatment at the discretion of the treating physician. Discontinue if no response after 2 cycles or unacceptable toxicity

DOSE MODIFICATIONS:

1. **Hematology**: on treatment day

ANC (x 10^9/L)		Platelets (x 10^9/L)	Dose
greater than or equal to 1	and	greater than or equal to 90	100%
less than 1	or	less than 90	Omit dose; recheck labs in one week
If two consecutive doses are omitted then abandon cycle. After toxicity has resolved begin new cycle at 75% of previous dose.			

2. **Non–Hematologic Toxicities**: may include
   - Mucositis
   - Transient truncal rash
   - Fatigue
   - Nausea
   - If doses must be omitted for Grade 2 toxicity twice in previous cycles, then commence next cycle at 75% dose when treatment is resumed.
   - For Grade 3 toxicity, delay treatment until resolution of symptoms, then resume at 75% dose.
   - For Grade 4 toxicity, discontinue treatment.
   - Doses reduced for toxicity should not be re-escalated.

Grade	Stomatitis	Diarrhea	Dose
1	Painless ulcers, erythema or mild soreness	Increase of 2 to 3 stools/day or mild increase in loose watery colostomy output	100%
2	Painful erythema, edema, or ulcers but can eat	Increase of 4 to 6 stools, or nocturnal stools or moderate increase in loose watery colostomy output	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	Increase of 7 to 9 stools/day or incontinence, malabsorption; or severe increase in loose watery colostomy output	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	Increase of 10 or more stools/day or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output requiring parenteral l support; dehydration	Omit until toxicity resolved then resume at 50%.

PRECAUTIONS:

1. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Renal Dysfunction**: Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare). Use caution with pre-existing renal dysfunction.
3. **Pulmonary Toxicity**: Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.
4. **Possible interaction with warfarin has** been reported and may occur at any time. Close monitoring is recommended (monitor INR weekly during gemcitabine therapy and for 1 to 2 months after discontinuing gemcitabine treatment).

Call Dr. Susan Ellard or tumour group delegate at (250) 712-3900 or 1-888-563-7773 with any problems or questions regarding this treatment program.

Date Activated: 01 July 2008

Date Revised: 1 Jul 2017 (Minot typo corrected)