BC Cancer Protocol Summary for Palliative Chemotherapy for Pancreatic Adenocarcinoma, Gallbladder Cancer, and Cholangiocarcinoma Using Gemcitabine

Protocol Code	*GIPGEM*
Tumour Group	*Gastrointestinal*
Contact Physician	*GI Systemic Therapy*

ELIGIBILITY:

- Metastatic or unresectable pancreatic adenocarcinoma, gallbladder cancer or cholangiocarcinoma
- ECOG 0 to 2

TESTS:

- Baseline: CBC & Diff, creatinine, ALT, alkaline phosphatase, total bilirubin, albumin, sodium, potassium, random glucose, HbA1c
- Baseline if clinically indicated: ECG, CEA, CA19-9, GGT
- Prior to Day 1: CBC & Diff, creatinine, total bilirubin, ALT
- Prior to Days 8 and 15: CBC & Diff
- If clinically indicated: CEA, CA19-9, alkaline phosphatase, albumin, GGT, sodium, potassium, random glucose, HbA1c, ECG
- For patients on warfarin, weekly INR during treatment until stable warfarin dose established, then INR prior to each cycle

PREMEDICATIONS:

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

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	1000 mg/m^2 on Days 1, 8, and 15	IV in 250 mL NS over 30 minutes

Repeat every 28 days. Continue treatment as long as there is evidence of a clinical response, usually a partial response or stable disease associated with symptom improvement (decreased pain, weight gain, improved performance status) or until there is unacceptable toxicity

DOSE MODIFICATIONS:

1. Hematology – On Treatment Day

ANC (x 10^9/L)		Platelets (x 10^9/L)	Dose
Greater than 1.0	and	Greater than 100	100%
0.5 to 1.0	or	50 to 100	75% or delay, based on clinical assessment
Less than 0.5	or	Less than 50	Delay

2. Non – Hematologic Toxicities

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 mild 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 support; dehydration	Omit until toxicity resolved then resume at 50%.

- Doses reduced for toxicity should not be re-escalated.
- If doses must be omitted for Grade 2 toxicity twice in previous cycles, then commence next cycle at 75% dose when treatment is resumed.

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. **Drug Interaction**: Possible interaction between gemcitabine and 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 month after discontinuing gemcitabine treatment).

Call the GI Systemic Therapy physician at your regional cancer centre or the GI Systemic Therapy Chair Dr. Janine Davies at (604) 877-6000 or 1-800-670-3322 with any problems or questions regarding this treatment program.

References:

1. Burris HA 3rd, Moore MJ, Andersen J et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. J Clin Oncol. 1997 Jun;15(6):2403-13.
2. Dingle BH, Rumble RB, Brouwers MC et al. The role of gemcitabine in the treatment of cholangiocarcinoma and gallbladder cancer: a systematic review. Can J Gastroenterol. 2005 Dec;19(12):711-6