BCCA Protocol Summary for Adjuvant Chemotherapy for Pancreatic Adenocarcinoma Using Gemcitabine

**Protocol Code**  
GIPAJGEM

**Tumour Group**  
Gastrointestinal

**Contact Physician**  
GI Systemic Therapy

**ELIGIBILITY:**
- Pancreatic adenocarcinoma
- Node-positive margin-negative ampullary cancer (cancers of the gall bladder, and biliary system excluded)
- Macroscopic complete resection
- Adequate marrow reserve (ANC greater than or equal to 1.5 x 10⁹/L, platelets greater than 100 x 10⁹/L)
- Adequate renal (Creatinine less than or equal to 1.5 x ULN) and liver function (bilirubin less than or equal to 26 micromol/L; AST/Alkaline Phosphatase less than or equal to 5 x ULN)
- ECOG 0 to 2

**TESTS:**
- Baseline: CBC, diff and platelets; creatinine, bilirubin, appropriate tumour markers and imaging study
- Prior to each treatment: CBC, diff and platelets
- If clinically indicated: bilirubin, creatinine

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

**TREATMENT:**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Drug</th>
<th>Dose</th>
<th>BCCA Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 6</td>
<td>gemcitabine</td>
<td>1000 mg/m² /week x 3 weeks then 1 week rest (4 weeks = 1 cycle)</td>
<td>IV in 250 mL NS over 30 minutes</td>
</tr>
</tbody>
</table>

**DOSE MODIFICATIONS:**

1. Hematology – On Treatment Day

<table>
<thead>
<tr>
<th>ANC (x 10⁹/L)</th>
<th>Platelets (x 10⁹/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater than 1</td>
<td>and</td>
<td>greater than 100</td>
</tr>
<tr>
<td>0.5 to 1</td>
<td>or</td>
<td>50 to 100</td>
</tr>
<tr>
<td>less than 0.5</td>
<td>or</td>
<td>less than 50</td>
</tr>
</tbody>
</table>

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

- 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.

Date Activated: 01 Oct 2008

Date Revised: 1 June 2017 (Precautions Updated)

References: