BC Cancer Protocol Summary for Therapy of Kaposi Sarcoma using DOXOrubicin Pegylated Liposomal

**Protocol Code**  
KSLDO

**Tumour Group**  
Sarcoma

**Contact Physician**  
Dr. Barbara Melosky

**ELIGIBILITY:**
- Extensive cutaneous or systemic visceral Kaposi Sarcoma, including persistent or relapsing disease
- Adequate hematologic, liver and cardiac function
- Performance status ECOG 3 or better

**TESTS:**
- Baseline: CBC and diff, platelets, bilirubin, ALT, Alk Phos, LDH, GGT
- Before each treatment: CBC and diff, platelets
- If clinically indicated: Bilirubin, GGT, Alk Phos, LDH, ALT, protein level, albumin, urea, creatinine, cardiac function (ECG, echocardiogram or MUGA scan)

**PREMEDICATIONS:**
- Antiemetic protocol for NON-EMETOGENIC chemotherapy (see protocol SCNAUSEA).
- Regular antiemetics not usually required.

**TREATMENT:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BC Cancer Administration Guideline</th>
</tr>
</thead>
</table>
| DOXOrubicin pegylated liposomal           | 20 mg/m²    | **Initial dose:** at rate of 1mg/min  \[Initial dose:** at rate of \]
|                                           | IV in 250 mL D5W | **Subsequent doses, if no prior infusion reaction:** infuse over 1 hour                |

Repeat every 14 days until best response (usually 6 cycles).
DOSE MODIFICATIONS:

1. **Hematological**

<table>
<thead>
<tr>
<th>ANC (x10^9/L)</th>
<th>Platelets (x10^9/L)</th>
<th>Dose (all drugs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater than equal to 1.0 and greater than or equal to 75</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>0.5 to less than 1.0 or 50 to less than 75</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>less than 0.5 or less than 50</td>
<td>Delay</td>
<td></td>
</tr>
</tbody>
</table>

2. **Hepatic dysfunction:**

<table>
<thead>
<tr>
<th>Total Bilirubin micromol/L</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 21</td>
<td>100%</td>
</tr>
<tr>
<td>21 to 50</td>
<td>50%</td>
</tr>
<tr>
<td>greater than 50</td>
<td>25%</td>
</tr>
</tbody>
</table>

3. **Stomatitis**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Symptoms</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Painless ulcers, erythema, or mild soreness</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>Painful erythema, edema or ulcers, but can eat</td>
<td>Delay then 100%</td>
</tr>
<tr>
<td>3</td>
<td>Painful erythema, edema or ulcers and cannot eat</td>
<td>Delay then 75%</td>
</tr>
<tr>
<td>4</td>
<td>Requires parenteral or enteral support</td>
<td>Delay then 50%</td>
</tr>
</tbody>
</table>
### 4. Hand-and-Foot Syndrome

<table>
<thead>
<tr>
<th>Toxicity Grade</th>
<th>Symptoms</th>
<th>Weeks Since Last Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 (cycle plus 1 week)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 (cycle plus 2 weeks)</td>
</tr>
<tr>
<td>0</td>
<td>No symptoms</td>
<td>Redose at 3-week interval</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Redose at 3-week interval</td>
</tr>
<tr>
<td>1</td>
<td>Mild erythema, swelling or desquamation not interfering with daily activities</td>
<td>Redose unless patient has experienced a previous Grade 3 or 4 skin toxicity in which case wait an additional week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Redose at 25% dose reduction; continue at 3-week interval</td>
</tr>
<tr>
<td>2</td>
<td>Erythema, desquamation, or swelling interfering with, but not precluding normal physical activities; small blisters or ulcerations less than 2 cm in diameter</td>
<td>Wait an additional week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Redose at 50% dose reduction; continue at 3-week interval</td>
</tr>
<tr>
<td>3</td>
<td>Blistering, ulceration or swelling interfering with walking or normal daily activities; cannot wear regular clothing</td>
<td>Wait an additional week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinue treatment</td>
</tr>
<tr>
<td>4</td>
<td>Diffuse or local process causing infectious complications, or a bedridden state or hospitalization</td>
<td>Wait an additional week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinue treatment</td>
</tr>
</tbody>
</table>
PRECAUTIONS:

1. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively.

2. **Cardiac Toxicity**: DOXOrubicin is cardiotoxic and must be used with caution, if at all, in patients with severe hypertension or cardiac dysfunction. Cardiac assessment recommended if lifelong dose of 450 mg/m² to be exceeded. Refer to BC Cancer Drug Manual.

3. **Extravasation**: DOXOrubicin pegylated liposomal is considered an irritant. Refer to BC Cancer Extravasion Guidelines.

Call Dr. Barbara Melosky or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References