BC Cancer Protocol Summary for DOXOrubicin for Use in Patients with Advanced Soft Tissue Sarcoma

Protocol Code: SAAVA
Tumour Group: Sarcoma
Contact Physician: Dr. Christine Simmons

ELIGIBILITY:
- Patients with an advanced soft tissue sarcoma
- Good performance status
- Adequate bone marrow, renal and hepatic function (bilirubin less than 2 x ULN)

EXCLUSION:
- Rhabdomyosarcoma in young adults

TESTS:
- Baseline and before each treatment: CBC & diff, platelets, creatinine, bilirubin, ALT, alk phos, GGT, LDH and clinical measure of tumour response
- Every second treatment: chest x-ray or other imaging to monitor response

PREMEDICATIONS:
- Antiemetic protocol for High/Moderate emetogenic chemotherapy (see protocol SCNAUSEA)

TREATMENT:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BC Cancer Administration Guidelines</th>
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</thead>
<tbody>
<tr>
<td>DOXOrubicin</td>
<td>75 mg/m²</td>
<td>IV push</td>
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- For patients greater than 65 years old, consider reducing dose to 60 mg/m²
- Repeat every 21 days x 6 cycles
DOSE MODIFICATIONS:

1. **Hematological:**

<table>
<thead>
<tr>
<th>ANC (x 10^9/L)</th>
<th>Platelets (x 10^9/L)</th>
<th>Dose</th>
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<tbody>
<tr>
<td>greater than equal to 1.5 and greater than equal to 100</td>
<td>100 %</td>
<td></td>
</tr>
<tr>
<td>1.0 to less than 1.5 or 70 to less than 100</td>
<td>80 %</td>
<td></td>
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<tr>
<td>less than 1.0 or less than 70</td>
<td>Delay one week</td>
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</tbody>
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2. **Mucositis:** Grade 3 or 4, reduce dose to 80%

3. **Nausea & Vomiting:** Grade 4 despite optimal use of antiemetics, reduce dose to 80% or QUIT

4. **Neutropenic Fever** (with ANC less than 0.5 x 10^9/L): Once counts have recovered, reduce dose to 80%

5. **Hepatic Dysfunction:** For bilirubin 1.5 to 2 times ULN, reduce dose to 50%

PRECAUTIONS:

1. **Cardiac Toxicity:** DOXOrubicin is cardiotoxic and must be used with caution in patients with severe hypertension or cardiac dysfunction. Cardiac assessment is recommended if lifelong dose of 450 mg/m² is exceeded (see BC Cancer Drug Manual).

2. **Extravasation:** DOXOrubicin causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.

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

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