**BC Cancer** Protocol Summary for DOXOrubicin for Adjuvant Use for Patients with Non-Metastatic Operable Large High Grade Soft Tissue Sarcoma

<table>
<thead>
<tr>
<th>Protocol Code:</th>
<th>SAAJA</th>
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<tbody>
<tr>
<td><strong>Tumour Group:</strong></td>
<td>Sarcoma</td>
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<tr>
<td><strong>Contact Physician:</strong></td>
<td>Dr Christine Simmons</td>
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**ELIGIBILITY/TESTS:**
- Adult (greater than or equal to 17 years of age) patients with:
  - localized, operable non-metastatic soft tissue sarcoma of the extremity but not rhabdomyosarcoma, Ewing’s Family of Tumours (EWFT) in adults.
  - or
  - high grade aggressive histologies with known poor prognosis
  - In certain instances for young patients with aggressive primitive histologies, locally advanced disease or large high grade synovial sarcomas, SAAI may be used - as before
- Patients must have normal cardiac function.
- Radiation therapy will generally follow chemotherapy – but can be given concurrently for selected patients.

**TESTS**
- Baseline: full clinical evaluation including recent (within 3 months) CT chest, CBC and diff, platelets, alk phos, ALT, albumin, and bilirubin.
- Before each treatment: CBC and diff, platelets
- If clinically indicated: bilirubin, ECG and measure of LVEF

**TREATMENT:**

<table>
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<tr>
<th>Drug</th>
<th>Dose</th>
<th><strong>BC Cancer Administration Guideline</strong></th>
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<tbody>
<tr>
<td>DOXOrubicin (ADRIAMYCIN®)</td>
<td>75 mg/m²</td>
<td>IV push</td>
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Repeat every 3 weeks x 5 cycles only (total dose 375 mg/m²).
DOSE MODIFICATIONS:

1. **Hematologic Toxicity**: Treatment day counts

<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 or equal to 1.5</td>
<td>greater than or equal to 100</td>
<td>100%</td>
</tr>
<tr>
<td>1.0 to less than 1.5</td>
<td>70 to less than 100</td>
<td>80%</td>
</tr>
<tr>
<td>less than 1.0</td>
<td>less than 70</td>
<td>delay one week</td>
</tr>
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</table>

* Absolute neutrophil count

2. **Mucositis**: Grade 3 or 4 give 80%
3. **Nausea & Vomiting**: Grade 4 - not helped by antiemetics give 80% of dose or QUIT.
4. **Neutropenic Fever**: with ANC less than 0.5 (x 10^9/L), give 80% of dose.
5. **Bilirubin**: 1.5 - 2 times normal, reconsider advisability of adjuvant chemotherapy.

PRECAUTIONS:

1. **Cardiomyopathy** is a well known toxicity of DOXOrubicin with cumulative dose of the drug over 400 mg/m². Occasionally this may occur with less drug – patients should be screened for any symptoms or signs of arrhythmia or congestive heart failure during therapy and on follow-up.

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.

Reference: