

## BCCA Protocol Summary for Doxorubicin for Adjuvant Use for Patients with Non-Metastatic Operable Large High Grade Soft Tissue Sarcoma

<b>Protocol Code:</b>	SAAJA
<b>Tumour Group:</b>	Sarcoma
<b>Contact Physician:</b>	Dr Meg Knowling

### 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, LFT's and bilirubin.
- Before each treatment: CBC and diff, platelets
- If clinically indicated: bilirubin, ECG and measure of LVEF

### TREATMENT:

Drug	Dose	BCCA Administration Guideline
Doxorubicin (ADRIAMYCIN®)	75 mg/m <sup>2</sup>	IV push

Repeat every 3 weeks x 5 cycles only (total dose 375 mg/m<sup>2</sup>).

### DOSE MODIFICATIONS:

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

ANC* (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
greater than 1.5	and	greater than 100	100%
1.0-1.5	or	70-100	80%
less than 1.0	or	less than 70	delay one week

\* 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<sup>9</sup>/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/m<sup>2</sup>. 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. Meg Knowling or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

Date Activated 1 Nov 2002

Date revised 1 May 2009 (unsafe abbreviations and symbols replaced)

#### Reference:

1. Anonymous (2000). Adjuvant chemotherapy for localised resectable soft tissue sarcoma in adults. Sarcoma Meta-analysis Collaboration (SMAC). Cochrane Database of Systematic Reviews [computer file](2): CD001419.
2. Bramwell V H. Adjuvant chemotherapy for adult soft tissue sarcoma: Is there a standard of care? [letter; comment]. J Clin Oncol 2001;19(5):1235-7.
3. Figueredo A, Bramwell VH, Bell R, Davis AM, Charette ML, et al. Adjuvant chemotherapy following complete resection of soft tissue sarcoma in adults: a clinical practice guideline. Sarcoma 2002;6(1): 5-18.