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:

Drug	**Dose**	**BC Cancer Administration Guideline**	
DOXOrubicin pegylated liposomal	20 mg/m^2	IV in 250 mL D5W	*Initial dose*: at rate of 1mg/min *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**

ANC (x10^9/L)		Platelets (x10^9/L)	Dose (all drugs)
greater than equal to 1.0	and	greater than or equal to 75	100%
0.5 to less than 1.0	or	50 to less than 75	50%
less than 0.5	or	less than 50	Delay

2. **Hepatic dysfunction**:

Total Bilirubin micromol/L	Dose
less than 21	100%
21 to 50	50%
greater than 50	25%

3. **Stomatitis**

STOMATITIS		
Grade	**Symptoms**	**Modification**
1	Painless ulcers, erythema, or mild soreness	None
2	Painful erythema, edema or ulcers, but can eat	Delay then 100%
3	Painful erythema, edema or ulcers and cannot eat	Delay then 75%
4	Requires parenteral or enteral support	Delay then 50%

4. Hand-and-Foot Syndrome

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

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/m^2 to be exceeded. Refer to BC Cancer Drug Manual.
3. **Extravasation**: DOXOrubicin pegylated liposomal is considered an irritant. Refer to BC Cancer Extravasation 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

1. Northfelt DW, Dezube BJ, Thommes JA, Levine R et al. Efficacy of pegylated-liposomal doxorubicin in the treatment of AIDS-related Kaposi's Sarcoma after failure of standard chemotherapy. J Clin Oncol 1997;15:653-9.