

# BC Cancer Protocol Summary for Treatment of Advanced Soft Tissue Sarcoma Using Gemcitabine

<b>Protocol Code</b>	SAAVGEM
<b>Tumour Group</b>	Sarcoma
<b>Contact Physician</b>	SA Systemic Therapy

## ELIGIBILITY:

Patient must:

- Have advanced soft tissue sarcoma not amenable to curative resection, and
- Be unfit for doublet therapy with SAAVGEMD or have started SAAVGEMD but is unfit to continue

Patient should have:

- Good performance status
- Adequate hematologic, liver and cardiac function

## TESTS:

- Baseline: CBC, & Diff
- Baseline, if clinically indicated: creatinine, ALT, total bilirubin
- Before each treatment: CBC & Diff
- If clinically indicated: creatinine, ALT, total bilirubin

## PREMEDICATIONS:

- Antiemetic protocol for low emetogenic potential chemotherapy (see SCNAUSEA)

## TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	900 mg/m <sup>2</sup> * on Days 1 and 8	IV in 250 mL NS over 30 minutes

\*Consider starting at 750 mg/m<sup>2</sup> for previously treated patients and escalate dose based on patient tolerance

Repeat every 21 days until disease progression.

## DOSE MODIFICATIONS:

### 1. Hematology:

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
Greater than or equal to 1.0	and	Greater than or equal to 100	100%
Less than 1.0	or	Less than 100	Delay until recovery, then proceed at 75%
Febrile neutropenia with previous cycle OR Greater than a 2 week delay due to hematological toxicity			75%

2. **Febrile Neutropenia:** If febrile neutropenia reoccurs despite dose reduction to 75%, discontinue treatment.

3. **Non–Hematologic Toxicities** may include:

- Mucositis
- Transient truncal rash
- Fatigue
- For Grade 3 toxicity, delay treatment until resolution of symptoms, then resume at 75%. If Grade 3 toxicity persists, discontinue gemcitabine.
- For Grade 4 toxicity, discontinue treatment.
- Doses reduced for toxicity should not be re-escalated.

## PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Renal Dysfunction:** Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare). Use caution with pre-existing renal dysfunction.
3. **Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.
4. **Drug Interaction – warfarin:** gemcitabine may cause increased anticoagulant effect of warfarin. Monitor INR closely during and for 1 to 2 months after gemcitabine therapy; adjust warfarin dose as necessary.

**Contact the Sarcoma Systemic Therapy physician at your regional cancer centre or Sarcoma Systemic Therapy Chair with any problems or questions regarding this treatment program.**

**REFERENCES:**

1. Maki, RG, Wathen JK, Shreyaskumar RP et al. Randomized Phase II Study of Gemcitabine and Docetaxel Compared With Gemcitabine Alone in Patients With Metastatic Soft Tissue Sarcomas: Results of Sarcoma Alliance for Research Through Collaboration Study 002. *J Clin Oncol* Jul 2007; 25(19): 2756-2763.
2. Merimsky O, Meller I, Flusser G et al. Gemcitabine in Soft Tissue or Bone Sarcoma Resistant to Standard Chemotherapy: a Phase II Study. *Cancer Chemother Pharmacol* 2000; 45: 177-181.