

BCCA Protocol Summary for Treatment of Loco-regionally Recurrent/Metastatic Nasopharyngeal Cancer not Amenable for Local Curative Therapy with Gemcitabine

Protocol Code:

HNNAVGEM

Tumour Group:

Head and Neck

Contact Physician:

Dr. Cheryl Ho

ELIGIBILITY:

- Loco-regionally recurrent/metastatic nasopharyngeal cancer not amenable for local curative therapy
- A “Class II Drug Registration Form” for gemcitabine must be completed at the time of initiation of treatment (or use the PPO for HNAVGEM if treated at a regional cancer centre). For other indications, an “Individual Use of Benefit Drug List Medication for an Undesignated Indication” form must be approved.

EXCLUSIONS:

- ECOG status greater than or equal to 3

TESTS:

- Baseline: CBC & differential, platelets, liver function tests, bilirubin
- Before each treatment: CBC & differential, platelets
- If clinically indicated: liver function tests, bilirubin

PREMEDICATIONS:

- Antiemetic protocol for non-emetogenic chemotherapy (see SCNAUSEA).

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Gemcitabine	1,250 mg/m ² /day on days 1 and 8 (total dose per cycle = 2,500 mg/m ²)	IV in 250 mL NS over 30 min

- Repeat every 21 days x 4-6 cycles ([may continue treatment or re-treat beyond 6 cycles if good response](#))

DOSE MODIFICATIONS:

1. Hematology – On Treatment Day

For gemcitabine day 1 of each cycle

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1	and	greater than 100	100%
0.5-0.99	or	75-100	75%
less than 0.5	or	less than 75	Delay

For gemcitabine day 8 of each cycle

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose**
greater than or equal to 1	and	greater than 100	100%
0.5-0.99	or	75-100	75%
less than 0.5	or	less than 75	Omit

****Dose adjustment only for the day of treatment the CBC is drawn**

2. Non – Hematologic Toxicities

Grade	Stomatitis		Diarrhea	Dose
1	Painless ulcers, erythema or mild soreness	and/or	Increase of 2-3 stools/day or mild increase in loose watery colostomy output	100%
2	Painful erythema, edema, or ulcers but can eat	and/or	Increase of 4-6 stools, or nocturnal stools or mild increase in loose watery colostomy output	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	and/or	Increase of 7-9 stools/day or incontinence, malabsorption; or severe increase in loose watery colostomy output	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	and/or	Increase of 10 or more stools/day or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output requiring parenteral I support; dehydration	Omit until toxicity resolved then resume at 50%.

Doses reduced for toxicity should not be re-escalated.

- If doses must be omitted for Grade 2 toxicity twice in previous cycles, then commence next cycle at 75% dose when treatment is resumed.

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.

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

Date Activated: 1 April 2006

Date Revised: 1 Sep 2010 (clarification of treatment duration)

References:

1. Foo, KF, Tan EH, Leong SS, et al. Gemcitabine in metastatic nasopharyngeal carcinoma of the undifferentiated type. Ann Oncol 2002;13:150-156.