BC Cancer Protocol Summary for Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Vinorelbine

Protocol CodeGOOVVINTumour GroupGynecologic OncologyContact PhysicianDr. Paul Hoskins

PREFACE:

- In <u>platinum sensitive</u> disease: patients should be considered for doublet therapy consisting of CARBOplatin plus either a taxane or gemcitabine or DOXOrubicin pegylated liposomal (e.g., GOOVCATR, GOOVCADR, GOOVCAG, GOOVPLDC)
- In <u>platinum resistant</u> disease (i.e., cancer progresses within six months of completing a platinum-containing treatment protocol): patients will ideally receive single agent CARBOplatin, as it is the least toxic and most convenient choice of the equally efficacious agents available (i.e., GOOVCARB)
- In <u>platinum refractory</u> disease (i.e., cancer progresses while being treated with a platinum) choose between available agents based upon toxicity profile and convenience of dosing regimen. Options include: GOOVTOP, GOOLDOX, GOOVGEM, GOOVETO, GOOVVIN, GOOVTAX3, GOOVDOC. If gemcitabine (GOOVGEM), topotecan (GOOVTOP) or DOXOrubicin pegylated liposomal (GOOVLDOX) is used, only one of these options will be reimbursed in any one patient. Subsequently, if a patient is thought likely to benefit from one of the other two, a request should be submitted to the BC Cancer Compassionate Access Program (CAP).
- Patients who will not benefit from further therapy after second or subsequent rounds of chemotherapy can be identified by the following formula: "day 1 of treatment N to day of progression on treatment N+1 is less than or equal to 6 months." They should be offered symptomatic management or investigational protocols.

ELIGIBILITY:

- Platinum refractory ovarian, primary peritoneal or Fallopian tube carcinoma
- Platinum resistant ovarian, primary peritoneal or Fallopian tube carcinoma in cases where patientspecific concerns dissuade the clinician from selecting single-agent CARBOplatin
- Platinum sensitive ovarian, primary peritoneal or Fallopian tube carcinoma in cases where actual or
 potential toxicity precludes the use of CARBOplatin or CISplatin alone or in combination with a taxane
 or gemcitabine.
- Adequate hematologic, liver and cardiac function
- PS ECOG 3 or better

EXCLUSIONS:

Hepatic dysfunction (see DOSE MODIFICATIONS, below)

TESTS:

- Mandatory baseline tests: CBC, including differential and platelets; bilirubin
- Suggested baseline tests: relevant tumour markers
- Before each cycle (Day 1): CBC, including differential and platelets, bilirubin (at physician's discretion)
- No labwork required prior to treatment on Day 8
- Tumour markers should be repeated each cycle
- Imaging (at physician's discretion)

PREMEDICATIONS:

Antiemetic protocol for chemotherapy with rare to low emetogenicity (see SCNAUSEA)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
vinorelbine	25 mg/m ² on Day 1 and Day 8	IV in 50 mL NS over 6 min, then flush line with 75 to 125 mL NS prior to removing/capping IV access

Repeat every 21 days until disease progression (usual treatment 9 cycles).

DOSE MODIFICATIONS:

1. **Hematological**: prior to new cycle (Day 1)

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /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 give 100% and change interval to 28 days

2. Hepatic:

Total bilirubin (micromol/L)	Vinorelbine dose
less than 35	100%
36 to 50	50%
greater than 50	25%

- 3. Non-Hematologic Toxicities: may include
- Constipation
- Venous irritation: if severe, consider central venous access device (PICC or PORTACATH®)
- Hair thinning: total hair loss uncommon. Alopecia is a cumulative toxicity.
- Neuropathy: Mild to moderate peripheral neuropathy, usually reversible on discontinuation of therapy.

PRECAUTIONS:

- 1. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively.
- Extravasation: Vinorelbine causes pain and tissue necrosis if extravasated. It is recommended to flush thoroughly with 75 to 125 mL NS after infusing vinorelbine. Refer to BC Cancer Extravasation Guidelines.

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