BCCA Protocol Summary for Androgen-Independent Prostate Cancer using Estramustine Phosphate (Interim Version)

Protocol Code
GUEMCYT

Protocol Group
Genitourinary

Contact Physician
Dr. Kim Chi

GU Systemic Therapy Contacts
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ELIGIBILITY/TESTS:
- This drug is not approved for use in combination with chemotherapy.
- Biopsy proven prostate cancer
- Metastatic disease or local progression after radiation
- Progressive evaluable disease despite castrate testosterone from orchiectomy or a medical equivalent
- Progression is defined as a 50% increase in an evaluable parameter such as a clinical or radiological mass, or PSA
- Commitment to remeasure the evaluable parameter at 1-2 month intervals and discontinue EMCYT® if there is a 50% rise from baseline or from best remission level achieved
- Documentation of the evaluable parameter to be available on request of the BCCA Tumour Group Chair or alternate
- Asymptomatic patients should consider delayed therapy

TREATMENT:
Estramustine phosphate 14 mg per kg bodyweight per day PO; i.e., one 140 mg capsule per 10 kg/day in 3-4 divided doses
Do not take with food, milk products or calcium antacids

DOSE MODIFICATIONS:
- If WBC less than 3.5 x 10^9/L or platelets less than 100 x 10^9/L, discontinue until recovery.

PRECAUTIONS:
- Monthly CBC, LFT, clinical & lab re-evaluation

CONTRAINDICATIONS:
- History of thromboembolic disease or heart failure
- WBC less than 3.5 x 10^9/L or platelets less than 100 x 10^9/L

SIDE-EFFECTS:
See BCCA Cancer Drug Manual
BENEFITS:
In a double-blind Phase 3 study of estramustine phosphate 280 mg bid, there was no significant difference from placebo in subjective response rate (9 of 50 vs 4 of 57, p=0.15), nor in time to progression or death. A higher proportion on estramustine had a PSA response (greater than 25% decrease in 29 of 61 vs 3 of 68). Interpretation is limited by small numbers. It remains unclear if estramustine has clinical benefit, and if so whether this is superior to other options such as high dose estrogen.

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

Date activated: 17 Jul 1993
Date revised: 01 May 2009 (unsafe abbreviations and symbols replaced)

REFERENCES