# BC Cancer Protocol Summary for Treatment of Prostate Cancer with High Dose Bicalutamide

| | |
|---|---|
| ***Protocol Code:*** | *GUPHDBIC* |
| ***Tumour Group:*** | *Genitourinary* |
| ***Contact Physicians:*** | *Dr. Christian Kollmannsberger*<br>*Dr. Scott Tyldesley* |

## ELIGIBILITY:

- Patients with localized **high-risk** prostate cancer treated with curative intent radiotherapy, and with **intolerance of, or contraindications to LHRH agonists or antagonists**
  **OR**
- Patients with localized **high-risk** prostate cancer with biochemical relapse post prostatectomy treated with curative intent salvage radiotherapy, and with **intolerance of, or contraindications to LHRH agonists or antagonists**
  **OR**
- Patients with localized **high-risk** prostate cancer and **intolerance of, or contraindications** to **palliative intent LHRH agonists or antagonists**, where treatment with high dose (150 mg) bicalutamide is alternative to active surveillance or watchful waiting.

## EXCLUSIONS:

- Patients with localized **low-risk** prostate cancer who would otherwise undergo active surveillance or watchful waiting, as treatment with high dose (150 mg) bicalutamide in this setting is associated with **increased mortality.**
- Baseline bilirubin > 1.5 x ULN (unless Gilbert syndrome documented)
- Baseline ALT > 2.5 ULN

## OTHER CONSIDERATIONS:

- Cardiovascular history and risk factors should be considered prior to initiation of therapy as per treatment with LHRH agonists. Cardiology referral should be considered prior to initiation of therapy in patients with history of stroke, myocardial infarction, angina or peripheral vascular disease.

## TESTS:

- Baseline: CBC and differential, platelets, creatinine, bilirubin, Alk Phos, ALT, testosterone, PSA, sodium, potassium.
- Before each physician visit (4 weeks= 1 cycle): PSA
- Prior to cycles 2 and 3: Alk Phos, ALT, bilirubin
- Cycle 4 onwards: Alk Phos, ALT, bilirubin, testosterone every 3 months
- If clinically indicated: ECG, potassium, sodium, HbA1c, cholesterol.

## TREATMENT:

| Drug | Dose | BC Cancer Administration Guideline |
|---|---|---|
| bicalutamide | 150 mg daily | PO |

One cycle consists of 4 weeks (30 days).

### Duration of therapy:

Adjuvant therapy in setting of curative intent radiotherapy for high risk localized prostate cancer: duration ≤ 36 months.

Adjuvant therapy in setting of salvage radiotherapy post-prostatectomy: duration ≤ 24 months.

Duration in the setting of palliative systemic therapy for high risk localized prostate cancer: until definitive disease or PSA progression or unacceptable toxicity, or patient request of discontinuation.

In all settings: Discontinue if definitive disease or PSA progression or unacceptable toxicity

## DOSE MODIFICATIONS:

**Dose level -1:** bicalutamide 100 mg PO daily

## PRECAUTIONS:

- **Cardiovascular risk:** Assessment of cardiovascular risk factors, monitoring of signs and symptoms of development of cardiovascular disease and management according to clinical practice guidelines should be considered.
- **Gynecomastia and breast tenderness:** Gynecomastia (38%) and breast tenderness (39%) are common with bicalutamide 150 mg monotherapy. It is related to unopposed action of circulating estrogen during monotherapy.
- **Hepatic impairment:** Bicalutamide is extensively metabolized in the liver and should be used with caution in patients with moderate to severe hepatic impairment.

**Call Dr. Christian Kollmannsberger or Dr Scott Tyldesley or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

## References:


1. McLeod DG, Iversen P, See WA, et al, Bicalutamide 150 mg plus standard of care vs standard of care alone for early prostate cancer. BJU International 2005: 97: 247-254
2. Shipley WU, Seiferheld HR, Lukka PP, et al, Radiation with or without antiandrogen therapy in recurrent prostate cancer. NEJM 2017: 376(5): 417-428
3. AstraZeneca Canada Inc. Casodex® product monograph. Mississauga, Ontario. 13 July 2017