BC Cancer Protocol Summary for Treatment of Cutaneous T-cell Lymphoma (Mycosis Fungoides/Sézary Syndrome) with Alitretinoin

Protocol Code	*LYALIT*
Tumour Group	*Lymphoma*
Contact Physician	*Dr. Vincent Ho*

ELIGIBILITY:

Cutaneous T-cell lymphoma including mycosis fungoides and Sézary syndrome:
- Not responsive to topical steroids or mechlorethamine, or
- Not responsive to phototherapy, or patients cannot access phototherapy.

EXCLUSIONS:

- Pregnancy or breast feeding
- High risk factors for pancreatitis (prior pancreatitis, uncontrolled hyperlipidemia, excessive alcohol consumption, uncontrolled diabetes mellitus, biliary tract disease etc), hepatic insufficiency, vitamin A intake greater than or equal to 15,000 unit/day

TESTS

- Baseline: cholesterol, triglyceride, TSH, ALT
- Baseline (required, but results do not have to be available to proceed with first treatment; results must be checked before proceeding with cycle 2): HBsAg, HBsAb, HBcoreAb
- If clinically indicated: cholesterol, triglyceride, TSH, ALT, lipase
- If clinically indicated: HBV viral load (see protocol SCHBV)
- For females of childbearing potential:
    - Baseline: two pregnancy tests (HCG quantitative blood) done minimum 3 weeks apart; second test within 11 days of initiating therapy
    - Every week for 4 weeks during cycle 1: pregnancy test (HCG quantitative blood)
    - Prior to each cycle: pregnancy test (HCG quantitative blood)
    - 5 weeks following end of treatment: pregnancy test (HCG quantitative blood)

PREMEDICATIONS:

None

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
alitretinoin	30 mg once daily	PO

One cycle consists of 28 days. Treat until disease progression

DOSE MODIFICATIONS:

Dose reduction if required: 10 mg once daily

PRECAUTIONS:

1. **Pregnancy Prevention:** alitretinoin is a known teratogen.
    a. Physicians should **only** prescribe alitretinoin to females of childbearing potential if **ALL** the conditions described in the **TOCTINO Pregnancy Prevention Program for women of childbearing potential** are met.
    b. Physicians prescribing alitretinoin to female patients of childbearing potential **must** use the TOCTINO Pregnancy Prevention Program. This Program includes comprehensive information about the potential risks of alitretinoin, a checklist for criteria which **must** be met prior to prescribing, detailed information on birth control options, a patient acknowledgement form to be completed, and monthly pregnancy reminders for physicians to use at each patient visit during the treatment period.
2. **Hepatitis B Reactivation:** Low risk for hepatitis B reactivation. See SCHBV protocol for monitoring requirements.

References

1. Kapser C, Herzinger T, Ruzicka T, et al. Treatment of cutaneous T-cell lymphoma with oral alitretinoin. J Eur Acad Dermatol Venereol 2015;29:783-8. https://doi.org/10.1111/jdv.12684
2. GlaxoSmithKline Inc. Alitretinoin (^{Pr}TOCTINO) product monograph. Health Canada. https://pdf.hres.ca/dpd_pm/00051888.PDF Accessed Jun. 28, 2021.