

TYPE OF CANCER: Low Grade Recurrent B and T Cell Lymphoma
TYPE OF TRIAL: Phase I
TRIAL SPONSOR: Nevada Cancer Institute, CLL Topics & Oncovir, Inc

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STUDY SUMMARY

A Phase I Study of Intratumoral Poly-ICLC plus Low Dose Local Radiation in Low Grade Recurrent B and T Cell Lymphoma

TREATMENT OVERVIEW

- Patients will receive two doses of low dose irradiation to an accessible site of disease on day 1 and day 2
- Patients will then receive Poly-ICLC on day 3 and day 4 and twice a week during weeks 2, 3, 4, and 8

PRE-TREATMENT ASSESSMENTS

- Informed consent
- Demographics
- Medical history
- Physical Exam
- Vital Signs
- Performance status
- Blood draw for correlative studies
- EKG
- Tumor measurement by exam
- CT/PET

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

INCLUSION CRITERIA

1. Patients must be at least 18 years of age.
2. Patients must have biopsy confirmed low-grade B-cell lymphoma (follicular, marginal zone, or small cell/chronic lymphocytic leukemia) or mycosis fungoides. B-cell lymphoma patients must have failed at least one prior therapy (chemotherapy or immunotherapy) or mycosis fungoides patients failed at least 1 topical or systemic treatment.
3. Patients must have at least one accessible tumor site that can be injected with poly-ICLC.
4. Patients must have measurable disease other than the injection site.

5. Patients must have a Karnofsky performance status $\geq 70\%$.
6. Patients must have adequate hematologic, renal and liver function (i.e., absolute neutrophil count $\geq 1500/\text{mm}^3$, Platelets $\geq 100,000/\text{mm}^3$, creatinine ≤ 1.7 mg/dl, total bilirubin ≤ 1.5 mg/dl, transaminases ≤ 4 times above the upper limits of the institutional normal).
7. Patients must be able to provide written informed consent.
8. Patients with the potential for pregnancy or impregnating their partner must agree to follow acceptable birth control methods to avoid conception. Women of childbearing potential must have a negative pregnancy test. While animal testing has been negative, the anti-proliferative activity of this experimental drug may theoretically be harmful to the developing fetus or nursing infant.
9. Required washout period for prior therapy:
 - Topical therapy: 2 weeks.
 - Chemotherapy: 4 weeks
 - Radiotherapy: (including phototherapy): 4 weeks
 - Biological therapies: 4 weeks
 - Other investigational therapy: 4 weeks
 - Rituximab: 12 weeks

EXCLUSION CRITERIA

1. Any history of autoimmune or antibody mediated disease including: systemic lupus, erythematosus, rheumatoid arthritis, multiple sclerosis, Sjogren's syndrome, autoimmune thrombocytopenia, autoimmune hemolytic anemia, pure red cell aplasia, but excluding controlled thyroid disease, or the presence of autoantibodies without clinical autoimmune disease.
2. Off nucleoside or bendustine therapy for a minimum of 6 months
3. Prior treatment with Campath
4. Known history of human immunodeficiency virus (HIV), hepatitis B or hepatitis C (active, prior treatment, or both).
5. Patients with active infection or with a fever $> 38.5^\circ\text{C}$ within three days prior to the first scheduled treatment.
6. CNS metastases.
7. Prior malignancy (active within 5 years of screening) except basal cell or completely excised non-invasive squamous cell carcinoma of the skin, or in situ squamous cell carcinoma of the cervix.
8. Current anticoagulant therapy (ASA X 325 mg/day allowed).
9. Significant cardiovascular disease (i.e., NYHA class 3 congestive heart failure; myocardial infarction within the past 6 months; unstable angina; coronary angioplasty within the past 6 months; uncontrolled atrial or ventricular cardiac arrhythmias).
10. Pregnant or lactating.
11. Any other medical history, including laboratory results, deemed by the investigator to be likely to interfere with their participation in the study, or to interfere with the interpretation of the results.