# For Patients with T Cell Acute Lymphoblastic Leukemia

**EA9213 Available Through ECOG-ACRIN Cancer Research Group**

A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL)

## Patient Population

See Section 3.0 for Complete Eligibility Details

**Preregistration** - Step 0 (must be able to undergo diagnostic bone marrow aspirate following preregistration if not performed previously):

- Age ≥ 18 years
- Must have documented T cell ALL and must be in first or later hematologic CR/CRI after a minimum of 2 blocks of intensive chemotherapy (patients ≥ 65 years of age that are judged unfit for 2 blocks may enroll after one cycle of chemotherapy as long as they are in CR/CRI at least 28 days after initiation of leukemia directed therapy [see protocol for details])

**Registration** - Step 1:

- Patients in hematologic CR/CRI must have persistent/recurrent MRD ≥ 10^-4 (confirmed by flow cytometry)
- Patients may have undergone prior allogeneic stem cell transplant, but may not have GVHD that requires ongoing immunosuppressive therapy
- ECOG PS 0-2, adequate lab values
- HIV, HBV, HCV patients are eligible per protocol
- No active CNS involvement at time of Step 1 registration (prior CNS involvement is permitted)
- Patients with a prior/concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety/efficacy assessment of the investigational regimen are eligible
- Patients with known history/current symptoms of cardiac disease, or history of treatment with cardiotoxic agents should be NYHA class 2B or better

## Treatment Plan

See Section 5.0 for Complete Treatment Details

- All patients will receive daratumumab-hyaluronidase once weekly for up to 4 doses during Course 1
- Bone marrow biopsy will be done on Day 29
- MRD negative patients (Day 29) may receive an additional 4 weekly doses of daratumumab-hyaluronidase during Course 1B (for 8 total doses)
- MRD positive patients may receive an additional 4 weekly doses of daratumumab-hyaluronidase in combination with chemotherapy during Course IA (for 8 total doses)
  - Chemotherapy to include physician’s choice of HyperCVAD part B with high dose cytarabine and methotrexate or Capizzi methotrexate
  - A bone marrow biopsy will be repeated on Day 64 or on count recovery to assess response
  - If counts do not recover by Day 84 a bone marrow MRD assessment should be performed
  - MRD negative patients can:
    - Undergo allogeneic stem cell transplant at the treating physician’s discretion (but they may not receive additional daratumumab)
    - Receive donor lymphocyte infusion and remain on treatment with daratumumab
    - If no transplant, proceed to Course 2 with daratumumab-hyaluronidase once every 2 weeks for 8 doses
  - Responding patients will undergo surveillance bone marrow biopsies with MRD assessment performed as per local standards
  - MRD positive patients on Day 64 will come off study

**NOTE:**

- Prophylaxis/treatment with intrathecal chemotherapy for central nervous system ALL is at the physician’s discretion and is allowed during daratumumab-hyaluronidase cycles
- Administer pre- and post-medications per protocol

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### Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

### Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

**Please Enroll Your Eligible Patients!**