**Follicular Lymphoma Clinical Trials**

The following clinical trials are currently open and accruing for patients with follicular lymphoma.

Contact Kalin Morrell (Assistant Clinical Research Manager), kalin_morrell@dfci.harvard.edu, 617-582-8713 to discuss a patient.

**TRIALS FOR RELAPSED/REFRACTORY PATIENTS**

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See the following pages for more information about these trials.

These trials are offered through Dana-Farber/Harvard Cancer Center, an NCI-designated Comprehensive Cancer Center.
TRIALS FOR PATIENTS WITH RELAPSED/REFRACTORY DISEASE

18-311: A multi-cohort phase 1b clinical trial of rituximab in combination with immunotherapy in untreated and previously-treated follicular lymphoma

Rationale: This study is a phase 1b/2 study studying the efficacies of immunotherapies in newly diagnosed and relapsed follicular lymphoma patients. There will be three arms that will be open for enrollment: Rituximab, utomilumab (4-1BB agonist antibody) and avelumab (anti-PDL1 antibody); PF4518600 (Ox-40 agonist antibody), rituximab, and utomilumab; and rituximab, PF4518600, avelumab. Treatment is limited to 6 cycles for all arms. We are currently only open for relapsed follicular patients.

Key Eligibility Criteria:
- Histologically confirmed diagnosis of B-cell iNHL with histological subtype limited to FL Grade 1, Grade 2, or Grade 3a or Marginal Zone Lymphoma (MZL) nodal or extranodal, based on criteria established by the World Health Organization (WHO) 2016 classification.
- Patients can have had prior had CAR-T cell therapy or other genetically modified T-Cell therapy
- Patients must be relapsed or refractory after 2 or more prior lines of therapy. One prior therapy must have included an anti-CD20 monoclonal antibody combined with an alkylating agent (single agent CD-20 antibody will not count as a line of therapy for eligibility)

Treatment Schedule:
Patients will be required to come into clinic 7 times during the first 28-day cycle, including a screening tumor biopsy along with an on-treatment biopsy. After the first cycle, patients will be required to come into clinic twice a month for their treatments for six months. Afterwards, they will be required to come to clinic once every 3 months.

Principal Investigator: Caron Jacobson, MD

Slots Available at Last Update: 16. Please email us for the latest information.
17-313: A phase 1b/2 trial of Hu5F9-G4 in combination with rituximab in patients with relapsed/refractory B-cell non-Hodgkin lymphoma. Hu5F9-G4 is a monoclonal antibody which is designed to block a protein called CD47, which is widely expressed on human cancer cells.

**Rationale:** This is a phase 1b/2 for relapsed/refractory DLBCL and indolent lymphomas (marginal zone and follicular lymphoma). This study is using rituximab in combination with Hu5F9-G4, an anti-CD47 drug. We are currently open with the combination arm and will be opening with a chemotherapy + HuF59-G4 arm.

**Key Eligibility Criteria:**
- Patients must have had their last treatment either 3 weeks prior or 4 half-lives (up to a maximum of 4 weeks) whichever is longer
- Follicular lymphoma grade 1-3
- Patients cannot be transfusion dependent, requiring more than 2 units of RBC transfusions during the 4-week screening period

**Treatment Schedule:**
Patients will be required to come to clinic for treatment once a week for the first four weeks. After the first cycle, patients will come to clinic twice a month for their treatments. Day 1 will be a combination of Rituximab + Hu5F9-G4 and Day 15 will be a single of infusion of HuSF9-G4. Patients will also be required to have a screening biopsy performed along with one done at Day 22 unless a biopsy is deemed not clinically feasible by the treating physician. Treatment can continue indefinitely at this time with a continued combination of rituximab + HuF59-G4 until Cycle 7 at which time they will continue to get HuF59-G4 and rituximab every other cycle.

**Principal Investigator:** Ann LaCasce, MD, MMSc

**Slots Available at Last Update:** Slots will vary. Please email us for the latest slot availability.
17-075: A phase 2 multicenter study of axicabtagene ciloleucel in patients with relapsed/refractory indolent non-Hodgkin lymphoma (iNHL) (ZUMA-5)

Rationale: Yescarta was FDA approved in the DLBCL population and these results provide significant hope that CAR T cells may help to meet the unmet medical need present in patients with relapsed/refractory or early-progressing iNHL.

Key Eligibility Criteria:
- Relapsed or refractory disease after 2 or more prior lines of therapy. Prior therapy must have included an anti-CD20 monoclonal antibody combined with an alkylating agent (single agent anti-CD20 antibody will not count as line of therapy for eligibility).
  - Stable disease (without relapse) > 1 year from completion of last therapy is not eligible.
- No known history or suspicion of central nervous system (CNS) involvement by lymphoma

Treatment Schedule:
Patients will have a single leukapheresis for collection of T cells. After successful manufacturing of CAR T-cells, patients will receive 3 days of conditioning chemotherapy in the clinic followed by a single infusion of axicabtagene ciloleucel in the hospital, where they will remain for a minimum of 7 days or until CAR T-cell related toxicities resolve to grade 1 or better. Patients are then followed every 1-6 months through month 60.

Principal Investigator: Caron Jacobson, MD

Slots Available at Last Update: Slots will vary. Please email us for the latest slot availability.