Hodgkin Lymphoma Clinical Trials

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

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TRIALS FOR RELAPSED/REFRACTORY PATIENTS

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Page</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17-282</td>
<td>p. 2</td>
<td>A randomized, open-label, phase 3 trial of nivolumab plus brentuximab vedotin versus brentuximab vedotin alone in patients with relapsed/refractory or ineligible for autologous stem cell transplant (ASCT) advanced stage classical Hodgkin lymphoma (CheckMate 812: CHECKpoint pathway and nivoluMAb clinical trial evaluation 812)</td>
</tr>
<tr>
<td>18-582</td>
<td>p. 3</td>
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</tr>
</tbody>
</table>

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

17-282: A randomized, open-label, phase 3 trial of nivolumab plus brentuximab vedotin versus brentuximab vedotin alone in patients with relapsed/refractory or ineligible for autologous stem cell transplant (ASCT) advanced stage classical Hodgkin lymphoma (CheckMate 812: CHECKpoint pathway and nivoluMAb clinical trial evaluation 812)

Rationale: This is a phase 3 open-label randomized trial between BV alone and BV +Nivo. This is open-label and unblinded.

Key Eligibility Criteria:
- Relapsed/refractory classical Hodgkin lymphoma
- ASCT ineligible (by comorbidity or chemorefractoriness) or relapse after ASCT
- Not BV refractory (if prior BV exposure, must have achieved at least PR and not progressed within 3 months of last treatment)
- No active pneumonitis, grade 2 or above neuropathy, autoimmune disease, prior malignancy (unless >3y ago with no anticipation of needing therapy)

Treatment Schedule:
Patients will be required to come every three weeks for treatment. BV will be given for maximum of 16 cycles; nivo (on the experimental arm) is given until CR, progression or toxicity. All patients will be scanned after 5 cycles of treatment and every 5 cycles thereafter. Patients will have 2 required follow upon visits in clinic after the discontinuation of treatment and will be followed every 3 months thereafter for survival. Patients must get all their treatments at Dana-Farber and will not be able to go locally for treatment.

Principal Investigator: Philippe Armand, MD PhD

Slots Available at Last Update: This is a large multi-center trial and we currently have many slots open. Please email us for the latest information.
**18-582**: A phase 1/2 clinical study to evaluate the safety and efficacy of a combination of MK-4280 and pembrolizumab (MK-3475) in patients with hematologic malignancies

**Rationale**: This is a phase 1/2 study to evaluate the safety and efficacy of MK-4280 in combination with pembrolizumab for patients with PD-1/L1 naïve or refractory R/R classical Hodgkin lymphoma, R/R DLBCL or R/R indolent non-Hodgkin lymphoma. The primary goals of the study are to examine the safety and tolerability and to establish a preliminary recommended phase 2 dose of MK-4280 in combination with pembrolizumab. MK-4280 is a humanized IgG4 mAb that antagonizes LAG-3. Because of LAG-3’s proposed role on both effector T-cells and Tregs, it is one of several immune checkpoint molecules where simultaneous blockade of both cell populations has the potential to enhance antitumor immunity. This trial provides an option for patients with Hodgkin lymphoma who have progressed on prior PD-1 blockade. We recently completed a similar trial of LAG3/PD1 combined blockade with another set of antibodies that showed several responses in PD1-refractory Hodgkin patients.

**Key Eligibility Criteria:**
- R/R classical Hodgkin lymphoma, including both PD-1 naïve and PD-1 refractory. Prior brentuximab is NOT required.
- The trial is also open for DLBCL and indolent B-NHL though we have other, higher priority trials for those patients at present.
- Confirmed measurable disease (1.5cm long or 1cm short axis)
- Able to have a tumor biopsy at screening or archival tissue within the past 3 months
- Principal exclusion criteria: CNS involvement, significant heart disease, prior anti-LAG-3 treatment, prior CAR-T cell therapy, allotransplant within last 5 years, secondary malignancy in the past 3 years that is progressing or requiring active treatment, immunodeficiency, autoimmune disease or chronic systemic steroid therapy, HIV or active HepB/HepC.

**Treatment Schedule:**
Cycles are 21 days and patients will need to come to clinic 4 times in cycle 1, and then on day 1 of each cycle thereafter. Pembrolizumab and MK-4280 infusions will be given on Day 1 of each visit, for up to 35 cycles (~2 years) or until a protocol determined standard is met to discontinue treatment.

**Principal Investigator**: Philippe Armand, MD, PhD

**Slots Available at Last Update**: Please call/email the latest slot availability. The trial is currently in phase 1 so slots are available only intermittently.

<return to page 1>