1 Recruiting  Questionnaire and Tissue Banking For Multiple Myeloma, Waldenstrom Macroglobulinemia and Related Disorders

Conditions: Multiple Myeloma; Waldenstrom's Macroglobulinemia; Smoldering Multiple Myeloma; Lymphoblastic Lymphoma

Intervention: Dana-Farber Cancer Institute; Steven and Michele Kirsch Foundation for Waldenstrom's Macroglobulinemia

Phase: Number Enrolled: 1000

Start Date: December 2009

Completion Date:

Outcome Measures: Databank; Unique characteristics

2 Unknown † Efficacy of Bortezomib (Velcade(R)) in Patients With Advanced Waldenström Macroglobulinemia

Condition: Advanced Waldenstrom's Macroglobulinemia

Intervention: Drug: BORTEZOMIB

Sponsor: Assistance Publique - Hôpitaux de Paris

Phase: Phase II

Number Enrolled: 34

Funded By: Other

Start Date: October 2008

Completion Date: October 2011

Outcome Measures: Complete and partial remission, defined by the 2nd Workshop on Waldenstrom's macroglobulinemia; Duration of the response; Overall survival; Quality of life

3 Unknown † Trial Comparing Chlorambucil to Fludarabine in Patients With Advanced Waldenström Macroglobulinemia

Conditions: Waldenström Macroglobulinemia; Lymphoplasmacytic Lymphoma; Splenic Marginal Zone Lymphoma

Interventions: Drug: Chlorambucil; Drug: Fludarabine

Sponsors: French Study Group on Chronic Lymphoid Leukemia; Groupe d'Etudes de Lymphomes de L'Adulte; Groupe Ouest Est d'Etude des Leucémies et Autres Maladies du Sang GOELAMS;
4 Recruiting **Bortezomib and Rituximab for Patients With Waldenstrom's Macroglobulinemia**

Condition: Waldenstrom's Macroglobulinemia  
Interventions: Drug: Bortezomib; Drug: Rituximab; Drug: Valacyclovir  
Sponsors: M.D. Anderson Cancer Center; Millennium Pharmaceuticals, Inc.  
Phase: Phase II  
Number Enrolled: 38  
Funded By: Other / Industry  
Start Date: August 2006  
Completion Date:  
Outcome Measure: Overall response rate to Bortezomib-Rituximab, and autologous stem cell collection rate after induction therapy with Bortezomib-Rituximab

5 Recruiting **Escalating Dose Study in Subjects With Relapsed or Refractory B Cell Non-Hodgkin Lymphoma, Chronic Lymphocytic Leukemia, and Waldenstrom's Macroglobulinemia**

Conditions: B Cell Non-Hodgkin's Lymphoma; Chronic Lymphocytic Leukemia; Waldenstrom Macroglobulinemia  
Intervention: Drug: AVL-292  
Sponsors: Avila Therapeutics; The Leukemia and Lymphoma Society  
Phase: Phase I  
Number Enrolled: 60  
Funded By: Industry / Other  
Start Date: June 2011  
Completion Date: December 2012  
Outcome Measures: Safety, tolerability, and dose limiting
toxicities will be determined using AEs, PE, ophthalmologic examinations, clinical laboratory tests, vital signs, ECGs and echocardiograms/MUGA scans.; Establish recommended Phase 2 dose, after completing dose escalation in Part 1 and evaluating accumulated safety, PK, and PD data from the dose escalation phase (Part 1); evaluate the Pharmacokinetic parameters of AVL-292; evaluate the Pharmacodynamics of AVL-292 by measurement of free Btk; Characterize preliminary anti-tumor efficacy of AVL-292 in relapsed and/or refractory B-NHL, CLL and WM

6 Not yet recruiting Ofatumumab and Bortezomib in Treating Patients With Previously Untreated Waldenstrom Macroglobulinemia

   Condition: Waldenstrom Macroglobulinemia
   Interventions: Biological: ofatumumab; Drug: bortezomib; Other: laboratory biomarker analysis
   Sponsors: Roswell Park Cancer Institute; National Comprehensive Cancer Network
   Phase: Phase II
   Number Enrolled: 28
   Funded By: Other
   Start Date: February 2012
   Completion Date: Overall response rate (CR + PR + MR) of ofatumumab in combination with bortezomib; Frequency of complete remission (CR); Frequency of near (n)CR; Frequency of very good partial response (VGPR); Frequency of PR; Time to progression; Progression-free survival; Duration of response; Frequency and severity of toxicity as graded according to the Cancer Therapeutic Evaluation Program (CTEP) Common Toxicity Criteria (CTC) version 4.0

7 Recruiting Carfilzomib, Rituximab and Dexamethasone in Waldenstrom's Macroglobulinemia

   Condition: Waldenstrom's Macroglobulinemia
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Title</th>
<th>Condition</th>
<th>Interventions</th>
<th>Sponsors</th>
<th>Phase</th>
<th>Number Enrolled</th>
<th>Funded By</th>
<th>Start Date</th>
<th>Completion Date</th>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 Recruiting</td>
<td><strong>Dose Escalation Study of INK128 in Relapsed or Refractory Multiple Myeloma or Waldenstrom Macroglobulinemia</strong></td>
<td>Relapsed or Refractory Multiple Myeloma; Waldenstrom Macroglobulinemia</td>
<td>Drug: INK128</td>
<td>Intellikine</td>
<td>Phase I</td>
<td>56</td>
<td>Industry</td>
<td>June 2010</td>
<td>August 2013</td>
<td>determine the dose limiting toxicities</td>
</tr>
<tr>
<td>9 Recruiting</td>
<td><strong>Pomalidomide, Dexamethasone and Rituximab in Waldenstrom's Macroglobulinemia</strong></td>
<td>Waldenstrom's Macroglobulinemia</td>
<td>Drug: pomalidomide; Drug: dexamethasone; Drug: rituximab</td>
<td>Dana-Farber Cancer Institute; Celgene Corporation</td>
<td>Phase I</td>
<td>24</td>
<td>Other / Industry</td>
<td>May 2010</td>
<td>August 2012</td>
<td>Safety Profile, Tolerability and Maximum Tolerated Dose</td>
</tr>
<tr>
<td>10 Recruiting</td>
<td><strong>A Study of Belimumab in Treating Symptomatic Waldenstrom's Macroglobulinaemia</strong></td>
<td></td>
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</tbody>
</table>
11 Not yet recruiting Open-label Study of the Safety and Activity of ONX 0912 in Patients With Hematological Malignancies

Condition: Multiple Myeloma; Waldenstrom's Macroglobulinemia; Mantle Cell Lymphoma
Intervention: Drug: ONX 0912
Sponsor: Onyx Therapeutics, Inc.
Phases: Phase I / Phase II
Number Enrolled: 176
Funded By: Industry
Start Date: August 2011
Completion Date: August 2015
Outcome Measures: Determine the MTD of ONX 0912 in patients with hematological malignancies; Estimate the best Overall Response Rate (ORR)

12 Unknown† Collecting Stem Cells in Patients With Waldenstrom's Macroglobulinemia

Condition: Lymphoma
Intervention: Procedure: leukapheresis
Sponsors: Herbert Irving Comprehensive Cancer Center; National Cancer Institute (NCI)
Phase:
Number Enrolled: 40
Funded By: Other / NIH
Start Date: November 2005
13 Unknown†  **Chlorambucil or Fludarabine as First-Line Therapy in Treating Patients With Previously Untreated Waldenström Macroglobulinemia, Splenic Lymphoma, or Lymphoplasmacytic Lymphoma**

- **Condition:** Lymphoma
- **Interventions:** Drug: chlorambucil; Drug: fludarabine phosphate; Procedure: quality-of-life assessment
- **Sponsor:** Taunton and Somerset Hospital
- **Phase:** Phase III
- **Number Enrolled:** 400
- **Funded By:** Other
- **Start Date:** June 2006
- **Completion Date:** 
- **Outcome Measures:** Response to therapy (complete and partial response rates); Duration of response; Improvement in hematological parameters; Toxicity; Quality of life as assessed by the European Organization for Research and Treatment of Cancer Quality of Life-30 questionnaire; Survival

14 Recruiting  **Bortezomib, Rituximab, and Dexamethasone With or Without Temsirolimus in Treating Patients With Untreated or Relapsed Waldenstrom Macroglobulinemia or Relapsed or Refractory Mantle Cell or Follicular Lymphoma**

- **Conditions:** Cognitive/Functional Effects; Fatigue; Lymphoma; Neurotoxicity; Therapy-related Toxicity
- **Interventions:** Biological: rituximab; Drug: bortezomib; Drug: dexamethasone; Drug: temsirolimus
- **Sponsors:** Eastern Cooperative Oncology Group; National Cancer Institute (NCI)
- **Phases:** Phase I / Phase II
- **Number Enrolled:** 164
- **Funded By:** Other / NIH
- **Start Date:** October 2011
- **Completion Date:** 
- **Outcome Measures:** MTD and recommended phase II dose of temsirolimus in combination with bortezomib, rituximab, and
dexamethasone (Phase I); Progression-free survival of patients treated with temsirolimus in combination with bortezomib, rituximab, and dexamethasone (Phase II); Toxicity of temsirolimus in combination with bortezomib, rituximab, and dexamethasone (phase I); Response rates and duration of response (Phase II); Time to disease progression (Phase II); Duration of response (Phase II); Time to next therapy (Phase II); Overall survival of patients (Phase II); Treatment-related fatigue and physical and functional well-being of these patients (Phase II); Health-related quality of life

15 Recruiting Phase 1 Study of Oral MLN9708 in Patients With Advanced Nonhematologic Malignancies or Lymphoma

Conditions: Lymphoma; Waldenstrom's Macroglobulinemia; Nonhematologic Malignancies

Interventions: Drug: MLN9708 Capsule B formulation;
Drug: MLN9708 Capsule A or B formulation

Sponsor: Millennium Pharmaceuticals, Inc.

Phase: Phase I

Number Enrolled: 56

Funded By: Industry

Start Date: November 2011

Completion Date: July 2013

Outcome Measures: Arm 1: Ratio of geometric mean Cmax and AUC0-tlast of MLN9708 administered as Capsule B formulation with ketoconazole versus when administered as a single agent and 90% confidence intervals (CI);
Arm 2: Ratio of geometric mean Cmax and AUC0-tlast of Capsule B formulation versus Capsule A formulation and 90% CI;
Arm 3: Capsule B formulation ratio of geometric mean Cmax and AUC0-tlast of MLN9708 administered as Capsule B formulation with food versus without food and 90% CI; Adverse events, serious adverse events, assessments of clinical
16 Recruiting **Pomalidomide for Relapse/Refractory Waldenstrom’s**
- **Conditions:** Lymphoma; Myeloma
- **Intervention:** Drug: Pomalidomide
- **Sponsors:** M.D. Anderson Cancer Center; Celgene Corporation
- **Phase:** Phase I
- **Number Enrolled:** 30
- **Funded By:** Other / Industry
- **Start Date:** October 2010
- **Completion Date:**
- **Outcome Measure:** Maximum Tolerated Dose (MTD)

17 Recruiting **Rituximab, Cyclophosphamide, Bortezomib, and Dexamethasone in Treating Patients With Relapsed or Refractory Low-Grade Follicular Lymphoma, Waldenstrom Macroglobulinemia, or Mantle Cell Lymphoma**
- **Condition:** Lymphoma
- **Interventions:** Biological: rituximab; Drug: bortezomib; Drug: cyclophosphamide; Drug: dexamethasone; Other: questionnaire administration; Procedure: quality-of-life assessment
- **Sponsors:** Mayo Clinic; National Cancer Institute (NCI)
- **Phase:** Phase II
- **Number Enrolled:** 36
- **Funded By:** Other / NIH
- **Start Date:** October 2008
- **Completion Date:**
- **Outcome Measures:** Proportion of responses (complete response or partial response); Overall survival; Progression-free survival; Duration of response; Time to treatment failure; Adverse events

18 Recruiting **A Pilot Study of the Safety and Activity of Escalating Doses of ON 01910.Na in Patients With Relapsed Mantle Cell Lymphoma, Multiple Myeloma, Chronic Lymphocytic Leukemia, and Related Lymphoid**
Malignancies

Conditions: Lymphoma, Mantle-Cell; Leukemia, Lymphocytic, Chronic, B-Cell; Leukemia, Hairy Cell; Waldenstrom Macroglobulinemia; Multiple Myeloma

Intervention: Drug: ON01910 Na
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Phase: Phase I
Number Enrolled: 34
Funded By: NIH
Start Date: March 2009
Completion Date:
Outcome Measures: Safety of escalating doses ON01910.Na at day 28.; The reduction in lymph nodes, quantification of circulating lymphoma cells, assessment of extranodal disease sites, and/or measurement of the malignant monoclonal proteins in the serum or urine after 4 cycles of therapy (day 56).