
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:
Sponsors: Dana-Farber Cancer Institute; Steven and Michele Kirsch Foundation for Waldenstrom's Macroglobulinemia
Phase:
Number Enrolled: 1000
Funded By: Other
Start Date: December 2009
Completion Date:
Outcome Measures: Databank; Unique characteristics

2 **Not yet recruiting** [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;
Département de Biostatistiques et
Informatique Médicale DBIM

Phase: Phase III
Number Enrolled: 366
Funded By: Other
Start Date: June 2001
Completion Date: December 2008
Outcome Measures: Patient overall response; Biological study;
Quality of life; Response duration;
Treatment toxicity; Event free survival;
Overall survival

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 Recruiting [Everolimus, Bortezomib and/or Rituximab in Patients With Relapsed/Refractory Waldenstrom's Macroglobulinemia](#)

Condition: Waldenstrom's Macroglobulinemia
Interventions: Drug: Everolimus; Drug: Rituximab; Drug: Bortezomib
Sponsors: Dana-Farber Cancer Institute; Novartis; Millennium Pharmaceuticals, Inc.
Phases: Phase I / Phase II
Number Enrolled: 134
Funded By: Other / Industry
Start Date: March 2010
Completion Date: October 2012
Outcome Measures: Phase I: To determine the safety and maximum tolerated dose (MTD) of the combination of everolimus/rituximab or everolimus/bortezomib/rituximab.; Phase II Study Arm A: To assess the depth of response to the combination of everolimus/rituximab.; Phase II Arm B: To assess the depth of response to the combination of everolimus/bortezomib/rituximab.; To assess the safety of the combination of everolimus/rituximab or everolimus/bortezomib/rituximab in the Phase II study.; To assess overall response rate, duration of response, time to progression, and progression free

survival in these patients in the Phase II study.; To identify molecular regulators of response/resistance using tumor samples pre and post-treatment.

7 Recruiting [Dose Escalation Study of INK128 in Relapsed or Refractory Multiple Myeloma or Waldenstrom Macroglobulinemia](#)

Conditions: Relapsed or Refractory Multiple Myeloma;
Waldenstrom Macroglobulinemia
Intervention: Drug: INK128
Sponsor: Intellikine
Phase: Phase I
Number Enrolled: 56
Funded By: Industry
Start Date: June 2010
Completion Date: August 2013
Outcome Measure: determine the dose limiting toxicities

8 Recruiting [Pomalidomide, Dexamethasone and Rituximab in Waldenstrom's Macroglobulinemia](#)

Condition: Waldenstrom's Macroglobulinemia
Interventions: Drug: pomalidomide; Drug:
dexamethasone; Drug: rituximab
Sponsors: Dana-Farber Cancer Institute; Celgene
Corporation
Phase: Phase I
Number Enrolled: 24
Funded By: Other / Industry
Start Date: May 2010
Completion Date: August 2012
Outcome Measure: Safety Profile, Tolerability and Maximum
Tolerated Dose

9 Recruiting [A Study of Belimumab in Treating Symptomatic Waldenstroms Macroglobulinaemia](#)

Condition: Symptomatic Waldenstroms
Macroglobulinaemia
Intervention: Drug: Belimumab
Sponsors: Cancer Trials Australia; Human Genome
Sciences
Phase: Phase II
Number Enrolled: 15
Funded By: Other / Industry

Start Date: November 2009
Completion Date: January 2013
Outcome Measures: Safety of Belimumab infusions in symptomatic WM; Reduction of IgM paraprotein; Reduction of splenomegaly and/or lymphadenopathy; Improvement in anaemia; Correlate the degree of response with Belimumab levels

10 Not yet recruiting [Open-label Study of the Safety and Activity of ONX 0912 in Patients With Hematological Malignancies](#)

Conditions: 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)

11 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
Completion Date:
Outcome Measure: Number of days to adequate stem cell harvest

12 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

13 Not yet
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: June 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

14 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)

15 Unknown † [Combination Therapy Using Lenalidomide \(Revlimid\)- Low Dose Dexamethasone and Rituximab for Treatment of Rituximab-Resistant, Non-Aggressive B-Cell Lymphomas](#)

Conditions: Follicular Lymphoma; Marginal Zone B-Cell Lymphoma; MALT Lymphoma; Lymphoma of Mucosa-Associated Lymphoid Tissue; Lymphoma, Small Lymphocytic; Waldenstrom Macroglobulinemia; Mantle-Cell Lymphoma
Intervention: Drug: lenalidomide-low dose dexamethasone plus rituximab
Sponsors: University of Pennsylvania; Celgene Corporation
Phase: Phase II
Number Enrolled: 25
Funded By: Other / Industry
Start Date: July 2008
Completion Date: August 2010
Outcome Measures: Response rate to lenalidomide-dexamethasone + rituximab therapy in relapsed small B-cell lymphoma with rituximab resistance; Time until

progression after lenalidomide-dexamethasone + rituximab therapy in relapsed small B-cell lymphomas with rituximab resistance; Compare the response rate for the previous rituximab-containing regimen to that obtained subsequently to lenalidomide-dexamethasone + rituximab therapy; Determine the toxicity profile of lenalidomide-dexamethasone + rituximab therapy in patients who have received a previous rituximab-containing combination regimen

16 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

17 Recruiting [Donor Lymphocyte Infusion After Stem Cell Transplant in Treating Patients With Follicular Lymphoma, Small Lymphocytic Non-Hodgkin Lymphoma, Waldenstrom Macroglobulinemia, or Chronic Lymphocytic Leukemia](#)

Conditions: Graft Versus Host Disease; Leukemia; Lymphoma
Interventions: Biological: T cell-depleted hematopoietic stem cell transplantation; Biological:

alemtuzumab; Biological: donor lymphocytes; Drug: cyclosporine; Drug: fludarabine phosphate; Drug: melphalan; Other: laboratory biomarker analysis; Procedure: allogeneic hematopoietic stem cell transplantation; Procedure: bone marrow aspiration

Sponsor: Cancer Research UK
Phase: Phase II
Number Enrolled: 86
Funded By: Other
Start Date: March 2011
Completion Date:
Outcome Measures: Progression-free survival at 1 year; Incidence, grade, or pattern of graft-versus-host disease; Proportion of patients attaining multi-lineage full donor chimerism in peripheral blood; Incidence of infection requiring inpatient treatment; Rate of reconstitution of T-cell subsets and viral-specific immunity; Proportion of patients with detectable minimal residual disease; Cumulative incidence of non-relapse mortality at 1 year; Overall survival and non-relapse mortality

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).