

Selected Protocols for the Treatment of Hematologic Malignancies

Treatment Group	ID Number	Phase	Study Name	Principal Investigator
Leukemia – AML, MDS	08-269	I	A Phase I trial of escalating dose of RAD001 in combination with PKC412 in patients with relapsed, refractory or poor prognosis acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS)*	Richard Stone, MD 617-632-2214
Leukemia – MDS	10-020	I	Phase I dose ranging study of Ezatiostat Hydrochloride in combination with Lenalidomide in patients with non-deletion(5q) low-intermediate risk MDS	David Steensma, MD 617-632-5202
Leukemia – MDS, CMML, AML	09-311	IB	A phase IB, open-label, multicenter, dose-escalation study of oral Panobinostat (LBH589) administered with 5-Azacitidine (Vidaza®) in adult patients with myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) or acute myeloid leukemia (AML)	Daniel DeAngelo, MD, PhD 617-632-2645
Leukemia – ASM, MCL	10-198	II	A single-arm, phase II, open-label study to determine the efficacy of 100 mg twice daily oral dosing of Midostaurin administered to patients with aggressive systemic mastocytosis (ASM) or mast cell leukemia (MCL) +/- an associated hematological clonal non-mast cell lineage disease	Daniel DeAngelo, MD, PhD 617-632-2645
Leukemia – CML, ALL	10-291	II	A pivotal phase II trial of Ponatinib (AP24534) in patients with refractory chronic myeloid leukemia (CML) and Ph+ acute lymphoblastic leukemia (ALL)	Daniel DeAngelo, MD, PhD 617-632-2645
Leukemia – AML	08-112	III	A phase III randomized, double-blind study of induction (Daunorubicin/Cytarabine) and consolidation (high-dose Cytarabine) chemotherapy + Midostaurin (PKC412) (IND#101261) or placebo in newly diagnosed patients < 60 years of age with FLT3 mutated acute myeloid leukemia (AML)*	Richard Stone, MD 617-632-2214
Leukemia – CML-CP	10-396	IV	A single-arm, open-label, multicenter study of Complete Molecular Response (CMR) in adult patients with newly diagnosed Philadelphia Chromosome Positive (Ph+) chronic myelogenous leukemia in chronic phase (CML-CP)	Martha Wadleigh, MD 617-632-6685

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Lymphoma – NHL	08-063	Pilot	A pilot study of Gleevec (imatinib mesylate) in relapsed/refractory T cell non-Hodgkin's lymphoma	Eric Jacobsen, MD 617-632-6633
Lymphoma – CLL	09-421	I/II	A phase I/II study of Pyrimethamine, a STAT3 inhibitor, for the treatment of relapsed chronic lymphocytic leukemia/small lymphocytic lymphoma	Jennifer Brown, MD, PhD 617-632-6692
Lymphoma – NHL	08-066	II	A phase II trial of Bortezomib + Lenalidomide for relapsed/refractory mantle cell lymphoma*	Ann LaCasce, MD 617-632-5959
Lymphoma – CLL	08 183	II	A two-arm, multi-center trial of Revlimid and Rituximab for first-line treatment in patients with chronic lymphocytic leukemia (CLL)	Jennifer Brown, MD, PhD 617-632-6692
Hodgkin Lymphoma	09-354	II	A Phase II trial of response adapted therapy of stage III-IV Hodgkin lymphoma using early interim FDG-PET imaging	Ann LaCasce, MD 617-632-5959
Multiple Myeloma	08-273	I/II	Phase I/II trial of combination Plerixafor (AMD3100) and Bortezomib in relapsed or relapsed/refractory multiple myeloma	Irene Ghobrial, MD 617-632-4198
Multiple Myeloma	09-355	I/II	Phase I/II study of combination of Aurora Kinase Inhibitor MLN8237 and Bortezomib in relapsed or refractory multiple myeloma*	Jacob Laubach, MD 617-582-7102
Multiple Myeloma	10-226	I/II	Multicenter phase I/II study on the anti-tumor activity, safety and pharmacology of IPH2101, a human monoclonal anti-KIR, combined with Lenalidomide in patients with multiple myeloma experiencing a first relapse	Nikhil Munshi, MD 617-632-5607
Multiple Myeloma	10-264	I/II	An open-label, dose-escalation phase I/II study of the oral form of MLN9708, a second-generation Proteasome Inhibitor, administered in combination with Lenalidomide and low-dose Dexamethasone in patients with newly diagnosed multiple myeloma requiring systemic treatment*	Paul Richardson, MD 617-632-2104
Multiple Myeloma	09-401	III	A phase III randomized study to assess the efficacy and safety of Perifosine added to the combination of Bortezomib and Dexamethasone in multiple myeloma patients previously treated with Bortezomib	Paul Richardson, MD 617-632-2104
Multiple Myeloma	10-083	III	A multi-center, randomized, double-blind, placebo-controlled phase III study of Panobinostat in combination with Bortezomib and Dexamethasone in patients with relapsed multiple myeloma	Robert Schollossman, MD 617-632-5126

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Multiple Myeloma	10-106	III	A randomized phase III study comparing conventional dose treatment using a combination of Lenalidomide, Bortezomib and Dexamethasone (RVD) to high-dose treatment with peripheral stem cell transplant in the initial management of myeloma in patients up to 65 years of age*	Paul Richardson, MD 617-632-2104
Waldenström's Macroglobulinemia	10-007	I	Phase I study of Pomalidomide, Dexamethasone and Rituximab (PDR) in Waldenström's macroglobulinemia	Steven P. Treon, MD, PhD 617-632-2681
Waldenström's Macroglobulinemia	10-143	I	A phase I, open-label, dose-escalation study of oral administration of single agent INK128 in subjects with relapsed or refractory multiple myeloma or Waldenström's macroglobulinemia	Irene Ghobrial, MD 617-632-4198
Waldenström's Macroglobulinemia	09-280	I/II	Phase I/II Study of combination Everolimus (RAD001) and Rituximab (Rituxan) OR Everolimus, Bortezomib (Velcade, PS-341) and Rituximab in patients with relapsed and/or relapsed/refractory Waldenström's macroglobulinemia based on risk stratification	Irene Ghobrial, MD 617-632-4198
Waldenström's Macroglobulinemia	09-214	II	Phase II study of Everolimus (RAD001) in primary therapy of Waldenström's macroglobulinemia	Steven P. Treon, MD, PhD 617-632-2681
Bone Marrow/ Stem Cell Transplant	08-274	I	A phase I study of reduced-intensity, sequential double umbilical cord blood transplantation using Ex-Vivo 16, 16 Dimethyl-Prostaglandin E2 expanded umbilical cord blood units*	Corey Cutler, MD, MPH, FRCPC 617-632-5946
Bone Marrow/ Stem Cell Transplant	11-007	II	Bortezomib-based graft-versus-host disease prophylaxis after myeloablative allogeneic stem cell transplantation for patients lacking HLA-matched related donors	John Koreth, MBBS., D.Phil 617.632.2949
Bone Marrow/ Stem Cell Transplant	06-158	I/II	Fludarabine-based conditioning for allogeneic marrow transplantation from HLA-compatible unrelated donors in severe aplastic anemia	Joseph H. Antin, MD 617-632-2525
Bone Marrow/ Stem Cell Transplant	05-021	II	A phase II study of allogeneic transplant for older patients with AML in first morphologic complete remission using a non-myeloablative preparative regimen (CALGB 100103) (CTN 0502)*	Edwin Alyea, MD 617-632-3903

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Bone Marrow/ Stem Cell Transplant	08-372	II	Phase II trial of non-myeloablative allogeneic hematopoietic cell transplantation for patients with relapsed follicular non-Hodgkin's lymphoma beyond first complete response*	Philippe Armand, MD, PhD 617-632-2305
Bone Marrow/ Stem Cell Transplant	09-073	III	A phase III multicenter randomized trial comparing Tacrolimus/Sirolimus/Methotrexate versus Tacrolimus/Methotrexate or Cyclosporine/Mycophenolate Mofetil for GVHD prophylaxis after reduced-intensity conditioned allogeneic stem cell transplantation for patients with lymphoma*	Philippe Armand, MD, PhD 617-632-2305

The clinical trials listed above are conducted through Dana-Farber/Harvard Cancer Center, an NCI-designated Comprehensive Cancer Center, and are available at other member institutions.

*This trial is also available at Massachusetts General Hospital Cancer center. For more information call 877-789-6100.

If you are interested or would like more information about the clinical trials listed, please contact the principal investigator. For a broader listing of treatment protocols, visit our website at www.dfbwcc.org/clinicaltrials.

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