

UPDATE ON TRIALS (March 2010)

Ongoing and Open for Enrollment

Disease	Trial	Trial Design	Eligibility Criteria	Sponsor	PI	Rnurse	Screen Failures	Enrolled	Open to enrollment?	Accrual Goal
Multiple Myeloma	CC-5013-MM-020 (Revlimid + Dex vs. MPT Regimen)	Phase III, Randomized, Open-Label, 3 Arm Study	Untreated MM and either ≥ 65 years or not SCT candidate.	Celgene Corporation	Kevin Song	Cindy Manchulenko	Screen Failures: 6	Screening: 0 Enrolled: 11	Yes	10
	AMD3100-3102 LTF Study	Long-term Follow-Up Study of subjects who received at least 1 dose of AMD3100 or placebo on	Subjects who received at least 1 dose of AMD3100 or placebo on AMD3100-3102 study	Genzyme	Clay Smith	Anna Koochin	N/A	1	Closed	1

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Acute Myeloid Leukemia	CPX-351-205	Phase IIB, Open-Label, CPX-351 (Cytarabine: Daunorubicin) Liposome Injection vs. Cytarabine and Daunorubicin	Age ≥18 and ≤60 years; relapsed AML after initial CR of > 1 month duration; ECOG 0-2; EF > 50%	Celator Pharmaceuticals Inc.	Donna Hogge	Lisa Basque	Screen Failure: 2	Screening: 0 Enrolled: 2	Yes	5
	CBMTG -RICT	Phase III; RICT vs Control group	1st CR; 51-70 years	CBMTG	Donna Hogge	Grace Lee	Pre-Screen Failures :4 Screen Failure: 1	Enrolled: 1	Yes	15
	Molecular Basis of Familial MDS/AML		Familial MDS/AML (affected and unaffected members of families with a history of MDS/AML)	n/a	Cindy Toze	Anna Koochin	0	35	Yes	

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ALL	Adult ALL Trial (AL.5)	Phase II, Open-Label	ALL, excluding mature B-Cell ALL; no prior anti-leukemic tx except ≤ 1 week steroids, radiation tx, or hydra; Age 18-50 years;	NCIC	Yasser Abou Mourad	Lisa Basque	0	5	Yes	5/year
MDS	Romiplostim (AMG 531)	Phase II, Randomized (2:1), Double Blind, Placebo Controlled	Low or intermediate-1 risk MDS; mean of two platelet counts ≤ 20 or ≤ 50 with hx of bleeding	Amgen	Tom Nevill	Grace Lee	Declined:3 Screen Failure: 2	Screening: 0 Enrolled: 3	Yes	6
CML and Ph+ ALL	AMN107 2109	Open-Label, EAP	CML - CP, AP, BC: Resistant or intolerant to Gleevec 600 mg (No prior Dasatinib)	Novartis	Donna Forrest	Cindy Manchulenko	Screen Failures: 2	Enrolled: 4	Yes	5
	CAMN107-2405 Nilotinib vs. Imatinib	Phase III, Open-Label, Randomized Trial Nilotinib vs. Imatinib in patients with persistend CML-CP treated previously by Imatinib	Age ≥ 18 years, CML-CP, Documented CCyR, Persistent disease (documented by 2 PCR positive tests), tx with Imatinib at least 2 years (400mg or 600 mg), no previous TKI tx	Novartis	Donna Forrest	Winnie Wong	Screen Failure: 1 Declined: 4	Screening:1 Enrolled: 6	Yes	10

Supportive Care and BM Transplant	Posaconazole ("Early POS Study")	Phase II, Open-Label	Early Treatment of Refractory Fungal Infections	Shering-Plough Canada Inc.	Maryse Power	Lisa Basque	5	3	1	
Hematology/Apheresis	Dalteparin Sodium Injection (Fragmin)	Open-label, single-arm, phase IV	Age ≥18, newly diagnosed, symptomatic proximal deep-vein thrombosis of the lower extremity, pulmonary embolism, or both, active malignancy.	Eisai Inc.	Agnes Lee	Jill Scott/Davina Gallagher	N/A	1	yes	50

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BM Transplant	G-CSF Mobilized PBSCT vs. G-CSF Stimulated Marrow Transplantation (Related Donors) CBMTG 0601	Phase III, Randomized.	Age 16-65 years, eligible for matched (6/6), related donor transplant	CBMTG/NIH	Cindy Toze	Holly Kerr and Jill Scott	Screen Failures/ Declined/ Ineligible: 15	14	Yes	35
	Hematology Cell Bank			N/A	Clayton Smith	Anna Koochin		Patients Consented: 849 Total Samples Collected to date: 3495	Yes	

Coming Soon

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Multiple Myeloma	Pomalidomide	Phase I/II, Open-Label, Dose-Escalation Study. Phase I: Maximum Tolerated Dose; Phase II: Pomalidomide alone vs. Pomalidomide + Dexamethasone	Relapsed and refractory MM; at least 2 prior therapies; Prior tx with at least 2 cycles of Lenalomide and Bortezomib; No prior hx of other malignancies in the past 3 years; Peripheral neuropathy \leq grade 2	Celgene Corporation	Kevin Song	Cindy Manchulenko	N/A	** Have 8 pt's on waiting list	No ***opening in ~2 weeks	10
	CLBH589-2207	Phase Ib, Open-label, dose escalation study, LBH589 plus IV bortezomib	Relapsed MM; at least 1 prior therapy (prior tx with bortezomib ok); Peripheral neuropathy \leq grade 1	Novartis	Heather Sutherland	Xin Zhou	N/A	N/A	No	2-5
	Carfilzomib + Revlimid + Dex	Phase 3, unblinded study comparing carfilzomib + Rev + Dex VS Rev + Dex in subjects with relapsed MM	Relapsed MM after 1-3 prior therapies.	Proteolix	Kevin Song	Cindy Manchulenko	NA	NA	No	5-10

	Busulfan and bortezomib	Phase 2a, PK directed dose for daily IV busulfan with bortezomib followed by autologous SCT in subjects with relapsed MM after prior auto HSCT to evaluate 6-month response, assess safety profile and the test dose method	Age 18-75, relapsed MM and are eligible for planned auto HSCT, had at least 1 yr prior previous auto HSCT, ECOG 0-2, minimum stem cell dose of 2.0 x 10 ⁶ CD34+ cells/kg collected. Excl: t(4;14) or p53gene del, prior use of busulfan or mylotarg	Otsuka	Kevin Song	Winnie Wong	N/A	N/A	No	2-3
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Acute Myeloid Leukemia	TALL	Open-label, single-arm, for AML/MDS, oral drug temozolomide (Temodal)	Newly diagnosed, untreated AML/MDS, pt's must exhibit low MGMT expression and not suitable for standard induction therapy.	Schering-Plough, part of Merck	Donna Hogge	Cindy Manchulenko	N/A	N/A	No	5
CML and Ph+ ALL	OCT-1	A study investigating the predictive value of intracellular and plasma Imatinib levels in newly diagnosed patients with chronic myeloid leukemia in chronic phase.	Age ≥18, newly diagnosed with CML in chronic phase based on bone marrow aspirate and blood counts. No prior treatment with Imatinib	Hamilton Health Sciences	Donna Forrest	Jill Clark	N/A		No	5

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Hematology/Apheresis	Rituximab	Open-label, single-arm, phase II	<p>Inclusion: ≥18 years; relapsed or refractory TTP-HUS requiring therapy.</p> <p>Exclusion: Alternate cause of hemolytic microangiopathy; Congenital or familial TTP; Drug induced TTP; TTP post transplant; Prior Rituximab tx; Hx Hep B or C;</p>	Canadian Apheresis Group	Paul Yenson	Lisa Basque/Jill Clark	N/A	N/A	No	5
MDS	None at Present									
CML	None at Present									
GVHD	Rituximab for cGVHD	Phase II study of Rituximab combined with Prednisone or Standard Therapy for the Initial Treatment of Chronic Graft vs Host Disease	≥18 years of age, post allogeneic stem cell transplant with previously untreated classical C-GVHD requiring systemic therapy, ECOG 0-2.	University Health Network	Raewyn Broady	Jill Clark	N/A	N/A	No	5

Closed to Enrollment and Ongoing

Disease	Trial	Trial Design	Eligibility Criteria	Sponsor	PI	Rnurse	Enrolled	Off Study	Actively Following Up	Data Locked
Multiple Myeloma	CNT0328 (IL6)	Phase II; Part 1: Open-label, single arm CNT0328 + Velcade; Part 2: Randomized, double-blind, placebo controlled.	Primary refractory disease or disease progression after initial response to 1-3 prior lines of tx. Velcade naïve.	Centocor & Janssen-Ortho	Heather Sutherland	Cindy Manchulenko	12	2	10	NA
	MY.10	Phase III, Randomized: Thalidomide + Prednisone vs. Observation	60-100 days post auto SCT	NCIC	Kevin Song	Grace Lee	8	3	5	
	Doxil-MMY-3001	Phase 2, un-blinded, randomized study for relapsed refractory MM, Randomized to receive either Velcade alone or Doxil + Velcade	Relapsed/refractory MM with 1-3 lines of prior therapy, velcade naïve.	Janssen-Ortho	Heather Sutherland	Cindy Manchulenko	12	12	4	NA
	PX-171-003 Carfilzimidib	Phase II, Open-label, Single-arm Study	Subjects responsive to standard first line therapy and refractory to most current tx; Prior tx with Velcade and Thalidomide or Revlimid	Proteolix, Inc.	Kevin Song	Lisa Basque	6	5	1	

Acute Myeloid Leukemia	CPX-351-204	Phase IIB, Open-Label, CPX-351 (Cytarabine: Daunorubicin) Liposome Injection vs. Cytarabine and Daunorubicin	Age ≥60 and <76; De novo AML or Secondary ML (hx of MDS or myeloproliferative disease): ECOG 0-2; EF >50%; No prior tx for AML (aside from Hydrea)	Celator Pharmaceuticals Inc.	Donna Hogge	Grace Lee	11		11	
	Mylotarg	Phase III, Randomized: SOC vs. SOC + Mylotarg	Previously untreated, de novo AML, < 61 years	NCIC	Tom Nevill	Winnie Wong	25	10	15	
	DTIL3	Phase I/II	Relapsed or refractory, elderly or poor risk AML	n/a	Donna Hogge	Winnie Wong	19	19	0	

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CML and Ph+ ALL	Bosutinib vs. Imatinib	Phase III, Randomized, Open-label, Bosutinib vs. Imatinib	Newly diagnosed Ph+ CML-CP; Previously untreated except hydroa and/or anagrelide.	Wyeth	Donna Forrest	Xin Zhou	3	1	2	No
	AMN107 2303 (CML at diagnosis)	Phase III, Randomized, Nilotinib vs. Imatinib	Newly diagnosed Ph+ CML-CP. Previously untreated except hydroa and/or anagrelide.	Novartis	Donna Forrest	Grace Lee	3	0	3	No
	BMS CA-180035	Phase III, Randomized, BMS 354825	CML - CP, AP, BC: Resistant or intolerant to Imatinib	Bristol Meyers Squibb	Donna Forrest	Xin Zhou	3	2	1	No

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	G-CSF Mobilized PBSCT vs. Marrow Transplantation (Unrelated Donors) BMT CTN 0201	Phase III, Randomized	Up to 66 years of age, eligible for matched, unrelated donor transplant	NIH/NMDP	Cindy Toze	Holly Kerr and Jill Scott	1			