

## UPDATE ON TRIALS (April 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 $\geq 65$ years or not SCT candidate.	Celgene Corporation	Kevin Song	Cindy Manchulenko	Screen Failures: 6	Screening: 0 Enrolled: 11	Yes	10
	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 <b>and</b> Bortezomib; No prior hx of other malignancies in the past 3 years; Peripheral neuropathy $\leq$ grade 2	Celgene Corporation	Kevin Song	Cindy Manchulenko	8	2	Yes	10

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<b>Acute Myeloid Leukemia</b>	CPX-351-205	Phase IIB, Open-Label, CPX-351 (Cytarabine: Daunorubicin) Liposome Injection vs. Cytarabine and Daunorubicin	Age ≥18 and ≤60 years; <b>relapsed</b> 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	
<b>ALL</b>	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	1	7	Yes	5/year
<b>MDS</b>	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

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<b>CML and Ph+ ALL</b>	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 persistent 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
<b>Supportive Care and BM Transplant</b>	Posaconazole ("Early POS Study")	Phase II, Open-Label	Early Treatment of Refractory Fungal Infections	Shering-Plough Canada Inc.	Maryse Power	Lisa Basque	Screen Failure: 3	5	yes	10

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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
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	Hematology Cell Bank			N/A	Clayton Smith	Anna Koochin		Patients Consented: 874 Total Samples Collected to date: 3582	Yes	

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Coming Soon

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<b>Multiple Myeloma</b>	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	Xin Zhou	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 $2.0 \times 10^6$ 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
Hematology/Apheresis	Rituximab	Open-label, single-arm, phase II	<b>Inclusion:</b> ≥18 years; relapsed or refractory TTP-HUS requiring therapy. <b>Exclusion:</b> Alternate cause of hemolytic microangiopathy; Congenital or familial TTP; Drug induced TTP; TTP post transplant; Prior Rituximab tx; Hx Hep B or C;	Canadian Apheresis Group	Paul Yenson	Lisa Basque	N/A	N/A	No	5

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<b>MDS</b>	None at Present									
<b>CML</b>	None at Present									
<b>GVHD</b>	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	Winnie Wong	N/A	N/A	No	5

## UPDATE ON TRIALS (April 2010)

### Closed to Enrollment and Ongoing

Disease	Trial	Trial Design	Eligibility Criteria	Sponsor	PI	Rnurse	Enrolled	Off Study	Actively Following Up	Data Locked
<b>Multiple Myeloma</b>	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
	AMD3100-3102 LTF Study	Long-term Follow-Up Study of subjects who received at least 1 dose of AMD3100 or placebo on AMD3100-3102 study	Subjects who received at least 1 dose of AMD3100 or placebo on AMD3100-3102 study	Genzyme	Clay Smith	Anna Koochin	N/A	1	<b>Closed</b>	1

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	PX-171-003 Carfilzomib	Phase II, Open-label, Single-arm Study	Subjects responsive to standard first line therapy and refractory to most current tx; Prior tx with Velcade <b>and</b> 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; <b>De novo AML or Secondary ML</b> (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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<b>CML and Ph+ ALL</b>	Bosutinib vs. Imatinib	Phase III, Randomized, Open-label, Bosutinib vs. Imatinib	Newly diagnosed Ph+ CML-CP; Previously untreated except hydra 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 hydra 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
	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			