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DEPARTMENT OF LYMPHOMA & MYELOMA CLINICAL TRIALS

JUNE 2006

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History®

LARRY W. KWAK, M.D., PH.D.
 Department Chairman

The Department of Lymphoma and Myeloma is one of the largest programs of its kind—more than 1,200 new patients are seen annually. Our research activities continue to grow at a steady pace with more complex, intense and intricate studies. This level of research, patient care and clinical trials conducted each year contribute to the exceptionally high degree of skill and experience in diagnosing and treating lymphoma and myeloma patients.

HODGKIN LYMPHOMA TEAM



We would like to introduce you to members of our Hodgkin Lymphoma Team: (left – right) Shellie Tingle, Research Nurse; Mona Gilliam, Advanced Practice Nurse; Michelle Fanale, M.D.; Amy Wedgewood, Advanced Practice Nurse; Hiroe Nakamura, Senior Research Data Coordinator; and Team Leader Anas Younes, M.D.

ANAS YOUNES, M.D.
 Director of Clinical Investigation
 and Translational Research
 Focus on Hodgkin Lymphoma

In this issue of the Department of Lymphoma and Myeloma's Clinical Trials newsletter, we are pleased to report that our Hodgkin lymphoma clinical trial program incorporates a variety of novel promising therapies.

Our clinical trials for Hodgkin lymphoma offers treatment options to 1) newly diagnosed patients with poor-risk features (Rituximab + ABVD); 2) Salvage therapy prior to stem cell transplant (ICE with platelet growth factor support AMG531); and 3) novel new drugs program for patients who relapse after stem cell transplant (Campath, HSP-90 inhibitor 17-AAG, anti-IL13 monoclonal antibody, anti-CD30 monoclonal antibody in combination with gemcitabine, MCG103 HDAC inhibitor, and anti-Bcl protein small molecule inhibitor).

For details and for more information about available and upcoming protocols, our Hodgkin Lymphoma Team Leader Anas Younes, M.D., can be contacted at ayounes@mdanderson.org. Hodgkin Team Member Michelle Fanale, M.D., can be contacted at mfanale@mdanderson.org. Both can also be reached by telephone at 713.792.2860.

As always, our faculty are willing to accept patient referrals of all disease types, including Hodgkin lymphoma. Please feel free to contact the Principal Investigator or any faculty member to inquire on these treatments or to make a referral. A complete list of our faculty and their contact information is shown elsewhere in this Newsletter.

We look forward to working with you and assisting you in taking care of your Hodgkin lymphoma patients.

Hodgkin Lymphoma Disease Presentation	Current Clinical Trial	Major Inclusion Criteria	Principal Investigator
Newly diagnosed with poor risk features (IPS score 3 or higher)	Rituxan + ABVD	Stage 2 bulky, 3, or 4 with poor risk features	A. Younes
Relapsed/Refractory Pre-Transplant	ICE + platelet growth factor AMG531	Relapsed or refractory classical Hodgkin lymphoma	M. Fanale
Relapsed, Post Stem Cell Transplant	Anti-IL13 monoclonal antibody	No limit to prior treatment regimens, Platelet count > 50 K	A. Younes
	17-AAG (Anti heat shock protein-90 small molecule)	No limit to prior treatments, No lung or cardiac disease	A. Younes
	Campath	No limit to prior treatment regimens, No extranodal disease	A. Younes
	Anti-CD30 plus gemcitabine	No limit to prior therapy, Platelet count > 100,000	M. Fanale
	GX15-070MS (Anti Bcl-protein family small molecule)	No limit to prior regimens, No limit to platelet counts	A. Younes
	MG-0103 (Histone deacetylase inhibitor, oral formulation)	No limit to prior therapy Platelets > 25,000	A. Younes

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UNTREATED DISEASE	SHORT TITLE	PHASE	PRINCIPAL INVESTIGATOR
HODGKIN LYMPHOMA:			
	Rituxan + ABVD	II	Younes
LYMPHOMA – LOW GRADE / FOLLICULAR:			
	High Risk Follicular Lymphoma (R-FND, Zevalin, then Rituxan)	II	McLaughlin
	Biovaxid Vaccine s/GM-CSF in first remission	III	Neelapu
LYMPHOMA – INTERMEDIATE / HIGH GRADE:			
	Aggressive B-Cell NHL (R-CHOP + Peg Lipo Doxorubicin)	II	Rodriguez
	DLBCL > 65 years (R-CHOP/Zevalin)	II	Rodriguez
	Aggressive B-Cell NHL < 60 years	II	Fayad
PERIPHERAL T-CELL LYMPHOMA:			
	Newly DX (Hyper CVIDD)	II	Pro
PREVIOUSLY TREATED DISEASE	SHORT TITLE	PHASE	PRINCIPAL INVESTIGATOR
HODGKIN LYMPHOMA:			
	17-AAG	II	Younes
	Campath	II	Younes
	Anti-IL13	I/II	Younes
	Gemcitabine + anti CD30	II	Fanale
	ICE + platelet growth factor	I/II	Fanale
	GX15-070MS	II	Younes
	MGCD0103	II	Younes
LYMPHOMA – INTERMEDIATE / HIGH GRADE:			
	Rituxan-Ref'y aggressive B-Cell LCL/MCL (Avastin + Rituxan)	II	Pro
	Anti-hu CSD0 MAb SGN-40	I	Younes
	Single Dose Escalation Study, BI 2536 BS	I	Younes
	SGN 30 (Anti CD30mAb) Relapsed non Sclerosing	II	Younes
	17-AAG	II	Younes
	B-Cell NHL + CLL (CCI-779)	II	Pro
	NHL Dose Escalation/Safety Tolerance Study (PPI-2458)	I	Fayad
	Depsipeptide in Diffuse Large-Cell or Relapsed Mantle Cell NHL	II	Fayad
	hA20 for CD20+ B-Cell NHL	I	Fayad
	NHL - CNTO 328 (Anti IL-6)	I	Kurzrock
	MGCD0101 (HDAC Inhibitor)	II	Younes

PREVIOUSLY TREATED DISEASE	SHORT TITLE	PHASE	PRINCIPAL INVESTIGATOR
LYMPHOMA – LOW GRADE:			
	MGCD0103	II	Younes
	Low Grade B-Cell NHL (Nipent, Cytoxan, Rituxan)	II	Samaniego
	NHL Dose Escalation/Safety Tolerance Study (PPI-2458)	I	Fayad
	B-Cell NHL + CLL (CCI-779)	II	Pro
	Zevalin in Relapsed/Refractory Non-Follicular, Indolent B-Cell	II	Samaniego
	NHL - CNTO 328 (Anti IL-6)	I	Kurzrock
MANTLE CELL LYMPHOMA:			
	17-AAG	II	Younes
	Zevalin in Relapsed or Refractory Mantle Cell Lymphoma	II	Younes
	Rituxan for Relapsed or Aggressive Mantle Cell	II	Romaguera
	Anti-huCD40 mAb SGN-40 in NHL	I	Younes
	Single Dose Escalation Study, BI 2536 BS	I	Younes
	Rituxan-Refractory Aggressive B-Cell LCL/MCL – (Avastin + Rituxan)	II	Pro
	Epothilone B (BMS 247550) in Aggressive NHL	II	Pro
	CCI-779 vs Investigator Choice for Relapsed MCL	III	Romaguera
	CC-5013 and Rituxan, Relapsed MCL	I-II	Wang
	Depsipeptide in Diffuse Large Cell or Relapsed MCL	II	Fayad
	NHL - CNTO 328 (Anti IL-6)	I	Kurzrock
MYELOMA / WALDENSTROM'S:			
	Amplimexon in Previously Treated Multiple Myeloma	I/II	Weber
	SAHA + Bortezomib in Advance Myeloma	I	Weber
	AMG 162 in Myeloma	II	Vadhan
	Lenalidomide + Dexamethasone in Previously Treated – Multiple Myeloma	I	Weber
	Oral Antiprimod in Relapsed or Refractory Myeloma	I	Talpaz
	NHL- CNTO 328 (Anti IL-6)	I	Kurzrock
ORBITAL LYMPHOMA:			
	Zevalin- for Low-Grade Follicular NHL of the Orbit	PILOT	Esmaeli
PERIPHERAL T-CELL LYMPHOMA:			
	MEDI-507 for CD2+ T-Cell Lymphoma or Leukemia	I	Pro
	Single Dose Escalation Study, BI 2536 BS	I	Younes
RADIATION / LYMPHOMA:			
	Radiation therapy alone for Stage 1 & 2 MALT	Other	Ha
	Pre-XRT Chemotherapy w/Methotrexate, Rituximab and Temozolomide; and Post-XRT Temozolomide in primary CNS	I/II	Ha
	Rituximab + Temozolomide in prior treated primary CNS lymphoma	II	Hs
SUPPORTIVE CARE PROTOCOLS:			
	Zometa and Bone Mineral Density – Lymphoma	N/A	Hagemester