Welcome to the Spring 2014 Stanford Cancer Institute Clinical Research Newsletter! This quarterly publication is designed to inform our colleagues in the medical community, and especially physicians who are considering treatment options for their patients with cancer, about current clinical trials and research studies available at the Stanford Cancer Institute. Many of these trials provide access to novel therapies including new “targeted” agents, often not available in the community.

As the director of the Stanford Blood and Marrow Transplant (BMT) program, I am pleased to introduce this issue presenting Stanford’s BMT, Lymphoma, and Hematology programs. Each of our featured programs is nationally recognized for improving patient outcomes by translating clinical research into new treatments.

Our BMT Program offers cutting edge medicine and excellent long-term follow up care to patients with a variety of malignant and non-malignant diseases. We support cross-disciplinary research into the molecular and genetic underpinnings of hematological disorders. In collaboration with the Center for Clinical Immunology at Stanford, the program is developing new ways to boost the immune tolerance of transplanted blood or marrow-derived stem cells.

The Stanford Lymphoma Program offers multidisciplinary, personalized diagnostics and treatment for patients with Non-Hodgkin’s Lymphoma (NHL) and Hodgkin’s Disease. For over 50 years Stanford researchers and clinicians have helped define the standard of care for lymphomas, pioneering breakthrough immunotherapies and monoclonal antibodies. This innovative program continues its groundbreaking work including a vaccine trial to treat follicular NHL and trials of targeted therapies.

The Stanford Hematology Program offers state-of-the-art diagnostics, clinical trials and treatment regimens for patients with a variety of hematologic disorders. Clinical trial offerings include early stage trials of novel agents to late stage randomized trials comparing different therapies. Hematologists work closely with specialists in BMT, infectious diseases, radiation oncology, and interventional radiology. This program is committed to improving outcomes and quality of life through contributions to the prestigious National Comprehensive Cancer Network (NCCN) guidelines and the Southwest Oncology Group (SWOG).

Phase 1 and 2 trials from our Developmental Therapeutics Program are also included in the newsletter. This program includes physician researchers in various areas of oncology, all interested in developing novel anticancer therapies.

We hope that when you deem it appropriate to refer a patient to an academic medical facility, you will consider the NCI-designated Stanford Cancer Institute for one of our more than 300 clinical trials. We, in turn, will make every effort to deliver great care to your patient, keep you informed of the patient’s treatment and response, and work closely with you and your staff to coordinate returning the patient to your care.

Robert Negrin, MD
Professor of Medicine
Division Chief, Blood and Marrow Transplantation
The Stanford Lymphoma Program is an international leader in lymphoma research offering a multidisciplinary, personalized approach to diagnostics and treatment for patients with Non-Hodgkin’s Lymphoma (NHL) and Hodgkin’s Disease (HD).

For over 40 years Stanford researchers and clinicians have helped to define the standard of care for lymphomas worldwide, pioneering breakthrough immunotherapies and monoclonal antibodies and offering advanced treatments that are not yet available at other institutions. In addition, the program offers national cooperative group clinical trials that lead the integration of new drugs and imaging techniques into front-line therapy.

**LEADING EDGE RESEARCH**
Stanford Lymphoma Program members focus their research on lymphoma pathogenesis; diagnostic and therapeutic profiling of lymphoma subtypes; novel diagnostics and immunotherapeutics; Phase I and II clinical trials; cancer survivorship; and cutaneous lymphomas.

**RESEARCH HIGHLIGHTS INVOLVE**
- The discovery of Rituximab, a revolutionary lymphoma treatment and the best biological therapy available today to treat lymphoma.

Stanford Cancer Institute researchers and physicians discovered the therapeutic effects of this monoclonal antibody and have been instrumental in developing its many applications. Some of the earliest Rituximab trials were carried out by Stanford physicians, with their patients having early access to this groundbreaking treatment. Two ongoing trials are now attempting to further increase the power of Rituximab by targeting the body’s immune response.

- Continuing Innovation. Stanford lymphoma research focuses on:
  - A vaccine strategy to treat follicular NHL that is based on a combination of low dose radiation to one site of tumor and the injection of an immune stimulant directly into that same site. An immune response ensues against the tumor and attacks the tumor throughout the body.
  - An innovative clinical trial combining immunotherapy with hematopoietic stem cell...
transplantation for Mantle Cell Lymphoma. This trial is also developing a highly sensitive method of detecting disease relapse prior to current imaging or laboratory tests.

— Clinical trials of antibodies conjugated to a drug and directed against a target on lymphoma cells. One example is Brentuximab vedotin (now known as Adcetris) that is revolutionizing the treatment of recurrent Hodgkin’s Disease. Other such agents are under study for Non-Hodgkin’s Lymphoma.

— Clinical trials of novel orally administered drugs that target the signaling molecules (BTK, SYC and PI3Kinase) inside lymphoma cells that are responsible for their uncontrolled growth. One example targeting BTK is Ibrutinib (now known as Imbruvica) that is similarly revolutionizing the treatment of Non-Hodgkin’s Lymphoma, specifically Mantle Cell Lymphoma and Chronic Lymphocytic Leukemia.

— Clinical trials of immune checkpoint modulators that “take the brakes off or push on the gas pedal” of the body’s immune response against the lymphoma cells. Novel trials are attempting to remove the suppressive T cells inside the lymph nodes (targeting CTLA-4), increase the strength of the tumor killing T cells (targeting PD-L1), and enhance the power of the immune response following rituximab treatment (targeting CD137).

• Cutaneous lymphoma research that includes:
  — Traditional therapies used more effectively. This has been exemplified by the modification of Stanford’s total skin electron beam therapy (TSEBT), known as the “Stanford TSEBT technique”, by reducing the total dose by two-thirds and combining with a potential radiation-enhancing systemic agent, such as a histone deacetylase inhibitor. This novel low-dose total skin electron beam therapy results in dramatic clearing of disease with significantly less toxicity.
  — A collaboration with genomics groups at Stanford to decipher the molecular mechanism of cutaneous lymphoma and discover new molecular targets for development of newer therapies.
  — Novel allogeneic HSCT regimen utilizing preparatory regimen of TSEBT, total lymphoid irradiation (TLI) and anti-thymocyte (ATG). TLI/ATG conditioning results in effective graft versus lymphoma effect with reduced complication of graft versus host disease. The TSEBT contributes towards more effective elimination of tumor cells in the skin, a site where response has eluded systemic therapies.

• Genetics. Genome sequencing to more rapidly identify the unique mutations in each patient’s tumor. Recent identification of a set of two genes whose expression predicts survival in diffuse large B cell lymphoma (DLBCL), the most common form of non-Hodgkin’s lymphoma. This new test identifies which patients need more aggressive therapy.

TRANSLATIONAL RESEARCH: ADVANCED TREATMENT, CUSTOMIZED CARE

The Lymphoma Program also includes an array of features demonstrating its dedication to translational research and customized care. Among these highlights are:

• Advanced therapies for NHL comprising:
  — Blood and marrow transplants
  — Immunotherapy
  — Experimental treatments through clinical trials
Stanford Lymphoma Program continued

• Advanced treatments for HD focusing on:
  — A unique and highly curative chemotherapy/radiotherapy program known as Stanford V (five).
  — Biologic therapy development focusing on monoclonal antibodies and antibody-drug conjugates.

• Innovative cutaneous lymphoma treatments and technologies:
  — Targeted therapies that attack tumor surface proteins, aberrant epigenetic regulation, signaling or cell survival pathways, or microenvironment.
  — Mogamulizumab (KW-0761), a bioengineered, humanized monoclonal antibody against CCR4, selectively expressed on tumor cells.
  — Brentuximab vedotin, an antibody-drug-conjugate that targets CD30, commonly expressed on tumor cells in cutaneous T-cell lymphomas.
  — Improved denileukin diftitox, a fusion toxin of IL-2R and diphtheria toxin, which targets CD25 on CTCL cells surface. It may also deplete Treg cells leading to immune enhancement of anti-tumor activity.
  — Low-dose (12 Gy) total skin electron beam therapy combined with vorinostat, a potentially radiation enhancing agent, to reduce overall toxicity of radiation while improving efficacy.
  — Pralatrexate, a newer anti-folate agent, combined with oral bexarotene, that demonstrates synergistic efficacy.
  — Novel/newer topical agents including topical histone deacetylase inhibitors and immune checkpoint monoclonal antibodies.
  — Non-myeloablative allogeneic hematopoietic stem cell transplantation using total skin electron beam therapy, total lymphoid irradiation, and anti-thymocyte globulin as novel preparatory regimen for patients with mycosis fungoides and Sezary syndrome.
  — Newer techniques utilizing rapid molecular diagnostic methods or new immunostains for earlier and more accurate diagnosis.

• Blood and marrow transplantation (BMT), with the single largest group of patients being treated with allogeneic or autologous marrow grafting. Among Stanford innovations is the non-myeloablative allogeneic transplant, an outpatient procedure with limited side effects and minimal need for hospitalization. Stanford researchers are also investigating the efficacy of vaccine therapy concurrent with autologous BMT to prevent relapse, as well as after allogeneic BMT as treatment for relapsed lymphoma.

• A clinical database offering diagnostic results, treatment, and outcomes for more than 10,000 lymphoma and 5,000 Hodgkin’s Disease patients.

• New types of imaging that use new radiologic tracers for better delineation of disease.

• Multidisciplinary tumor boards, including:
  — HD tumor board that meets weekly involving physicians from the Division of Oncology, and the Department of Radiation Oncology, along with radiologists and pathologists to review newly diagnosed, complex patients.
  — Cutaneous lymphoma tumor board that meets twice a week and is jointly directed by the Departments of Dermatology and Radiation Oncology. This multidisciplinary clinic also involves physician partners in Medical Oncology, Dermatopathology, and BMT, to provide the most comprehensive evaluation and management.
STUDIES INCLUDE

Hodgkin’s Disease

• A Phase II Trial of Sequential SGN-35 Therapy with Adriamycin, Vinblastine, and Dacarbazine (S-AVD) for Older Patients with Untreated Hodgkin Lymphoma (LYMHD0009)

• A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients with Advanced Classical Hodgkin Lymphoma (LYMHD0011)

• A Phase I/II Single-Arm, Open-Label Study to Evaluate the Safety and Efficacy of Brentuximab Vedotin in Combination with Bendamustine in Patients with Relapsed or Refractory Hodgkin Lymphoma (HL) (LYMHD0012)

Non-Hodgkin’s Lymphoma

• E2408, A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs Bortezomib-BR (BVR) Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma (ECOGE2408)

• A Phase 2 Study of Brentuximab Vedotin in Combination with Standard of Care Treatment (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone [RCHOP]) as Front-Line Therapy in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) (LYMNHL0112)

• FLT-PET/CT vs FDG-PETCT for Therapy Monitoring of Diffuse Large B-cell Lymphoma (LYMIMG0001)

• Phase I/II Study of a CpG-Activated Whole Cell Vaccine Followed by Autologous “Immunotransplant” for Mantle Cell Lymphoma (LYMNHL0040-BMT212)

• A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton’s Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Bendamustine and Rituximab (BR) in Subjects with Newly Diagnosed Mantle Cell Lymphoma (LYMNHL0107)

• A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study (LYM0006-EXT)

• A Phase I Study of PF-05082566 as a Single Agent in Patients with Advanced Cancer, and in Combination with Rituximab in Patients with Non-Hodgkin’s Lymphoma (NHL) (LYMNHL0092)

• A Phase II Study of Brentuximab Vedotin in Relapsed or Refractory CD30-Positive NHL (LYMNHL0093)

• An Open-Label, Treatment-Option Protocol of Brentuximab Vedotin in Patients with Relapsed or Refractory Hodgkin Lymphoma, Systemic Anaplastic Large Cell Lymphoma, or CD30-Positive Cutaneous T-cell Lymphoma (LYMNHL0095-EXT)

• A Phase 1, Open-Label, Placebo-controlled, Dose-Escalating Phase IB Study to Assess the Safety, Pharmacodynamics and Pharmacokinetics of SHP-141, A Histone Deacetylase Inhibitor, Administered Topically

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• highlighted studies are Stanford investigator initiated
The Stanford Blood and Marrow Transplant (BMT) program is a nationally recognized authority in BMT research, and the largest BMT program in Northern California. Stanford BMT clinical trials ensure the smooth translation of research findings into the most advanced patient care available today.

For more than 25 years, with its cutting edge medicine, excellent long-term follow up care of patients, and multidisciplinary team of specialists, the BMT Program treats patients from around the world with a variety of malignant and non-malignant diseases, including lymphoma, myeloma, leukemia, myelodysplastic syndrome, and selected solid tumors.

**STANFORD BMT RESEARCH DISCOVERIES, NEW THERAPIES WITH GLOBAL IMPACT**

In addition to successful clinical practice, Stanford BMT researchers are converting their discoveries into new therapies, advancing the efficacy of hematopoietic cell transplantation for patients worldwide.

The BMT Program supports cross-disciplinary research into the molecular and genetic underpinnings of hematological disorders, improving patient outcomes by translating clinical research into new treatments. In collaboration with the Center for Clinical Immunology at Stanford, the program is developing new ways to boost the immune tolerance of transplanted blood or marrow-derived stem cells. Furthermore, its state-of-the-art laboratory is exploring novel cellular and vaccine-based therapies that target hematologic disease at its most basic origins.

**STANFORD BMT CUTTING EDGE RESEARCH FOCUSES ON**

- Cellular Therapeutics – translational research investigating specific cell populations, such as regulatory T-cells, cytokine induced killer (CIK) cells, tumor vaccines, memory T-cells and hematopoietic stem cells.
- Investigations of novel approaches to the prevention and treatment of Graft-vs.-host disease (GVHD).
- Haploidentical hematopoietic cell transplantation.
- Novel TLI/ATG allogeneic preparative regimen that reduces rates of GVHD and lowers transplant-related risks in select disease types.
- Tolerance induction with combined bone marrow solid organ transplantation.
STANFORD BMT – DISTINCT FEATURES
The BMT program has been very successful with a history of limited morbidity rates and acute mortality that is well below most published reports. Some of its many highlights include:

• Inpatient and Outpatient Transplants.
  — Stanford has expertise in managing all transplant types—autologous, allogeneic-related donor and allogeneic-unrelated donor—and in handling the most complicated cases.
  — Stanford has provided transplants to more than 4500 adult patients and performs over 300 transplants annually, with almost one-half performed in its outpatient Infusion Treatment Area with no scheduled inpatient admission.
  — Stanford has a dedicated 22-bed inpatient BMT unit, staffed by nurses who specialize in the care of BMT patients. All rooms are equipped with special HEPA filtration systems.

• Physician Expertise.
  — Twelve physicians focus exclusively on BMT with a dedicated Immunocompromised Host Infectious Disease service.
  — Patient follow up occurs over the long-term to provide support and consultation and to accurately reflect long-term outcomes, with ongoing tracking of over 90% of patients.

• Dedicated BMT Laboratory. Specialties include:
  — Good Tissue Practice/Good Manufacturing Practice processing capabilities and state-of-the-art technologies.
  — High speed cell sorting holding great promise for future treatment and prevention of graft-vs.-host disease (GVHD).

• FACT Accreditation. Stanford’s BMT program is fully accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) and is a member of the BMT Clinical Trials network.

• National Marrow Donor Program (NMDP) accredited transplant center, apheresis center, and collection center. Stanford’s Blood and Marrow Transplant group was recently recognized by the National Marrow Donor Program for collecting over 250 peripheral blood stem cell collections for marrow transplant. Since its start in 1987, the Stanford BMT team has collected over 400 donations. BMT also received special recognition for excellence in performance surrounding donor care, product integrity, data submission, and overall service.

• Community Involvement. Faculty and Staff collaborate with patients, their families, and the medical community by contributing to the global discussion on key biomedical and technological issues shaping the future of blood and marrow transplantation. This includes:
  — Regularly conducting educational seminars for participants in the Leukemia and Lymphoma Society’s Team in Training, American Cancer Society, the Bay Area Multiple Myeloma Support Group, the Fattal Foundation, and medical audiences at community hospitals and Grand Rounds across the country.
  — Actively participating in the American Society of Blood and Bone Marrow Transplantation, the American Society of Hematology, and other organizations.

STUDIES INCLUDE
• Allogeneic Hematopoietic Cell Transplantation Using a Non-Myeloablative Preparative Regimen of Total Lymphoid Irradiation and Anti-Thymocyte Globulin for Older Patients with Hematologic Malignancies (BMT153)

• **highlighted studies are Stanford investigator initiated**
• Total Lymphoid Irradiation and Anti-Thymocyte Globuline as Conditioning for Non-Myeloablative Allogeneic Hematopoietic Cell Transplantation for the Treatment of Myelodysplastic Syndromes and Myeloproliferative Disorders (except CML) (BMT168)

• Autologous Followed by Non-myeloablative Allogeneic Transplantation for Non-Hodgkin’s Lymphoma (BMT185)

• Defibrotide for Hematopoietic Stem Cell Transplant (SCT) Patient with Severe Hepatic Veno-occlusive Disease (VOD): A Treatment IND Study (BMT196)

• A Phase II Study of Non-myeloablative Allogeneic Transplantation Using Total Lymphoid Irradiation (TLI) and Antithymocyte Globulin (ATG) in Patients with Cutaneous T Cell Lymphoma (BMT206)

• A Randomized Phase II Study of Imatinib and Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Cell Transplantation (BMT211)

• Post Transplant Infusion of Allogeneic Cytokine Induced Killer Cells as Consolidate Therapy after Non-Myeloablative Allogeneic Transplantation in Patients with Myelodysplasia or Myeloproliferative Disorders (BMT217)

• Intratumoral Injection of an Immunostimulatory CpG, SD-101, Combined with Local Radiation for the Treatment of Recurrent or Progressive Lymphoma after Allogeneic Hematopoietic Cell Transplantation (BMT235)

• Phase I/II Trial for Patients with Advanced Hematologic Malignancies Undergoing Myeloablative Allogeneic HCT with a T cell Depleted Graft with Simultaneous Infusion of Conventional T Cells and Regulatory T Cells (BMT236)

• A Phase III, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of BAL8557 versus a Caspofungin Followed by Voriconazole Regimen in the Treatment of Candidemia and Other Invasive Candida Infections (BMT239U)

• A Randomized, Prospective, Double Blind, Placebo Controlled, Phase III Study of US-ATG-F Prophylaxis as a Supplement to Standard of Care Prophylaxis to Prevent Moderate to Severe Chronic GVHD in Adult Acute Myeloid Leukemia, Acute Lymphoid Leukemia, and Myelodysplastic Syndrome Patients after Allogeneic Stem Cell Transplantation from Unrelated Donors (BMT240)

• A Phase 1, Open-Label, Multicenter, Dose-Escalation Study to Evaluate the Safety and Tolerability of Intravenous Administration of RGI-2001 in Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplantation (AHSCT) (BMT241)

• Early Behavioral Intervention in BMT Recipients with Sleep Disturbance: Assessing Its Impact on Quality of Life, Fatigue and Cognitive Function (BMT242)

• A Phase I Study of CD8+ Memory T-Cell Donor Lymphocyte Infusion for Relapse of Hematolymphoid Malignancies Following Matched Related Donor Allogeneic Hematopoietic Cell Transplantation (BMT243)

• A Multi-Center, Phase III, Randomized Trial of Reduced Intensity Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood versus HLA-Haploidentical Related Bone Marrow for Patients with Hematologic Malignancies (BMT248)

• A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy and Safety of a Therapeutic Vaccine, ASP0113, in Cytomegalovirus (CMV)-Seropositive Recipients Undergoing Allogeneic, Hematopoietic Cell Transplant (HCT) (BMT253)
Stanford Cancer Center’s Developmental Therapeutics Program, led by Branimir I. Sikic, MD, offers Phase 1 and 2 clinical trials using novel therapeutics.

Dr. Sikic’s clinical interests are mainly in ovarian cancers and cancers of unknown primary. Other faculty participating in this effort include Drs. Heather Wakelee and Joel Neal (lung cancers), Dimitri Colevas (head and neck cancers), George Fisher and Pamela Kunz (GI cancers), Mark Pegram and Melinda Telli (breast cancers), Sunil Reddy (melanoma), and Ranjana Advani and Holbrook Kohrt (lymphomas).

As a translational clinical studies program, Developmental Therapeutics brings together outstanding physicians with internationally regarded scientists to develop novel therapies and diagnostic modalities that utilize cutting-edge science and technologies. This research focuses on early clinical studies, investigator-initiated trials, the development of analytic approaches to enhancing the discovery of drugs and targets, and the analysis of clinical trials.

Below is a current sampling of available Phase 1 and Phase 2 studies.

**PHASE 1 STUDIES**

**Multiple Solid Tumor Sites**

- A Phase I, Open-Label, Dose-escalation Study of the Safety and Pharmacokinetics of MPDL3280A Administered Intravenously as a Single Agent to Patients with Locally Advanced or Metastatic Solid Tumors (VAR0082)

- A Phase I, Open-label, Dose-escalation, Safety and Pharmacokinetic Study of CDX-1127 in Patients with Selected Refractory or Relapsed Hematologic Malignancies or Solid Tumors (VAR0081)

- A Phase I Study of the Safety, Tolerability, Pharmacokinetics and Immunoregulatory Activity of BMS-663513 (Anti-CD137) in Subjects with Advanced and/or Metastatic Solid Tumors (VAR0071)

**Lymphomas**

- A Phase I Study of PF-05082566 as a Single Agent in Patients with Advanced Cancer, and in Combination with Rituximab in Patients with Non-Hodgkin’s Lymphoma (NHL) (LYMNHL0092)

- A Phase I/II Study of Intratumoral Injection of Iplilimumab in Combination with Local Radiation in Melanoma, Non-Hodgkin Lymphoma and Colorectal Carcinoma (VAR0090)

**PHASE 2 STUDIES**

**Thymic Cancers**

- A Phase 2 Study of Amrubicin in Relapsed or Refractory Thymic Malignancies (THOR0003)

**Small Cell Lung Cancer and Other High-Grade Neuroendocrine Tumors**

- A Phase IIa Intrapatient Dose Escalation Study of Desipramine in Small Cell Lung Cancer and Other High-Grade Neuroendocrine Tumors (VAR0087)

**highlighted studies are Stanford investigator initiated**
The Stanford Hematology Program is heavily invested in clinical research, including early stage trials of novel drugs and late stage, randomized trials comparing different therapies. It offers state-of-the-art diagnostics in collaboration with colleagues in hematopathology and is increasing the incorporation of molecular testing in both its diagnostic and therapeutic programs.

The Hematology program has very active research and treatment programs for a variety of hematologic disorders, including acute and chronic leukemias (ALL, AML, CLL, CML), multiple myeloma, amyloidosis, myelodysplastic syndromes, and myeloproliferative disorders.

Multi-disciplinary collaboration is often required to guide diagnosis and treatment. The program partners with infectious disease, transplant, and other physician specialists throughout the continuum of care of an individual patient.

The Hematology Program also offers consultative services for benign hematologic disorders including anemias, thrombotic disorders, and bleeding problems.

**STUDIES INCLUDE**

**Acute Myeloid Leukemia (AML)/Myelodysplastic Syndromes (MDS)**

- Azacitidine plus Lenalidomide Combination in Elderly Patients with Previously Treated AML and High-Risk MDS (VIREL2 Trial) (HEM0022)
- A Phase IB/II Study to Evaluate the Safety and Efficacy of Vismodegib in Relapsed/Refractory Acute Myelogenous Leukemia (AML) and Relapsed/Refractory High-Risk Myelodysplastic Syndrome (MDS) (HEM0035)
- A Phase Ib, Dose-Finding Study of Oral Panobinostat (LBH589) in Combination with
Idarubicin and Cytarabine Induction and High- 
Dose Cytarabine-Based Consolidation Therapy 
in Adult Patients Less Than or Equal to 65 
Years Old with Acute Myeloid Leukemia (AML) 
(HEMAML0015)

• A Phase 2, Multicenter, Randomized, Open-
Label, Parallel-Group Study of a Lenolidomide 
(Revlimid®) Regimen or a Sequential Azacitidine 
(Vidaza®) Plus Lenolidomide (Revlimid®) 
Regimen Versus an Azacitidine (Visada®) 
Regimen for Therapy of Older Subjects with 
Newly Diagnosed Acute Myeloid Leukemia 
(HEMAML0016)

• Phase III, Multicenter, Randomized, Trial of 
CPX-351 (Cytarabine:Daunorubicin) Liposome 
Injection versus Cytarabine and Daunorubicin in 
Patients 60-75 Years of Age with Untreated High 
Risk (Secondary) AML (HEMAML0019)

• A Phase 1b, Open-Label, Dose-Escalation Study 
of MLN4924 Plus Azacitidine in Treatment-Naïve 
Patients with Acute Myelogenous Leukemia Who 
Are 60 Years or Older (HEMAML0021)

• A Phase II Study of Decitabine in Combination 
with Midostaurin (PKC412) for Elderly Patients 
with Newly Diagnosed FLT3-ITD/TKD Positive 
Acute Myeloid Leukemia (AML) (SWOGS0919)

• A Randomized Phase III Study of Standard 
Cytarabine plus Daunorubicin (7+3) Therapy or 
Idarubicin with High Dose Cytarabine (IA) versus 
IA with Vorinostat (IA+V) in Younger Patients with 
Previously Untreated Acute Myeloid Leukemia 
(AML) (SWOGS1203)

• A Single-arm Study to Assess the Efficacy 
and Safety of Oral Rigosertib in Transfusion-
dependent, Low or Intermediate-1, 
Myelodysplastic Syndrome Patients Based on 
the International Prognostic Scoring System 
(HEMMD0027)

• Phase IIIB, Open-label, Multi-Center Study of the 
Efficacy and Safety of Rigosertib Administered 
as 72-hour Continuous Intravenous Infusions in 
Patients with Myelodysplastic Syndrome with 
Excess Blasts Progressing On or After Azacitidine 
or Decitabine (HEMMD0028)

Acute Lymphoblastic Leukemia (ALL)

• Phase II Study of SQ Bortezomib in Combination 
with Chemotherapy in Relapsed/Refractory 
Adult Acute Lymphoblastic Leukemia 
(HEMALL0008)

• An Open-label, Randomized Phase 3 Study of 
Inotuzumab Ozogamicin Compared to a Defined 
Investigator’s Choice in Adult Patients with 
Relapsed or Refractory CD22- Positive Acute 
Lymphoblastic Leukemia (ALL) (HEMALL0009)

• A Phase II Study of Dasatinib (Sprycel®) (IND 
#73969, NSC #732517) as Primary Therapy 
followed by Transplantation for Adults >= 
18 Years with Newly Diagnosed Ph+ Acute 
Lymphoblastic Leukemia by CALGB, ECOG and 
SWOG (SWOGC10701)

Chronic Lymphocytic Leukemia (CLL)

• A Dose Escalation Study of Ibrutinib with 
Lenalidomide for Relapsed and Refractory 
Chronic Lymphocytic Leukemia/Small 
Lymphocytic Lymphoma (HEM0032)

• A Phase 3, Randomized, Double-Blind, Placebo-

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• highlighted studies are Stanford investigator initiated
Controlled Study Evaluating the Efficacy and Safety of GS-1101 (CAL-101) in Combination with Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukemia (HEMCLL0013)
- A Phase 2 Open-Label Study of the Efficacy of ABT-199 (GDC-0199) in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia Harboring the 17p Deletion (HEMCLL0015)
- A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Alliance A041202)

Multiple Myeloma
- A Phase I/II Study of Amrubicin in Combination with Lenalidomide and Weekly Dexamethasone in Relapsed/Refractory Multiple Myeloma (HEMMYL0018)
- 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 (HEMMYL0021-BMT252)

Amyloidosis
- A Phase I Dose-Escalation Study of Carfilzomib in Patients with Previously-Treated Systemic Light-Chain (AL) Amyloidosis (HEM0024)
- A Phase I, Open Label, Dose Escalation Study of Intravenous Administration of Single Agent NEOD001 in Subjects with Light Chain (AL) Amyloidosis (HEM0027)

Myeloproliferative Disorders (MPD)
- A Phase II Study to Evaluate the Efficacy and Safety of GS-6624 in Adult Subjects with Primary, Post Polycythemia Vera or Post Essential Thrombocythemia Myelofibrosis (HEMMPD0013)
- A Pilot Study of Brentuximab Vedotin (SGN-35) in CD30-Positive Systemic Mastocytosis with or without an Associated Hematological Clonal Non-Mast Cell Lineage Disease (AHNMD) (HEMMPD0016)
- A Phase 2, Open-Label, Prospective Study Of PRM-151 In Subjects with Primary Myelofibrosis (PMF), Post-Polycythemia Vera MF (post-PV MF), or Post-Essential Thrombocythemia MF (post-ET MF) (HEMMPD0017)
- A Phase II Study of Non-myeloablative Allogeneic Transplantation Using Total Lymphoid Irradiation (TLI) and Anti-thymocyte Globulin (ATG) In Patients with Cutaneous T Cell Lymphoma (BMT206)