This issue is focused on our Lymphoma, Hematology, and Blood and Marrow Transplant Programs.

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. Work by the Stanford Lymphoma Program led to the discovery and development of Rituximab, the best biological therapy available today to treat lymphoma. This program continues its pioneering work with its current clinical trials including a trial of a vaccine 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, including acute and chronic leukemias (ALL, AML, CLL, CML), multiple myeloma, amyloidosis, myelodysplastic syndromes, and myeloproliferative disorders. Stanford's Hematologists work in close collaboration with specialists in Blood and Marrow Transplant, infectious diseases, radiation oncology, and interventional radiology. Faculty physicians from Stanford’s Hematology Program have been instrumental in improving patient survival and quality of life both locally and nationally through contributions to the prestigious National Comprehensive Cancer Network (NCCN) guidelines.

The Stanford Blood and Marrow Transplant (BMT) Program is nationally recognized for its treatment and research programs. Stanford BMT clinical trials ensure the smooth translation of its research findings into the most advanced patient care available today. 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. Its state-of-the-art laboratory is exploring novel cellular and vaccine-based therapies that target hematologic disease at its most basic origins.

As always, the newsletter contains a listing of some of the Phase 1 and 2 trials from our Developmental Therapeutics Program. This group of researchers includes myself (with special interests in ovarian cancers and cancers of unknown primary), as well as my colleagues 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 the best possible care to your patient, keep you informed of the patient’s treatment and response, and, if the treatments we offer are not appropriate for your patient, return them to your care.

Branimir (Brandy) I. Sikic, MD
Professor of Medicine (Oncology)
Director, Clinical and Translational Research Unit
Associate Director, Clinical Research, Stanford Cancer Institute
Stanford University School of Medicine
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, offering advanced treatments that are not yet available at other institutions.

**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 III 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.

**Translational Research**

**Advanced Treatment, Customized Care**

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

- Advanced therapies for NHL, comprising:
  - Blood and marrow transplants,
  - Peripheral blood stem cell transplants,
  - Immunotherapy such as rituximab,
  - Radiomunotherapy such as Zevalin and Bexxar, and
  - Experimental treatments through clinical trials.

- Advanced treatments for HD focusing on:
  - A unique and highly curative chemotherapy/radiation therapy program as Stanford V (five);
  - Customized biologic therapy development focusing on monoclonal antibodies and vaccines; and
  - Radiomunotherapy, a specialized treatment in which radioactive sources are targeted and carried directly to specific cancer cells.

- 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-myeloabative allogeneic transplant, an outpatient procedure with limited side effects and minimal need for hospitalization. Stanford researchers are also investigating the efficacy of vaccine therapy following BMT.

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

- Multidisciplinary tumor boards, including:
  - HD tumor board that meets weekly involving physicians from the Division of Oncology and Department of Radiation Oncology along with radiologists and pathologists to review newly diagnosed, complex patients;
  - Cutaneous Lymphoma tumor board that meets weekly and is jointly directed by the Departments of Dermatology and Radiation Oncology; and
  - Lymphoma follow-up tumor board; meets every other week.

**A World Leader in Cutaneous Lymphoma**

The Stanford Multidisciplinary Cutaneous Lymphoma Clinic (MCLC) is a leading center of excellence for clinical/translational research and treatment of patients with cutaneous lymphomas. In operation for over 30 years at Stanford, MCLC (tumor board) serves as a regional, national, and international referral center.

**MCLC (tumor board) features include:**

- A wide variety of clinical research protocols available for patient management, including biological skin-directed and systemic therapies such as immune stimulants, monoclonal antibodies, vaccines, new targeted agents, and novel radiation therapy strategies. Stanford leads efforts in therapeutic discoveries and FDA approval of new treatment options in cutaneous lymphoma.

- Novel non-myeloabative allogeneic HSCT regimen for patients with mycosis fungoides and Sézary syndrome is offered as part of close collaboration and joint patient management with our BMT faculty members and investigators.

- Tracking the long-term outcome of patients. The MCLC has an on-going cutaneous lymphoma database dating back to the 1950’s with long-term follow-up as long as 50 years for some patients. The mycosis fungoides database contains information about more than 2,000 patients. This valuable longitudinal database is critical for generating prognostic information vital for optimal patient management and stratification of clinical trials.

- Leadership in patient-oriented, translational research with established collaboration with our dermatology investigators who are world leaders in the study of genetic and epigenetic abnormalities in cutaneous malignancies.

**STUDIES INCLUDE:**

- **Hodgkin’s Disease**
  - Risk Adapted Stanford V-C with Radiotherapy for Clinical Stage I/IIA Favorable Hodgkin’s Disease: The GS Study (LYMHD0002)
  - Retreatment with SGN-35 in Patients with CD30-positive Hematologic Malignancies (LYMHD0006)
  - An Open-Label, Phase 2/3, Treatment-Option Protocol of Brentuximab Vedotin (SGN-35) in Patients with Progression of Hodgkin Lymphoma (LYMHD0008)
  - A Phase II Trial of Sequential SGN-35 Therapy with Adriamycin, Vinblastine, and Dacarbazine (S-A-Vd) for Older Patients with Untreated Hodgkin Lymphoma (LYMHD0009)
  - An Open-Label, Treatment-Option Protocol of Brentuximab Vedotin in Patients with Relapsed or Refractory Hodgkin Lymphoma (HL) or Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma (ALCL) (LYM0005-EX)
  - SB186, A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging (ECOGS0816)

- **Non-Hodgkin’s Lymphoma**
  - Follicular / Indolent B-Cell Unreated
    - Single-Agent CAL-101 for Low-Grade Lymphoma: A Phase 1/2 Study of Safety, Efficacy, and Flow-Cytometric Assessment of Tumor-Cell Signaling Events (LYMNL0031)

*highlighted studies are Stanford Investigator Initiated*
Clinical Research Newsletter for Colleagues in the Community
FALL 2011

The Stanford Hematology Program offers state-of-the-art diagnostics and treatment regimens for patients with a variety of hematologic disorders, including acute and chronic leukemias (ALL, AML, CLL, CML), multiple myeloma, amyloidosis, myelodysplastic syndromes, and myeloproliferative disorders.

- New molecular imaging modalities for diagnostic purposes and to assess response to treatment.
- Cutting Edge Translational Research. Stanford Hematology Program is at the leading edge of translational research, offering clinical trials for all types of hematologic malignancies. Clinical trials involving new agents, including targeted therapies, are the backbone of the program, which focuses on development of novel therapeutic strategies for elderly patients with leukemia, particularly AML and CLL.
- A multidisciplinary approach to the treatment of myelodysplastic syndromes, multiple myeloma, and amyloidosis.
- Targeted, oral therapies for myelofibrosis patients.
- Incorporation of molecular markers to aid in prognosis, guide radiology. They are also leaders in SWOG, one of the three national cooperative groups that conducts clinical trials for patients with cancer.

LEADING THERAPEUTIC RESEARCH

The Stanford Hematology Program’s clinical investigators and laboratory scientists are focused on developing novel treatments for a wide variety of hematologic disorders.

RESEARCH HIGHLIGHTS FEATURE:
- Innovative Treatments and Technologies. Stanford researchers are advancing new cancer treatments not yet commercially available, including:
  - Novel investigational therapeutics that are at all stages of development, from early phase I trials to randomized phase III studies.
  - Minimally invasive spine surgery for multiple myeloma patients.
  - Minimal invasive therapy for multiple myeloma patients.
  - Cutting edge therapies for multiple myeloma patients.

- Pharmacokinetics of Escalating Doses of DCDT2980S in Patients with Relapsed or Refractory Chronic Myelogenous Leukemia (BMT0801)
STUDIES INCLUDE:

Leukemia

- Multiple Histologies
  - An Open-Label, Dose Escalation, Phase 1 Study of MLN4924, a Novel Inhibitor of Nedd8-Activating Enzyme, in Adult Patients with Acute Myelogenous Leukemia and High-Grade Myelodysplastic Syndrome (HEM0011)
  - Study PMA112509, a Phase I/II Study of Eltrombopag in Thrombocytopenic Subjects with Advanced Myelodysplastic Syndrome (MDS) or Secondary Acute Myeloid Leukemia after MDS (sAML/MDS) (HEM0012)
  - A Phase 2 Single Arm Study to Investigate the Safety and Clinical Activity of CAL-101 in Combination with Rituximab in Elderly Patients with Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (HEM0021)
  - An Open-Label, Multicenter, Phase 1 Trial of the Safety and Pharmacokinetics of Escalating Doses of DCD7298(S) in Patients with Relapsed or Refractory B-Cell Non-Hodgkin’s Lymphoma (ALL) (SWOGCALGB10403)
  - A Phase II Study of Epnrutumab (NSC-716771) in Combination with Cytarabine and Fludarabine for Patients with Relapsed or Refractory Ph-Negative Precursor B-cell Acute Lymphoblastic Leukemia (ALL) (SWOGCALGB10603)

Acute Lymphoblastic Leukemia (ALL)

- An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (SWOGCALGB10403)
- A Phase II Study of Epnrutumab (NSC-716771) in Combination with Cytarabine and Fludarabine for Patients with Relapsed or Refractory Ph-Negative Precursor B-cell Acute Lymphoblastic Leukemia (ALL) (SWOGCALGB10603)
- Single Agent Lenalidomide in Adult Patients with Relapsed/Refractory Acute Lymphoblastic Leukemia (ALL) (HEMALL0006)

Acute Myeloid Leukemia (AML)

- A Phase I/II Trial of the Combination 5-azacitidine and Gemtuzumab Ozogamicin for Treatment of Relapsed AML (HEMAML0020)
- A Randomized Phase II Study of Oral Sapacitabine in Elderly Patients with Acute Myeloid Leukemia Previously Untreated or in First Relapse (HEMAML0009)
- A Phase 1/2 Study of Vorinostat (Zolinza®) in Combination with Gemtuzumab Ozogamicin (Mylotarg®) and Azacitidine (Vidaza®) in Patients 50 Years of Age and Older with Relapsed/Refractory non-APL Acute Myeloid Leukemia (AML) (HEMAML0014)

Multiple Myeloma and Amyloidosis

- A Phase 2 Study of Ciforafenib with High Dose Cytarabine and G-CSF Priming in Adult Patients Under Age 60 with Newly Diagnosed Acute Myeloid Leukemia or Advanced Myelodysplastic Syndrome (HEM0018)
- A Phase II, 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) (HEMMYLO017)
- CALGB10603, A Phase III Randomized, Double-Blind Study of Induction (5-Fluorouracil/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy + Midostaurin (PKC412) (IND # 103261) or Placebo in Newly Diagnosed Patients < 60 Years of Age with FLT3 Mutated Acute Myeloid Leukemia (AML) (SWOGCALGB10603)

Acute Promyelocytic Leukemia (APL)

- A Phase II Study of ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients With Previously Untreated High-Risk Acute Promyelocytic Leukemia (SWOGS05335)
- A Phase II Study of Oral Tambocor in Acute Promyelocytic Leukemia Patients Who Have Received Prior Therapy with ATRA and Arsenic Trioxide (STAR-1) (HEMAPL0011)

Chronic Lymphocytic Leukemia (CLL)

- A Phase 2 Single Arm Study to Investigate the Safety and Clinical Activity of CAL-101 in Combination with Rituximab in Elderly Patients with Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (HEM0021)
- Phase I Study to Investigate the Safety and Clinical Activity of CAL-101 in Combination with Chemotherapeutic Agents and CD20 mAb in Patients with Relapsed or Refractory Indolent B-cell Non-Hodgkin’s Lymphoma or Chronic Lymphocytic Leukemia (HEM0017)
- A Phase 1b Fixed-dose Study of Bruton’s Tyrosine Kinase (Btk) Inhibitor, PCI-31265, in Chronic Lymphocytic Leukemia (HEMCLL0010)
- A Phase 1 Study Evaluating the Safety of ABT-263 in Combination with either Fludarabine/Cyclophosphamide/Rituximab (FCR) or Bendamustine/Rituximab (BR) in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia (HEMCLL0009)
- A Phase II Study of Ibrutinib in Patients with Low Grade or Refractory Non-Hodgkin’s Lymphoma (Open Only to Marginal Zone Lymphoma or Chronic Lymphocytic Leukemia Patients) (LYNH-L0020)

Myelodysplastic Syndrome (MDS)

- A Pilot Study of Lenalidomide, Melphalan and Dexamethasone in AL Amyloidosis (HEM0010)
- A Pilot Study of Lenalidomide in Adult Diamond-Blackfan Anemia Patients with Red Blood Cell Transfusion-Dependent Anemia (HEM0010)
- A Multi-center, Randomized, Double-blind, Placebo-controlled Clinical Trial of Derezirax in Patients with Myelodysplastic Syndromes (Low/inter-1 Risk) and Transfusional Iron Overload (TELESCO) (HEMMD0002)
- Study PMA112509, a Phase I/II Study of Eltrombopag in Thrombocytopenic Subjects with Advanced Myelodysplastic Syndrome (MDS) or Secondary Acute Myeloid Leukemia after MDS (sAML/MDS) (HEM0012)

Myeloproliferative Disorders (MPD)

- A Single Arm, Phase II, Open-label Study to Determine the Efficacy of 100mg Twice Daily Oral Dosing of Midostaurin Administered to Patients with Aggressive Systemic Mastocytosis or Mast Cell Leukemia +/- an Associated Hematological Clonal Non-Mast Cell Lineage Disease (HEMPD0007)
- A Phase I/II, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability Pharmacokinetics and Pharmacodynamics of Orally-Administered CYT387 in Primary Myelofibrosis or Post-Polycythemia Vera or Post-Essential Thrombocytthemia Myelofibrosis (HEMPD0012)

- A Pilot Study of Lenalidomide, Melphalan and Dexamethasone in AL Amyloidosis (HEM0010)
- A Pilot Study of Lenalidomide in Adult Diamond-Blackfan Anemia Patients with Red Blood Cell Transfusion-Dependent Anemia (HEM0010)
- A Multi-center, Randomized, Double-blind, Placebo-controlled Clinical Trial of Derezirax in Patients with Myelodysplastic Syndromes (Low/inter-1 Risk) and Transfusional Iron Overload (TELESCO) (HEMMD0002)
- Study PMA112509, a Phase I/II Study of Eltrombopag in Thrombocytopenic Subjects with Advanced Myelodysplastic Syndrome (MDS) or Secondary Acute Myeloid Leukemia after MDS (sAML/MDS) (HEM0012)

Myeloproliferative Disorders (MPD)

- A Single Arm, Phase II, Open-label Study to Determine the Efficacy of 100mg Twice Daily Oral Dosing of Midostaurin Administered to Patients with Aggressive Systemic Mastocytosis or Mast Cell Leukemia +/- an Associated Hematological Clonal Non-Mast Cell Lineage Disease (HEMPD0007)
- A Phase I/II, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability Pharmacokinetics and Pharmacodynamics of Orally-Administered CYT387 in Primary Myelofibrosis or Post-Polycythemia Vera or Post-Essential Thrombocytthemia Myelofibrosis (HEMPD0012)
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.

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 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, and memory T-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.

**STANFORD BMT – DISTINCT FEATURES**
- **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 performs over 250 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.**
  - Nine physicians focus exclusively on BMT with a dedicated Immunocompromised Host Infection 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; and
  - 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**
- 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.

**STUDIES INCLUDE:**
- **Allogeneic Hematopoietic Cell Transplantation Using a Non-Myoeloblative Preparative Regimen of Total Lymphoid Irradiation and Anti-Thymocyte Globulin for Older Patients with Hematologic Malignancies (BMT153)**
- **Cytokine Induced Killer Cells as Post-Transplant Immunotherapy Following Allogeneic Hematopoietic Cell Transplantation (BMT162)**
- **Total Lymphoid Irradiation and Anti-Thymocyte Globulin 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)**
- **A Phase III Randomized, Multicenter Trial Comparing Sirolimus/Tacrolimus with Severe Hepatic Veno-occlusive Disease (BMT190)**
- **A California Cooperative Clinical Study Comparing Allogeneic Hematopoietic Cell Transplantation Using Nonmyeloablative Host Conditioning with Total Lymphoid Irradiation and Anti-thymocyte Globulin versus Best Standard of Care in Acute Myeloid Leukemia/AML in First Complete Remission (BMT190)**
- **A Phase III Remission, Multicenter Trial Comparing Sirolimus/Tacrolimus with Myeloblate with Severe Hepatic Veno-occlusive Disease (BMT190)**
- **A California Cooperative Clinical Study Comparing Allogeneic Hematopoietic Cell Transplantation Using Nonmyeloablative Host Conditioning with Total Lymphoid Irradiation and Anti-thymocyte Globulin versus Best Standard of Care in Acute Myeloid Leukemia/AML in First Complete Remission (BMT190)**
- **A California Cooperative Clinical Study Comparing Allogeneic Hematopoietic Cell Transplantation Using Nonmyeloablative Host Conditioning with Total Lymphoid Irradiation and Anti-thymocyte Globulin vs Best Standard of Care in Acute Myeloid Leukemia/AML in First Complete Remission (BMT190)**
- **Chronic GVHD Cohort Protocol (BMT193)**
- **Defibrotide for Hematopoietic Stem Cell Transplant (SCT) Patient with Severe Hepatic Veno-occlusive Disease (VOCD): A Treatment IND Study (BMT196)**

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.
• A Phase II Study of Autologous Followed by Nonmyeloablative Allogeneic Transplantation Using Total Lymphoid Irradiation (TLI) and Antithymocyte Globulin (ATG) in Multiple Myeloma Patients (BMT201)

• A Mucicenter Phase II/III Study of a Phospholipidic Inhibitor of BCh-ABL Tyrosine Kinase by Tasigna® (Nilotinib) after Hematopoietic Cell Transplantation for Philadelphia Chromosome-Positive Leukemias (BMT202)

• Phase II Trial of Non-Myeloablative Allogeneic Hematopoietic Stem Cell Transplantation for Patients with Relapsed Follicular Non-Hodgkin’s Lymphoma Beyond First Complete Response (BMT203)

• A Feasibility Trial of Post Transplant Infusion of Allogeneic Regulatory T Cells Simultaneously with Allogeneic Conventional T Cells in Patients with Hematologic Malignancies undergoing Allogeneic Myeloblastic Hematopoietic Cell Transplantation from Haploidentical Related Donors (BMT204)

• 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 (BMT205)

• A Randomized Phase 2 Study of Imatinib and Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Cell Transplantation (BMT211)

• A Trial of Single Autologous Transplant with or without Consolidation Therapy versus Tandem Autologous Transplant with Lenalidomide Maintenance for Patients with Multiple Myeloma (BMT213)

• 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)

• A Randomized, Double-blind, Placebo-controlled Phase 3 Study of SGN-35 (Brentuximab Vedotin) and Best Supportive Care (BSC) versus Placebo and BSC in the Treatment of Patients at High Risk of Relapsed Hodgkin Lymphoma (HL) Following Autologous Stem Cell Transplant (ASCT) (BMT220)

• A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD (BMT221)

• A Phase 1 Study of Nilotinib in Steroid Dependent / Refractory Chronic Graft versus Host Disease (BMT222)

• A Phase II/III Randomized, Multicenter Trial Comparing Sirolimus plus Prednisone, Sirolimus/Extracorporeal Photopheresis plus Prednisone, and Sirolimus/Calcineurin Inhibitor plus Prednisone for the Treatment of Chronic Graft-versus-Host Disease (BMT225)

• A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicenter Clinical Trial to Study the Safety, Tolerability, Efficacy, and Immunogenicity of V212 in Recipients of Allogeneic Hematopoietic Cell Transplantations (hCTs) (BMT226)

• Longitudinal Study of Immune Mediated Disorders after Allogenic HCT Protocol (BMT227)

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 Kurz (GI cancers), and Ramajna Advani (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 sampling of currently available Phase 1 and 2 studies.

PHASE 1 STUDIES

Multiple Solid Tumor Sites
• A Phase 1 Dose Escalation Study to Evaluate the Safety and Tolerability of HSCT1029 (AEG03620•2HCl) in Patients with Advanced Solid Tumors (VAR0031)

Liymphomas
• A Phase 1 Trial of an Anti-CD22 Monoclonal Antibody Conjugate DCDT2980S in Relapsed or Refractory B-Cell Non-Hodgkin’s Lymphomas (VAR0059)

PHASE 2 STUDIES

Ovarian Cancers
• A Phase 2 Study of Cabozantinib (XL-184), an Inhibitor of MET and VEGFR2, in Patients with Relapsed and Recurrent Ovarian Cancers (VAR0046)

Thymic Cancers and Lymphomas
• A Phase 2 Study of Amnubicin in Relapsed or Refractory Thymic Malignancies (THOR0030)

• Mantle Cell and Diffuse Large B-Cell Lymphomas

• Multicenter Phase 2 Study of Bruton’s Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Relapsed or Refractory Mantle Cell Lymphoma (LYMNHL0084)

• A Multicenter, Open-Label, Phase 2, Safety and Efficacy Study of the Bruton’s Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Subjects with Relapsed or Refractory de novo Diffuse Large B-cell Lymphoma (DLBCL) (LYMNHL0088)

Gastric Cancers
• A Phase 2 Study of Capecitabine, Carboplatin, and Bevacizumab for Metastatic or Unsectable Gastroesophageal Junction and Gastric Adenocarcinoma (G30002)

RESOURCES:
Clinical Trials Recruitment Specialist 650.498.7061
Referral Center 650.498.6000
Clinical Trials Web Search Engine cancer.stanford.edu/trials