

Clinical Research

Newsletter for Colleagues in the Community

Stanford
Cancer Institute

A National Cancer Institute
Designated Cancer Center



Welcome to the Spring 2017 issue of the Stanford Cancer Institute Clinical Research Newsletter for Colleagues in the Community. 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 available at the Stanford Cancer Institute, a National Cancer Institute designated Comprehensive Cancer Center. Many of these trials provide access to novel therapies including new “targeted” agents, often not available in the community.

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

This issue also features our Stanford Adolescent and Young Adult Cancer (SAYAC) Program, designed to meet the unique needs and treatment challenges of cancer patients ages 15 – 29. Survival rates for this population have not improved significantly in the last 30 years. The SAYAC Program is the first in the Bay Area and jointly operated between Lucile Packard Children’s Hospital and Stanford Health Care.

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,

offering advanced treatments that are not yet available at other institutions.

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. Its state-of-the-art laboratory is exploring novel cellular and vaccine-based therapies that target hematologic disease at its most basic origins.

Phase 1 and 2 trials from our Developmental Therapeutics Program are also included in the newsletter. This program, led by Dr. Shivaani Kummar, former leader of the National Cancer Institute’s Developmental Therapeutics Clinic and Early Clinical Trials Development Program, is continually expanding its trial offerings.

We hope that you will consider a Stanford Cancer Institute clinical trial when you deem it appropriate to refer a patient to an academic medical facility.

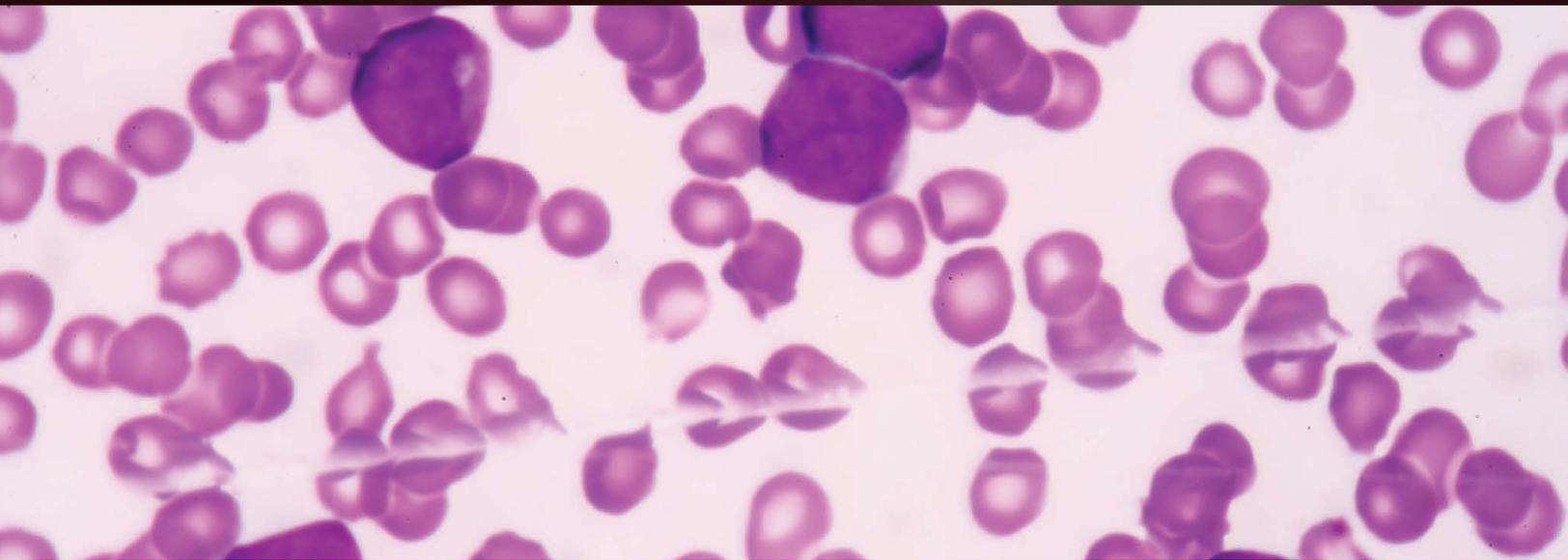
Robert Negrin, MD



*Professor of Medicine (Blood and Marrow Transplantation)
Division Chief, Blood and Marrow Transplant Program,
Stanford University
Medical Director, Clinical Bone Marrow
Transplantation Laboratory*

Stanford Lymphoma Program

Cutting Edge Research, Multidisciplinary Care



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 50 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, II, 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. 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.
 - 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 has revolutionized 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, SYK and PI3Kinase) inside lymphoma cells that are responsible for their uncontrolled growth. One example targeting BTK is Ibrutinib (now known as Imbruvica) that has revolutionized 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, increase the strength of the tumor killing T cells (targeting PD-L1), and CD47 antibodies.
- Cutaneous lymphoma research that includes:
 - Traditional Stanford-led therapies modernized and combined with immunotherapy to improve clinical outcome. 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 immune-augmenting systemic agent, such as a interferon-gamma or recombinant human IL-12. Combining low-dose TSEBT with immunotherapy offers safe, efficient, and reliable clearing of disease with durable clinical benefit.
 - 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. Based on the recent genomics discovery, we have designed and opened a trial that targets T-cell activation and survival pathways combining PI3k and proteasome inhibitors. An interdisciplinary effort for establishing a comprehensive genomic alteration panel for interrogating clinical samples to improve clinical management is in progress.
- 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. Our safe transplant method has reduced the 1-year transplant-related mortality to less than 5%. The TSEBT contributes towards more effective elimination of tumor cells in the skin, a site where response has eluded systemic therapies.
- New immunotherapy approaches are being explored in cutaneous T cell lymphoma (CTCL), including the immune checkpoint modulators (anti-PD-1 and anti-CD47 antibodies), more potent topical TLR agonists, or tumor-targeted immune modulation such as anti-KIR3DL2 antibody.
- 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
- Advanced treatments for HD focusing on:
 - Unique combinations of checkpoint inhibitors and brentuximab vedotin in front line and relapsed disease
- Innovative cutaneous lymphoma treatments and technologies:
 - Mogamulizumab (KW-0761), a bioengineered, humanized monoclonal antibody against CCR4, selectively expressed on tumor cells.
 - Humanized monoclonal antibody targeting KIR3DL2, which is highly and selectively expressed on neoplastic T cells in CTCL.
 - Low-dose (12 Gy) total skin electron beam therapy combined with recombinant human IL-12.
 - Novel/newer topical agents including topical histone deacetylase inhibitors and more potent TLR agonists.
 - 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.
 - Application of newer molecular diagnostic techniques for earlier and more accurate diagnosis and staging.
- 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, Blood and Marrow Transplantation/Medicine/Oncology, and Radiation Oncology. These multidisciplinary clinics provide the most comprehensive evaluation and management.

STUDIES INCLUDE

Hodgkin's Disease

- Brentuximab Vedotin Combined With AVD Chemotherapy in Patients With Newly Diagnosed Early Stage, Unfavorable Risk Hodgkin Lymphoma (LYMHD0015)
- A Study of Brentuximab Vedotin Combined With Nivolumab for Relapsed or Refractory Hodgkin Lymphoma (LYMHD0014)
- NCI-MATCH: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory Solid Tumors, Lymphomas, or Multiple Myeloma (ECOG-ACRIN-EAY131)
- A Phase I Study with an Expansion Cohort of the Combination of Ipilimumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (ECOG4412)

Non-Hodgkin's Lymphoma

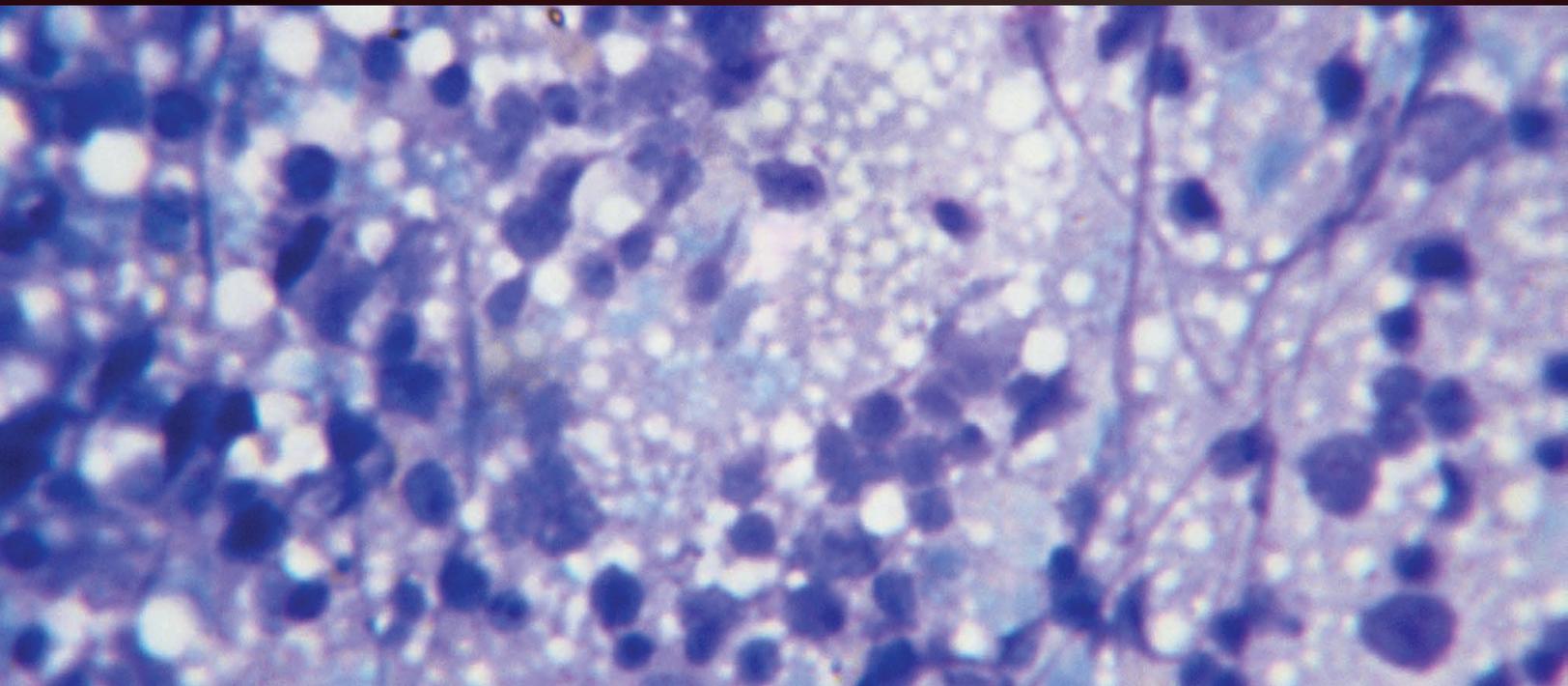
- TLR9 Agonist SD-101, Ibrutinib, and Radiation Therapy in Treating Patients with Relapsed or Refractory Grade 1-3A Follicular Lymphoma (LYMNHL0135)

- A Phase 1B, Multi-center, Open-label Study of Novel Combinations of CC-122,CC-223,CC-292 and Rituximab in Diffuse Large B-cell Lymphoma (DLBCL) (LYMNHL0115)
- An Open-Label, Multi-Center Phase I Study to Investigate the Safety and Tolerability of REGN1979, an Anti-CD20 X Anti-CD3 Bispecific Monoclonal Antibody, in Patients with CD20+ B-Cell Malignancies Previously Treated with CD20-Directed Antibody Therapy (LYMNHL0122)
- A Multi-Center Study of Ibrutinib in Combination with MEDI4736 in Subjects with Relapsed or Refractory Lymphomas (LYMNHL0129)
- A Study of Escalating Doses of DCDS0780A in Patients With Relapsed or Refractory B-cell Non-Hodgkin's Lymphoma (LYMNHL0128)
- A Phase 1 Study Evaluating Safety, Tolerability, and Pharmacokinetics of Escalating Doses of AGS67E Given as Monotherapy in Subjects with Refractory or Relapsed Lymphoid Malignancies (LYMNHL0117)
- NCI-MATCH: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory Solid Tumors, Lymphomas, or Multiple Myeloma (ECOG-ACRIN-EAY131)
- FLT-PET/CT vs FDG-PETCT for Therapy Monitoring of Diffuse Large B-cell Lymphoma (LYMIMG0001)
- A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study (LYM0006-EXT)
- A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Brentuximab Vedotin and CHP (A+CHP) Versus CHOP in the Frontline Treatment of Patients with CD30-Positive Mature T-cell Lymphomas (LYMNHL0100)
- Study of Tipifarnib in Subjects with Relapsed or Refractory Peripheral T-Cell Lymphoma (LYMNHL0130)
- FLASH [Fluorescent Light Activated Synthetic Hypericin] Clinical Study: Topical SGX301 (Synthetic Hypericin) for the Treatment of Cutaneous T-Cell Lymphoma (Mycosis Fungoides) (LYMNHL0124)
- Safety, Tolerability and Pharmacokinetic Study of MRG-106 in Patients With Cutaneous T Cell Lymphoma (CTCL), MF Subtype (LYMNHL0132)
- NM-IL-12 in Cutaneous T-Cell Lymphoma (CTCL) Undergoing Total Skin Electron Beam Therapy (TSEBT) (LYMNHL0133)
- Trial of Duvelisib in Combination with Either Romidepsin or Bortezomib in Relapsed/Refractory T-cell Lymphomas (LYMNHL0136)
- A First-in-Human Phase 1 Dose Escalation Trial of Hu5F9-G4 in Patients with Advanced Solid Malignancies (LYMNHL0137)
- A Trial of E7777 in Persistent and Recurrent Cutaneous T-Cell Lymphoma (LYMNHL0103)
- 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)
- Open-label, Multicenter Phase I Study of IPH4102, A Humanized Anti-KIR3DL2 Monoclonal Antibody, in Patients with Relapsed/Refractory Cutaneous T Cell lymphoma (LYMNHL0131)
- Prospective Multicenter International Observational Study for Determination of a Cutaneous Lymphoma International Prognostic Index Model and Impact of Major Therapies in Patients with Advanced Mycosis Fungoides and Sézary Syndrome (LYMNHL0134)

• *highlighted studies are Stanford investigator initiated*

Stanford Blood and Marrow Transplant

National Leader in Novel Research, Expert Care



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).

- Alternative donor transplantation using partially matched (haploidentical) donors, or cord blood or expanded cord blood units.
- 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 5500 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

- Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients on BMT CTN 0702 Protocol (BMT CTN 07LT) (BMT213-EXT)
- 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)
- 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 Multi-Center, Phase III, Randomized Trial of Reduced Intensity Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood versus HLA-Haploidentical Related Bone Marrow (Haplo) for Patients with Hematologic Malignancies (BMT248)
- A Phase 1 Safety and Tolerability Study of Infused Donor T Regulatory Cells in Steroid Dependent/Refractory Chronic Graft Versus Host Disease (BMT253)
- A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL) (BMT284)
- Post Transplant Infusion of Allogeneic CD8 Memory T-Cells as Consolidative Therapy After Non-Myeloablative Allogeneic Hematopoietic Cell Transplantation in Patients with Leukemia and Lymphoma (BMT288)
- Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus-Host Disease (BMT CTN 1301) (BMT298)
- Donor Umbilical Cord Blood Transplant with or without Ex-vivo Expanded Cord Blood Progenitor Cells in Treating Patients With Acute Myeloid Leukemia, Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia, or Myelodysplastic Syndromes (BMT291)
- Phase I/II MAHCT w/ TCell Depleted Graft w/ Simultaneous Infusion Conventional and Regulatory T Cell (BMT236)
- A Study of Obinutuzumab for Prevention of Chronic Graft-vs.-Host Disease After Allogeneic Peripheral Blood Stem Cell Transplantation (BMT304)
- Ibrutinib in Combination with Corticosteroids Versus Placebo in Combination with Corticosteroids in Subjects with New Onset Chronic Graft Versus Host Disease (cGVHD) (BMT311)
- A Study Evaluating KTE-C19 in Combination with Atezolizumab in Subjects with Refractory Diffuse Large B-Cell Lymphoma (DLBCL) (BMT306)
- Fructooligosaccharides in Treating Patients with Blood Cancer Undergoing Donor Stem Cell Transplant (BMT303)

• *highlighted studies are Stanford investigator initiated*

Stanford Adolescent and Young Adult Cancer Program



The Stanford Adolescent & Young Adult Cancer (SAYAC) Program is designed to provide a holistic healthcare approach to help meet the unique needs of teenagers and young adults with cancer. Even though medical treatments for pediatric and adult cancers have advanced over the past several decades, the survival rates for this population have not improved. Though the reasons for this are not yet clear, inadequate insurance, delays in diagnosis, and low enrollment on clinical trials are likely adding to this problem. The SAYAC program hopes to address these issues and explore other ways that might improve their survival and experience.

One of the first programs operated jointly between Lucile Packard Children's Hospital and Stanford Health Care, the SAYAC Program is the first adolescent and young adult (AYA) cancer program in the Bay Area designed specifically for patients aged 15-29. The team consists of Program Manager/Nurse Practitioner Pam Simon, CPNP, with the support of the co-medical directors Gary Dahl, MD, and Michaela Liedtke, MD, and Tamara Dunn, MD.

Since the launch of the program in 2015, the SAYAC Program has reached hundreds of patients with a variety of cancer diagnoses. The program assesses the age appropriate needs of each patient to create individualized,

tailored care and works closely with the patient's hematology/oncology specialists at both institutions as a complementary consult service.

Services offered through the SAYAC Program include:

- Fertility and Reproductive Health: Fertility preservation, sexual health, family planning, gynecologic guidelines
- Confidence/Body Image classes
- Adolescent and Internal Medicine: General medicine, psychiatric medical management
- Supportive Care: Acupuncture, yoga, reiki, meditation, spiritual care, nutrition support, mindfulness classes
- Peer to Peer Support: AYA Mentor Program, Recreational Therapy services, external partner programs, AYA support groups
- Psychology and Psychiatry: Mental health services
- Education/Career Services: Focus on continuing education during and after therapy, resources to assist with school/career goals
- Cancer Treatment: Enrollment in clinical trials, transition to long-term survivor care, treatment education taught with AYA focus
- Pain Management: Pharmacologic/non-pharmacologic management, symptom management
- Palliative Care: Medical and family planning, spiritual support for difficult decision-making

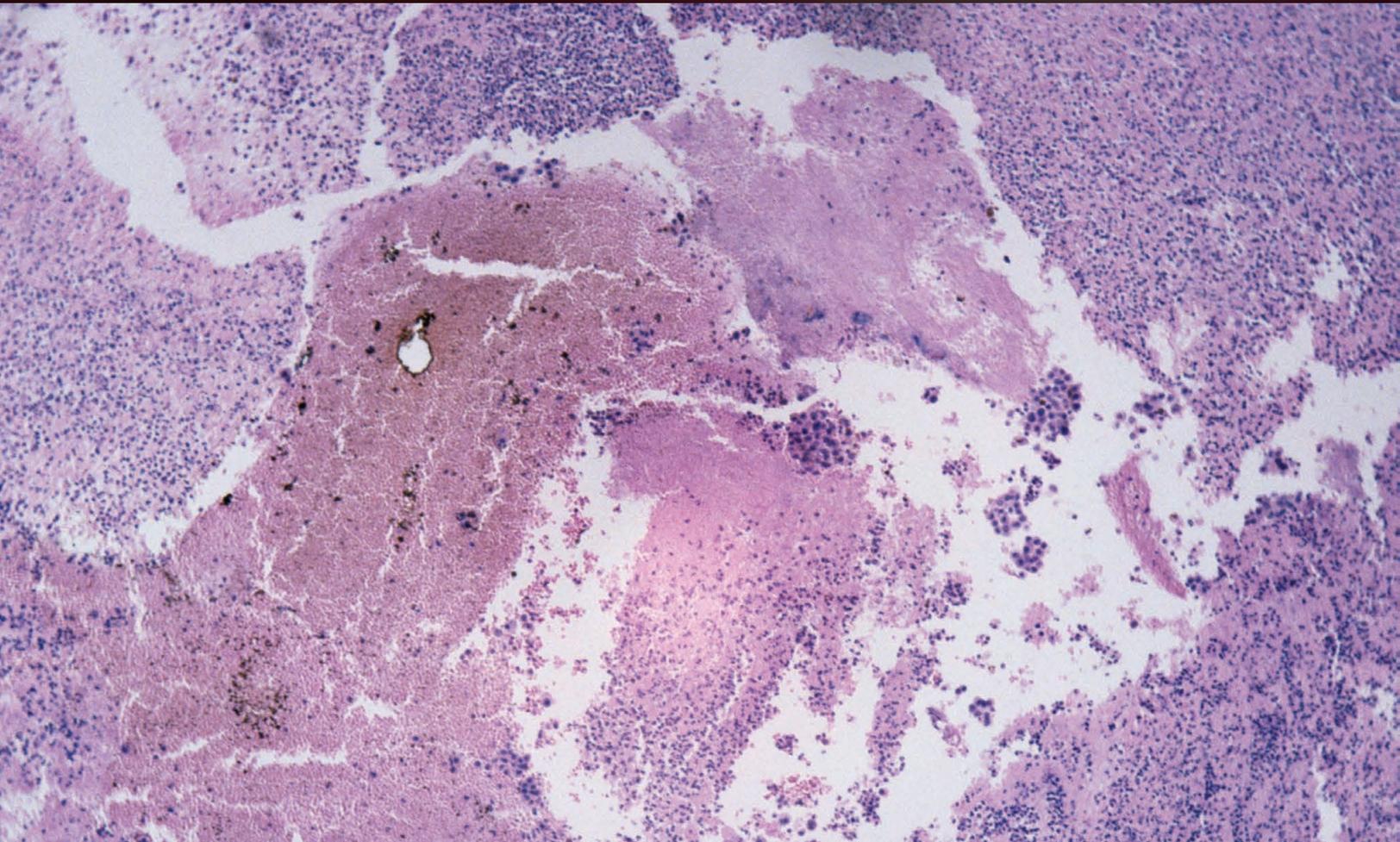
SAYAC Program Services may be requested by contacting **650.498.9404** or sayac@stanfordchildrens.org.

For more information visit:

<http://www.stanfordchildrens.org/en/service/adolescent-young-adult-cancer>

Developmental Therapeutics

Phase I and II Clinical Research Program for Multiple Cancers



Stanford Cancer Center's Developmental Therapeutics (DT) Program, led by director Shivaani Kummar, MD, offers Phase 1 and 2 clinical trials designed to evaluate new treatments for cancer. Other faculty participating in this effort include Drs. Heather Wakelee and Joel Neal (lung cancers), A. Dimitrios Colevas (head and neck cancers), George Fisher and Pamela Kunz (GI cancers), George Sledge, Suleiman Massarweh, Mark Pegram and Melinda Telli (breast cancers), Sunil Reddy (melanoma), Ranjana Advani (lymphomas), and Branimir I. Sikic.

DT Program Director Dr. Kummar is a Professor of Medicine in the Stanford Division of Oncology and former leader of the National Cancer Institute's Developmental Therapeutics Clinic and Early Clinical Trials Development Program. Her research interests focus on developing novel therapies for cancer. Dr. Kummar specializes in conducting

pharmacokinetic and pharmacodynamic driven first-in-human trials tailored to make early informed decisions regarding the suitability of novel molecular agents for further clinical investigation. Her studies integrate genomics and laboratory correlates into early phase trials, establishing the proof of mechanism and proof of concept in these

trials. Dr. Kummar has published numerous articles in medical journals and serves on a number of national and international scientific committees.

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. The program offers the opportunity for patients to enroll in clinical trials evaluating novel anticancer therapies. The overall goal of the program is to facilitate the development of promising, new treatments for cancer while ensuring the highest standards of patient safety.

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

PHASE 1 AND 2 STUDIES

Multiple Solid Tumor Sites

- An Open-Label Phase I Dose-Escalation Study to Evaluate the Safety, Tolerability, Maximum Tolerated Dose, Pharmacokinetics, and Pharmacodynamics of the Anti-C4.4a Antibody Drug Conjugate BAY 1129980 in Subjects with Advanced Solid Tumors Known to Express C4.4a (VAR0146)
- Phase 1/2 Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination with Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies (VAR0143)
- A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers (VAR0141)
- A Phase 1b/2, Open-Label, Multicenter, Dose-Escalation Trial of Intratumoral Injections of SD-101 in Combination with Pembrolizumab in Patients with Metastatic Melanoma (METS0003)

- A Phase 1/2 Dose-Escalation and Cohort Expansion Study of the Safety and Tolerability of Urelumab Administered in Combination with Nivolumab in Advanced/Metastatic Solid Tumors and B Cell Non-Hodgkins Lymphoma (VAR0126)
- Phase 1/2, First-in-Human, Dose-Escalation Study of X-396 in Patients with Advanced Solid Tumors and Expansion Phase in Patients with ALK+ Non-Small Cell Lung Cancer (VAR0098)
- A Phase 2 Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors (VAR0136)
- NCI 9938: Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors (VAR0144)

Opening soon

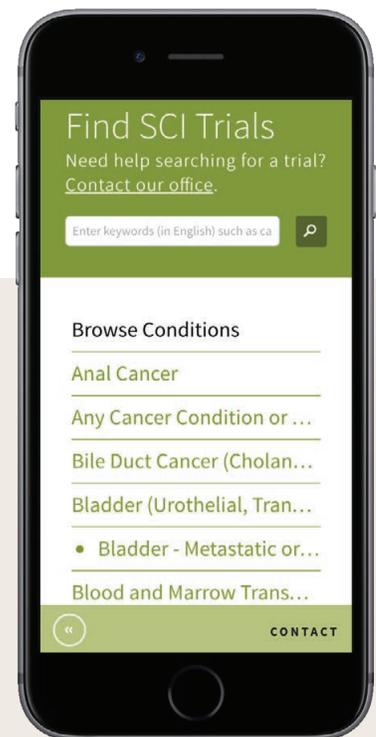
- A Phase I, First-in-Human, Open-Label, Dose-Escalation Study of MGD009, A Humanized B7-H3 x CD3 Dual-Affinity Re-Targeting (DART®) Protein in Patients with Unresectable or Metastatic B7-H3-Expressing Neoplasms and Neoplasms whose Vasculature Expresses B7-H3 (VAR0148)

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