

Oncology Update

Chao Family Comprehensive Cancer Center

Winter 2017

Message from the Director

Dear Colleagues,

As Director of the Chao Family Comprehensive Cancer Center at UC Irvine, it is a privilege to launch this publication to inform you about clinical trials open at UC Irvine that may benefit your patients. As Orange County's only National Cancer Institute-designated cancer center, my hope is that we can work together to provide the people of our county and surrounding areas access to the most current and comprehensive cancer care available. This electronic newsletter will be distributed several times per year, highlighting one of our areas of clinical expertise and ongoing clinical trials.

In the hematologic malignancies (lymphoma, myeloma, leukemia and myelodysplastic syndromes), UC Irvine Health has expanded its experience and expertise in recognition of the increasing clinical



Richard A. Van Etten, MD, PhD

need in our region. We have recently recruited several national experts to provide clinical care and conduct research. In addition, UCI plans to launch a hematopoietic stem cell transplant program for adults in 2017.

Last year, [Lauren Pinter-Brown, MD](#), joined UC Irvine Health from UCLA to launch a comprehensive lymphoma program. Dr. Pinter-Brown is an expert in lymphoid malignancies and is known for her expertise in cutaneous lymphomas and T cell lymphomas.

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Previously, [Susan O'Brien, MD](#), joined us from the MD Anderson Cancer Center in Texas. Dr. O'Brien is an internationally recognized expert on chronic lymphocytic leukemia (CLL) and serves as the Medical Director of the Sue and Ralph Stern Center for Cancer Clinical Trials and Research at UC Irvine.

My own background includes work with chronic myeloid leukemia (CML) and other hematologic malignancies, as well as NIH-funded

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UC Irvine Health

NCI

**Comprehensive
Cancer Center**

A Cancer Center Designated by the
National Cancer Institute

Director's Message

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translational research on CML and on high-risk B-cell acute lymphoblastic leukemia.

Our mission as a NCI cancer center is to be the regional resource for community hematologist/oncologists, providing expert opinions, coordinated treatment plans that keep care close to home, and access to the latest advances and experimental therapies. We look forward to partnering with you to deliver the highest standard of care for your patients.

Sincerely,



Richard A. Van Etten, MD, PhD

Director, Chao Family Comprehensive Cancer Center
University of California, Irvine

Professor of Medicine, Division of Hematology/Oncology,
UC Irvine School of Medicine

Contact Us

For more information about other cancer clinical trials at the Chao Family Comprehensive Cancer Center or whether we have one that might meet your patients' needs, please call 877-827-8839 or email us at ucstudy@uci.edu.

Cancer Center News

NCI renews UC Irvine's comprehensive cancer center designation

The National Cancer Institute has renewed the UC Irvine Health Chao Family Comprehensive Cancer Center designation as a comprehensive cancer center and bestowed an "excellent" rating in its scientific review of the center's capabilities. The distinction is the highest in the center's 24 years as a NCI-designated cancer center.

The Chao Family Comprehensive Cancer Center is one of only 47 NCI-designated comprehensive cancer centers in the United States. It is Orange County's only such center

and is the only local institution where people with advanced-stage or treatment-resistant diseases can access early-phase clinical trials involving the latest therapies.

UCI clinicians have led practice-changing research and trials that have [extended survival in lung cancer](#), [cervical cancer](#) and [metastatic breast cancer](#) and have called attention to significant disparities in [access to the top ovarian cancer treatments](#).

University of California Hematologic Malignancies Consortium

The University of California Hematologic Malignancies Consortium is a collaborative effort among UC physicians conducting clinical research in response to the need for access to large patient populations for hematologic malignancy trials. The consortium allows for investigator-initiated clinical trials to be opened through a centralized approval process at all

five UC cancer center sites: UC Davis, UC San Francisco, UCLA, UC San Diego and UC Irvine.

UC Irvine has opened a Phase 1b clinical trial study of ibrutinib and azacitadine for the treatment of patients with higher-risk MDS.

For more information, contact PI [Deepa Jeyakumar, MD](#), djeyakum@uci.edu.

Blood samples needed for myeloproliferative neoplasm research

UCI faculty member [Angela Fleischman, MD, PhD](#), has an active research study of the pathogenesis of myeloproliferative neoplasm (MPN). She is interested in collecting peripheral blood samples from MPN patients of all types for her laboratory on the UC Irvine

campus. Physicians with MPN patients that might be interested in participating should contact Dr. Fleischman directly at agf@uci.edu.

Go to www.mpnlab.org for more information about these studies.



Blood Cancer Spotlight: CLL

The Bruton's Tyrosine Kinase (BTK) inhibitor ibrutinib has been a breakthrough in treating chronic lymphocytic leukemia, but some physicians remain wary of potential side effects, such as atrial fibrillation and bleeding potential in patients on anti-coagulants.



Susan O'Brien, MD

There's an exciting trial now open that may address those concerns. Acalabrutinib is engineered to avoid those side effects and is backed up by our experiences in the phase I and II trials. UCI is one of the centers running the FDA registration trial that's testing ibrutinib head-to-head with acalabrutinib.

There's good news for participants randomized to either arm. Those in the acalabrutinib arm will get a drug shown in previous trials to have at least the same efficacy as ibrutinib and they likely won't experience that drug's side effects.

Those in to the ibrutinib arm will receive the current standard of care, which is very good. Participants in the ibrutinib arm will receive this drug free — an important consideration for older patients, as the copayments can be substantial. This trial is open to patients with high-risk relapse.

For details, see study UCI 15-88 in Featured Clinical Trials.

Featured Clinical Trials

UC Irvine malignant hematology program is growing its clinical trial portfolio in response to the urgent need for more therapies.

For information about the trials listed below, please contact the primary investigator.

Chronic Lymphocytic Leukemia

Study Title: Phase 3 randomized, multicenter, open-label study of ACP-196 versus ibrutinib

National Clinical Trials #: NCT02477696

UCI ID: UCI 15-88

Acalabrutinib is a novel BTK inhibitor that is more specific for BTK than ibrutinib. The lack of binding to other kinases may reduce the side effects that can be seen with ibrutinib such as atrial fibrillation. In addition, acalabrutinib does not interfere with platelet aggregation as ibrutinib does.

Relapsed patients with high-risk disease (17p or 11q deletions) are eligible. Ibrutinib is free for patients randomized to that arm.

Contact: PI [Susan O'Brien, MD](#), obrien@uci.edu

Lymphoma

Study Title: An Open-Label, Multicenter Phase 1 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

National Clinical Trials #: NCT02290951

UCI ID: UCI 15-18

This trial uses another innovative approach to redirecting the patient's own T cells to the tumor. It uses a bispecific antibody given intravenously, which binds to both the T cells and the malignant B cell to redirect the T cells towards the tumor cells. The first prototypic bispecific antibody was approved by the FDA within the past year to treat patients with refractory ALL. The current trial is using another bispecific antibody to treat patients with relapsed CLL and lymphoma.

Contact: PI [Susan O'Brien, MD](#), obrien@uci.edu

Myelofibrosis

Study Title: A Phase 2, Open-label, Translational Biology Study of Momelotinib in Transfusion-Dependent Subjects with Primary Myelofibrosis (PMF) or Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis

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Meet our hematologists



Elizabeth Brem, MD

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Interests: Lymphoma, hematologic malignancies



Angela Fleischman, MD, PhD

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Interests: Myeloproliferative disorders



Deepa Jeyakumar, MD

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Interests: Acute leukemia, CML, Non-Hodgkins lymphoma, hematology, lymphoma, myeloma



Edward Nelson, MD

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Interests: Hodgkin's lymphoma, tumor immunology and immunotherapy

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Featured Clinical Trials

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National Clinical Trials #: NCT02515630 UCI ID: UCI 15-67
Ruxolitinib (Jakafi), the JAK 1/2 inhibitor, is approved for the treatment of MF. This was a big step forward in a disease that previously had no standard therapy. However, well-known and sometimes dose-limiting toxicities include anemia and thrombocytopenia.

Momelotinib is a JAK inhibitor that appears to cause significantly less anemia. This oral agent is available on a phase 2 trial for transfusion-dependent patients with MF. The goal of this study is to determine the transfusion independence response rate in MF patients treated with momelotinib. This study is important because there is a real need for new agents for the treatment of anemia in MF.

Contact: PI [Angela Fleischman, MD, PhD](#), agf@uci.edu

Acute Myelogenous Leukemia/Myelodysplastic Syndrome

Study Title: Phase 1b Study of Ibrutinib and Azacitidine for the treatment of patients with higher risk MDS

National Clinical Trials #: NCT02553941 UCI ID: UCI 14-93

Through the UC Hematologic Malignancies Consortium, a collaborative partnership of the five UC medical centers, UC Irvine is participating in this investigator-initiated trial by our colleagues at UC Davis looking to establish a safe dose of Ibrutinib when used in combination with azacitidine. Using these two agents together may have synergistic and additive activity in higher-risk Myelodysplastic Syndromes. Ibrutinib is free for all patients.

Contact: PI [Deepa Jeyakumar, MD](#), djeyakum@uci.edu

Lymphoblastic Leukemia

Study Title: A phase II Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia (ALL)

National Clinical Trials #: NCT02003222 UCI ID: ECOG-E1910

UC Irvine is an active member of the National Cancer Institute's National Clinical Trials Network (NCTN). This phase 3 FDA registration trial funded by the NCTN is looking at the effectiveness of adding Blinatumomab, a bispecific CD19-directed CD3 T-cell engager that activates endogenous T cells when bound to the CD19-expressing target cells, to standard chemotherapy in patients with newly diagnosed ALL.

Blinatumomab is free for patients randomized to that arm.

Contact: PI [Deepa Jeyakumar, MD](#), djeyakum@uci.edu

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Meet our hematologists

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Susan O'Brien, MD

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Interests: Chronic lymphocytic leukemia, acute lymphoblastic leukemia



Richard Van Etten, MD, PhD

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Interests: Acute leukemia, CLL CML, Hematopoietic stem cell transplantation, immune therapy, lymphoblastic leukemia



Lauren Pinter-Brown, MD

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Interests: Antiphospholipid, B-cell lymphoma, General hematology, Hodgkin's lymphoma, Mucositis fungoides and other T-cell lymphomas, Non-Hodgkins lymphoma, stem cell transplant, Waldenstrom's disease

Featured Clinical Trials

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Study Title: A Phase I/II Study Evaluating KTE-C19 in Subjects with Relapsed/Refractory ALL

National Clinical Trials #: NCT 02614066

UCI ID: UCI 15-58

Targeting patients with the greatest unmet need in treatment of relapsed ALL, this trial uses the highly innovative and promising approach to cancer therapy of Chimeric Antigen Receptor-T cells (CAR-T cells) by which a patient's own T lymphocytes are genetically modified to target and kill cancer cells. This study will evaluate the safety and efficacy of a CAR-T therapy targeting the CD19 antigen expressed on B-cell acute lymphoblastic leukemia. The investigational agent, KTE-C19, is free for all patients.

Contact: PI [Susan O'Brien, MD, obrien@uci.edu](mailto:obrien@uci.edu)

Acute Myelogenous Leukemia

Study Title: A Phase III Open-label, Multicenter, Randomized Study of ASP2215 vs. Salvage Chemotherapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia with FLT3 Mutation

National Clinical Trials #: NCT02421939

UCI ID: UCI 15-69

For relapsed or refractory AML leukemia with mutations in the FLT3 tyrosine kinase, that is a Phase 3 study of the FLT3 inhibitor ASP2215 versus standard chemotherapy in AML patients.

Contact: PI [Deepa Jeyakumar, MD, djeyakum@uci.edu](mailto:djeyakum@uci.edu)

Multiple Myeloma

Study Title: A Phase I/II Study of PiC-D (Ixazomib in Combination with Pomalidomide, Clarithromycin and Dexamethasone) in Patients with Relapsed or Refractory Multiple Myeloma.

National Clinical Trials #: NCT02542657

UCI ID: UCI 14-96

The study's goal is to establish the maximum tolerate dose and the recommended phase II dose for pomalidomide, ixazomib, clarithromycin, and dexamethasone (PiC-D) in patients with multiple myeloma who are bortezomib and lenalidomide pre-treated. Options are limited in patients who are dual-refractory to lenalidomide and bortezomib. The emerging safety profile indicates that ixazomib is generally well-tolerated. Adverse events are consistent with the class-based effects of proteasome inhibition and are similar to what has been previously reported with bortezomib though the severity of some, for example peripheral neuropathy, is less.

Contact: PI [Elizabeth Brem, MD, ebrem@uci.edu](mailto:ebrem@uci.edu)

