Focus on: 2015 BMT Tandem Meetings

To refer a patient:

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Visit us at:
kucancercenter.org/BMT or kumed.com/BMT
3901 Rainbow Blvd.
Kansas City, KS 66160

PET scans predict relapse in patients with NHL

Haploidential HCT with cyclophosphamide for high-risk leukemias

Annual Symposium highlights with presentation access

Long-term outcomes after HCT for mantle cell lymphoma

Upcoming clinical trials - CAR-T cells for DLBCL and Survivin

HCT Research from the BMT Tandem Meetings

An update on research in HCT presented at the 2015 Blood and Marrow Transplantation (BMT) Tandem Meetings. Additional summaries of the latest HCT research are available by visiting BeTheMatchClinical.org/Research

Table 1. Transplant outcomes of 336 patients with NHL, by PET scan status.

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Haploidential HCT with cyclophosphamide for high-risk leukemias

In this retrospective study, Dr. Veronika Bachanova of the University of Minnesota and her colleagues analyzed the outcomes of 336 allogeneic transplants submitted to CIBMTR (Center for International Blood and Marrow Transplant Research). Transplants were performed between 2007 and 2012 at 81 centers, and all patients had chemosensitive non-Hodgkin lymphoma (NHL). PET scans were performed before transplantation to determine a patient’s disease status and optimal timing for transplantation. PET scans are commonly used in lymphoma staging and have been shown to help guide treatment choices. However, the role of PET in the context of allogeneic HCT for NHL is less definitive.

The investigators concluded that PET+ chemosensitive NHL patients may benefit from peri-transplant interventions to reduce the risk of relapse/progression. Because patients experienced long-term survival of nearly 60% regardless of PET status, they also noted that a positive PET scan should not prevent these patients from being considered for an allogeneic transplant.

Overall, the study found that PET+ status was associated with a higher risk of relapse/progression (Relative risk [RR]: 1.76; 95% CI 1.19-2.6; p=0.004) and lower non-relapse mortality (NRM), but was not predictive of overall survival or progression-free survival. PET status had no impact on incidence of grade II-IV acute GVHD or chronic GVHD. Other outcomes are shown in Table 1.

Patients ranged in age from 18-71 years, and there was no difference in median age of the cohort were more heavily pretreated, and more frequently had extranodal disease, marrow involvement, or bulky disease.

In 2015, the latest PET scans predict relapse in patients with NHL conference featured nationally-recognized experts in the field, attracting more than 230 attendees. See the summary on page 2 of the current issue of Transplant Connection for more details.

Haploidential HCT with cyclophosphamide for high-risk leukemias

Haploidential HCT has emerged as an attractive option for patients with high-risk hematologic malignancies who are not able to find a matched donor. However, the role of Haploidential HCT with cyclophosphamide for high-risk leukemias remains under investigation. The University of Kansas Cancer Center is one of the leading centers for Haploidential HCT and is dedicated to advancing research in this field.

The latest Haploidential HCT with cyclophosphamide for high-risk leukemias research presented at the 2015 Blood and Marrow Transplantation (BMT) Tandem Meetings is developed by the National Marrow Donor Program/Be The Match in support of its Network partnership with The University of Kansas Hospital.

Focus on: 2015 BMT Tandem Meetings

WHAT’S INSIDE:

• PET scans predict relapse in patients with NHL
• Haploidential HCT with cyclophosphamide for high-risk leukemias
• Annual Symposium highlights with presentation access
• Long-term outcomes after HCT for mantle cell lymphoma
• Upcoming clinical trials - CAR-T cells for DLBCL and Survivin
Welcome to Transplant Connection, The University of Kansas Cancer Center (KUCC) newsletter focusing on issues in hematopoietic cell transplantation (HCT) that we think will be of interest to our referral community. This issue focuses on a selection of the best HCT research presented at the 2015 Blood and Marrow Transplantation (BMT) Tandem Meetings. Additional summaries of the latest HCT research are available by visiting BeTheMatchClinical.org/Research.

**PET scans predict relapse in patients with NHL**

Positron emission tomography (PET) scans are commonly used prior to autologous transplantation to determine a patient’s disease status and optimal timing for transplantation. The clinical utility of PET imaging prior to allogeneic transplants for lymphomas is less definitive, but new research results from a large-scale study have demonstrated that PET scans can be used to predict risk of relapse in adults undergoing allogeneic HCT for non-Hodgkin lymphomas. [1]

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Patients ranged in age from 18-71 years, and there was no difference in median age of the PET+ and PET− cohorts: 55 vs. 54 years, respectively, (p=0.95). However, patients in the PET+ cohort were more heavily pretreated, and more frequently had extranodal disease, marrow involvement, or bulky disease.

On multivariate analysis, PET+ status was associated with a higher risk of relapse/progression (Relative risk [RR]: 1.76; 95% CI 1.19-2.6; p=0.004) and lower non-relapse mortality (NRM), but was not predictive of overall survival or progression-free survival. PET status had no impact on incidence of grade II-IV acute GVHD or chronic GVHD. Other outcomes are shown in Table 1.

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**BMT program highlights**

- Region's largest BMT and acute leukemia program including photopheresis and clinical trials.
- Region's first BMT program accredited by the Foundation for Accreditation of Cellular Therapy, or FACT. Received fifth accreditation in 2014.
- More than 2,600 successful transplants.
- Designated as a BMT-CTN core center.
- Designated as a Center of Excellence for all malignancies and HCT.
- Network member of the National Marrow Donor Program since 1995.
- Medicare-approved since 1977.

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Haploidentical HCT with cyclophosphamide for high-risk leukemias

Myeloblastic transplants using T-cell-replete haploidentical grafts and post-transplant cyclophosphamide can result in a 2-year overall survival (OS) of 57%, with cumulative incidence of relapse reaching 44% in 3 years according to results of a phase I/II study presented at the BMT Tandem Meetings. [2]

The study enrolled 97 patients with leukemias in complete remission or chemosensitive lymphomas with at least a partial remission transplanted at Johns Hopkins University. Median age of patients was 42 years (range, 1-65), and median number of HLA allele mismatches from haploidentical donors was 4/10.

Post-transplant immunosuppression was cyclophosphamide at 50 mg/kg/day on days 3 and 4, followed by mycophenolate mofetil for 30 days and tacrolimus for 6 months. Lead author Dr. Heather Symons noted that the selective depletion of proliferating alloreactive T cells brought about via post-transplant cyclophosphamide makes the agent very effective at controlling GVHD.

The cumulative incidence of relapse at three years was 44% with minimal residual disease (MRD) status associated with the incidence. For leukemia patients in clinical remission (CR) with no detectable MRD, the cumulative incidence of relapse at 2 years was 33% in CR1 and 27% in >CR2. For leukemia patients in any CR with detectable MRD by flow cytometry and/or cytogenetics and/or FISH, the cumulative incidence of relapse at 2 years was 60%.

In an oral presentation of the research, Dr. Symons concluded that haploidentical transplantation with post-transplant cyclophosphamide resulted in very low rates of acute and chronic GVHD, low transplant-related mortality at 30 days, and that haploidentical HCT warrants further study.

Dana-Farber/Harvard, Moffitt Cancer Center, Johns Hopkins and the University of Minnesota. Each speaker discussed optimal pathways of care for patients with highly variable and complex hematological malignancies.

Haploidentical HCT outcomes

At a median follow-up of 18 months, 1-year OS was 72%. Other outcomes are shown in Table 2.

### Table 2. Outcomes of 97 haploidentical transplants. GvHD = graft-versus-host disease; TRM = transplant-related mortality; EFS = event-free survival

<table>
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<th>Grade</th>
<th>Incidence (%)</th>
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<tbody>
<tr>
<td>I</td>
<td>6</td>
</tr>
<tr>
<td>II</td>
<td>3</td>
</tr>
<tr>
<td>III</td>
<td>2</td>
</tr>
<tr>
<td>IV</td>
<td>1</td>
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### Table 3. Five- and ten-year outcomes of 70 patients with MCL undergoing non-myeloablative HCT.

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Long-term outcomes after HCT for mantle cell lymphoma

A study of 70 patients with mantle cell lymphoma (MCL) undergoing non-myeloablative hematopoietic cell transplantation (HCT) demonstrated that a majority can achieve 5-year survival and can discontinue immunosuppressive medications. [3]

Patients were a median age of 57 years (range, 32-75) and underwent HCT using related (n=35) or unrelated (n=35) donors. The non-myeloablative conditioning regimen was 2 Gy total body irradiation alone or combined with fludarabine with or without rituximab.

Twenty-eight patients had received a prior autologous transplant, 7 had a tandem autologous/allogeneic procedure, and 35 patients had no prior autologous transplant. Twenty-five patients (36%) had relapsed/refractory disease at time of transplant.

Five-year overall survival (OS) was 55%. Among 33 patients with sufficient follow up, 10-year OS was 44%. At last follow up, 80% of surviving patients were off immunosuppression, with a median time to immunosuppression cessation of 35 months (range, 1-95). Other outcomes are shown in Table 3.

### CLINICAL TRIALS SPOTLIGHT: UPCOMING TRIAL OPPORTUNITIES

**Phase II multicenter CAR T-cell trial in relapsed/refractory diffuse large B-cell lymphoma**

The most frequent lymphoma subtype, diffuse large B-cell lymphoma (DLBCL) represents 30-35% of all non-Hodgkin lymphomas. One-third of patients have disease that is either refractory to initial therapy or relapses after standard therapy and have a poor prognosis with a median survival of 4 months and only 4% are alive after 1 year.

The purpose of this study will be to determine the safety and efficacy of CTL019 in adults with relapsed or refractory DLBCL by evaluating response rate. AutoT cells have been developed that are genetically modified ex-vivo to express a chimeric antigen receptor (CAR) consisting of a CD19 antigen recognition domain attached to intracellular signaling domains that mediate T-cell activation. Data from patients with B-cell ALL, CLL, and preliminary data in DLBCL show that CTL019 therapy has potent anti-tumor activity.

Eligibility criteria includes adults >18 years with relapsed or refractory DLBCL after 2 lines of chemotherapy and having failed or ineligible for HCT. Additional criteria include measurable disease, ECOG performance status ≤1 at screening, and adequate organ function. This trial is posted on clinicaltrials.gov as NCT02212201.

**Individualized Care Plans for HCT Survivors**

This randomized study will compare a personalized Survivorship Care Plan (SCP) with the routine standard of care (no SCP). The investigators hypothesize that the personalized SCP will enhance patient survivorship confidence in knowledge, increase adherence to recommended healthcare, improve health behaviors and reduce hematopoietic cell transplantation (HCT) - related emotional distress.

Eligibility criteria includes all adult >18 years at time of HCT survivors at 1-2 years after the most recent HCT with no evidence of relapse, disease progression or secondary cancer at last follow-up. All diagnoses, types of transplant (autologous or allogeneic related or unrelated), graft sources, and conditioning regimens are eligible. This trial is posted on clinicaltrials.gov as NCT02200333.

**Visit kancancercenter.org/cliclinaltrials to learn about additional BMT and hematological malignancy clinical trials.**

Highlights from our annual symposium

The Blood and Marrow Transplant Program’s third annual symposium was its biggest to date, attracting more than 230 attendees from more than 20 different healthcare institutions and companies from Kansas, Missouri and Iowa.

During the daylong symposium, held April 11, attendees reviewed the latest advances in the field of autologous and allogeneic transplantation — state-of-the-art treatment strategies, clinical trials research and outcomes of both autologous and allogeneic (related and unrelated) donors.

“Our BMT program continues to lead the region — not only in the number of patients treated, but also in our innovative approach to treating blood cancers,” said Joseph McGuirk, DO, BMT medical director.

“The symposium’s success plays a critical role in our effort to educate our referring physicians and the community about the success of our BMT program and our patient outcomes,” he added, “and the clinical advances in the field of stem cell transplantation and cellular therapeutics.”

The program featured speakers from The University of Kansas Cancer Center’s BMT program, along with nationally known speakers from Kansas, Missouri and Iowa.
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<tr>
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<th>100 days</th>
<th>6 months</th>
<th>1-year OS</th>
<th>2-year OS</th>
<th>3-year OS</th>
<th>8-year OS</th>
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<tr>
<td>III-V</td>
<td>Acute</td>
<td>7%</td>
<td>51%</td>
<td>44%</td>
<td>33%</td>
<td>21%</td>
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<td>Chronic</td>
<td>Gvhd</td>
<td>6 months</td>
<td>16%</td>
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<td>2-year overall survival</td>
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Slide presentations from the symposium are now available online at kucancercenter.org/bmtconference. These include:

- Advances in Stem Cell Transplantation and Cellular Therapeutics - Joseph McGuirk, DO
- Advances in the Management of Myelodysplastic Syndromes - Corey Cutter, MD
- Advances in Myeloma - Sunil Abhyankar, MD
- Updates in Multiple Myeloma - Sid Ganguly, MD

Save the date for our fourth annual symposium, Saturday, April 16, 2016. One of our featured speakers will be Dr. Carl June from the University of Pennsylvania Abramson Cancer Center. He will share the latest updates on his work in adoptive immunotherapy as an emerging therapy and the latest results in CAR T-cell therapy trials.

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To enroll a patient
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TRANSPLANT CONNECTION:
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Visit the Physicians Resource Center at: BeTheMatchClinical.org

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