Baylor Charles A. Sammons Cancer Center at Dallas Joins Multiple Myeloma Research Consortium

Joseph W. Fay, MD, medical oncologist on the medical staff at Baylor University Medical Center at Dallas, and medical director of the Division of Immunologic Therapy for Cancer at Baylor Research Institute, has announced that Baylor Charles A. Sammons Cancer Center at Dallas is now a member of the Multiple Myeloma Research Consortium (MMRC). The MMRC is an early stage drug development consortium comprising 16 world-renowned research institutions from across the country, including City of Hope, Dana-Farber Cancer Institute, H. Lee Moffitt Cancer Center and Research Institute, Mayo Clinic, and Mount Sinai School of Medicine. The mission of the MMRC is to accelerate the development of innovative treatments for patients with multiple myeloma (MM) by promoting and facilitating collaborative research between industry and academia.

MM is a malignancy of plasma cells that is characterized by bone destruction, renal failure, anemia, and hypercalcemia. It is increasing in incidence for unexplained reasons. It is typically a disease of older people, with more than 75% of new cases occurring in

Cluster of abnormal plasma cells in bone marrow aspirate from a patient with multiple myeloma.

(Continued on page 3)
From the Director

In Good Company

In this issue we highlight multiple myeloma, both because of our long and rich history of research and treatment of this disease and as an example of our commitment to clinical research. As discussed by Marvin Stone, MD, MACP, later in this issue, multiple myeloma was first described in 1844. At the beginning of the 20th century, around the same time that J. H. Wright identified plasma cells as the origin of myeloma tumors, what is now Baylor University Medical Center at Dallas was founded as the Texas Baptist Memorial Sanitarium. In 1976, Baylor Charles A. Sammons Cancer Center was founded, and Dr. Stone, a recognized leader in myeloma research and treatment, was chosen to be its first director.

The recent acceptance of Baylor Sammons Cancer Center as a member of the Multiple Myeloma Research Consortium (MMRC) (page 1) places us in the select company of leading institutions in myeloma research across the country and makes additional clinical trials available to our patients. In addition to the MMRC, we draw clinical trials to our center from some of the leading clinical research organizations in the country and in the world. These include the Southwest Oncology Group, the US Oncology Research Network, the National Surgical Adjuvant Breast and Bowel Project, and, more recently, the Cancer Immunotherapy Trials Network. Additionally, we perform trials stemming from discoveries here at Baylor Research Institute and trials brought to us from leading pharmaceutical companies and from our longstanding relationship with Texas Oncology. Through all of these sources, we maintain an active list of more than 100 cancer clinical trials and accrue an average of 800 patients to therapeutic trials annually. More information about our clinical trials activity can be found on page 12.

Much progress has been made in cancer treatment and research, but we all need to work together to accelerate that progress. Nationally, only 2% of all adults with cancer participate in clinical trials. We need to do better, and hopefully, through collaborations like those mentioned above, we will.

Also of note in this issue is the announcement that Baylor Dallas will become a clinical teaching campus for Texas A&M Health Science Center College of Medicine. We are excited about having A&M medical students here starting in December, and about the prospects of collaborating with the researchers at Texas A&M Health Science Center. My aggie friends tell me a great big Howdy is in order.
patients older than 70 years. While MM is treatable, it is only rarely curable. Newer systemic therapies (bortezomib, thalidomide, lenalidomide) and advances in autologous and allogeneic stem cell transplantation have significantly improved patient outcomes over the last 10 years, but the 5-year survival rate is still only about 35%. New treatment strategies are badly needed to improve this grim prognosis.

The MMRC is a powerful research model to fast-track promising myeloma therapies from bench to bedside. A key component of the MMRC model is the MMRC Tissue Bank, a unique resource that integrates myeloma tissue samples with corresponding genomic and clinical data. Through the implementation of strong quality control and auditing procedures, the MMRC Tissue Bank ensures that all tissue samples are of the highest quality. It has become a major resource for industry seeking fresh tissue samples to initiate validation studies. The MMRC Tissue Bank is the basis for basic science research exploring the biology of MM and for preclinical validation studies of innovative therapies.

A custom-designed data bank allows the standardization and sharing of clinical and research data to facilitate research efforts among consortium members. All information is collected and managed to be in compliance with the requirements of the Food and Drug Administration and the Health Insurance Portability and Accountability Act of 1996, as well as other federal and international regulations and standards.

Since its inception in 2004, the MMRC has partnered with pharmaceutical and academic sponsors to facilitate 19 phase I and phase II clinical trials involving novel treatment strategies aimed at high-priority targets. MMRC clinical trials include correlative studies to help in determining optimal treatment strategies for specific subgroups of patients with MM.

Researchers and clinicians at Baylor Sammons Cancer Center are excited about this new opportunity to expedite development of effective new therapies for MM. Dr. Fay commented: “Our membership in the MMRC enables us to significantly extend our clinical research to studies of the basic biology of myeloma. This unique capability will enable participation in and initiation of new treatment approaches for this disease. In addition, the MMRC will facilitate studies in the tumor immunology and immunotherapy of myeloma within Baylor Institute for Immunology Research and Baylor Sammons Cancer Center.”

Joseph Fay, MD

Serum immunofixation showing an IgG, lambda monoclonal protein in a patient with multiple myeloma.
The History of Myeloma

by Marvin J. Stone, MD, MACP

Multiple myeloma has probably existed for centuries, but the first documented report of a patient with “mollities ossium” (soft bones) was made by Samuel Solly in 1844. One year later, Henry Bence Jones, whom Florence Nightingale called “the best chemical doctor in London,” found that the urine of a mollities ossium patient exhibited a peculiar thermal solubility. He concluded that it contained an abnormal substance which he identified as a “hydrated deutoxide of albumen.” Although Bence Jones was incorrect, he rightly predicted that the finding of such an unusual protein in the urine of other patients would be of diagnostic value. During the next century, the presence of Bence Jones protein in urine did indeed make the diagnosis of myeloma in countless patients; thus, it was the first tumor marker. However, 117 years passed before Bence Jones proteins were correctly identified as free monoclonal immunoglobulin light chains. In 1900, J. H. Wright reported that myeloma tumors originated from plasma cells. Wright’s patient was probably the first in whom X-rays demonstrated characteristic lytic lesions in the ribs.

Because of destructive bone tumors, patients with myeloma manifested severe pain, especially in the spine. The disease was uniformly fatal, and there was no effective treatment for decades. Around 1930, occasional myeloma patients were found to have amyloidosis. Subsequently, the relationship of myeloma with amyloidosis became controversial and confusing. In the early 1980s, George Glenner and colleagues demonstrated that amyloid fibrils in patients with myeloma or nonhereditary systemic amyloidosis consisted of Bence Jones protein, i.e., free monoclonal immunoglobulin light chains or, more often, fragments from their variable region.

In 1960, Jan Waldenström recognized that many individuals with monoclonal peaks on serum protein electrophoresis did not have either myeloma or macroglobulinemia. Most remained stable, but a few progressed to overt malignancy. In 1978, Robert Kyle named this entity “monoclonal gammapathy of undetermined significance” (MGUS). Long-term studies showed that transformation to myeloma, macroglobulinemia, or light chain amyloidosis occurred in 1% of patients with MGUS per year. More recently, Ola Landgren reported that MGUS is a precursor in virtually all myeloma patients.

Treatment for myeloma came slowly. Prior to 1960, urethane was used without objective benefit. Then phenylalanine mustard (melphalan) came into use along with corticosteroids and, soon thereafter, cyclophosphamide. These drugs provided the first evidence of objective partial remission in 30% of patients and led to increased survival in responders. During the next three decades (1960–1990), no substantial advances in chemotherapy occurred. Bisphosphonates became available in the mid-1990s and were effective in reducing skeletal-related events in myeloma patients. Autologous stem cell transplantation was widely adopted in the late 1990s because it prolonged the duration of remission compared with melphalan and prednisone, although it did not result in cure. Allogeneic bone marrow transplantation has not been widely utilized in myeloma because of its high morbidity and mortality in this patient population.

During the past 10 years, novel agents such as thalidomide and the proteasome inhibitor bortezomib have been added to the therapeutic armamentarium. These agents, in combination with corticosteroids and/or alkylating agents, have yielded higher remission rates, including some complete remissions. Moreover, overall survival has improved. Although myeloma remains an incurable disease, the outlook for patients is clearly better. Further advances are eagerly awaited.

Skull X-ray showing numerous “punched out” lytic lesions caused by multiple myeloma.
### Upcoming Meetings of Interest to Oncologists

**October 2011**

12. **Advances in Breast Cancer Research: Genetics, Biology, and Clinical Applications**
   - October 12–15, 2011
   - San Francisco, California
   - [www.aacr.org/page3544.aspx](http://www.aacr.org/page3544.aspx)

15. **Translation of the Cancer Genome: Scientific, Clinical, and Operational Challenges**
   - October 15–18, 2011
   - San Francisco, California

16. **Metabolism and Cancer**
   - October 16–19, 2011
   - Baltimore, Maryland

22. **Tenth Annual AACR International Conference on Frontiers in Cancer Prevention Research**
   - October 22–25, 2011
   - Boston, MA

26. **MSTS/CTOS Annual Meeting 2011—Musculoskeletal Tumor Society/Connective Tissue Oncology Society**
   - October 26–29, 2011
   - Chicago, Illinois

**November 2011**

03. **Tumor Microenvironment Complexity: Emerging Roles in Cancer Therapy**
   - November 3–6, 2011
   - Orlando, Florida

10. **Eighth International Conference of the Society of Integrative Oncology**
   - November 10–12, 2011
   - Cleveland, Ohio
   - [www.integrativeonc.org](http://www.integrativeonc.org)

12. **AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics**
   - November 12–16, 2011
   - San Francisco, California

**December 2011**

06. **CTRC-AACR San Antonio Breast Cancer Symposium**
   - December 6–10, 2011
   - San Antonio, Texas
   - [www.sabcs.org](http://www.sabcs.org)

10. **2011 American Society of Hematology Annual Meeting and Exposition**
   - December 10–13, 2011
   - San Diego, California
   - [www.hematology.org/Meetings/Annual-Meeting/](http://www.hematology.org/Meetings/Annual-Meeting/)

**January 2012**

08. **AACR-IASLC Joint Conference on Molecular Origins of Lung Cancer: Biology, Therapy, and Personalized Medicine**
   - January 8–11, 2012
   - San Diego, California

19. **2012 Gastrointestinal Cancers Symposium**
   - January 19–21, 2012
   - San Francisco, California
   - [www.gicasymposium.org](http://www.gicasymposium.org)

26. **Multidisciplinary Head and Neck Cancer Symposium**
   - January 26–28, 2012
   - Phoenix, Arizona
   - [www.headandnecksymposium.org/index.htm](http://www.headandnecksymposium.org/index.htm)

**February 2012**

01. **2012 BMT Tandem Meetings**
   - February 1–5, 2012
   - San Diego, California
   - [www.asbmt.org/displaycommon.cfm?an=3](http://www.asbmt.org/displaycommon.cfm?an=3)

02. **Genitourinary Cancers Symposium**
   - February 2–4, 2012
   - San Francisco, California
   - [www.gucasymposium.org](http://www.gucasymposium.org)

11. **GI Cancer Conference**
   - February 11, 2012
   - Dallas, Texas
   - [www.camenaegroup.com](http://www.camenaegroup.com)
   - (See back cover for details)

18. **Scripps Cancer Center’s 32nd Annual Conference: Clinical Hematology and Oncology**
   - February 18–21, 2012
   - San Diego, California
Background: The Current Status of Frontline Treatment

As reviewed by Dr. Stone in the article about the history of multiple myeloma (MM), treatments for MM have developed slowly. Chemotherapy regimens based on melphalan, corticosteroids, and cyclophosphamide that were introduced around 1960 became the treatment standard for the next 30 years, followed by the introduction and adoption of autologous stem cell transplantation (ASCT) in the 1990s. The combination of a chemotherapy induction regimen and ASCT showed improved success in inducing lasting remissions in some patients, although cures were still uncommon.

After this slow start, the last 10 years have seen a dramatic improvement in treatment options for MM. The introduction of newer systemic therapies (bortezomib, thalidomide, lenalidomide) for use in induction chemotherapy has significantly improved patient outcomes.

Bortezomib is a proteasome inhibitor, a member of a new class of drugs that interfere with the programmed degradation of unneeded or damaged proteins by proteolysis. A second-generation proteasome inhibitor, carfilzomib, is now being tested for use in frontline therapy for MM.

Drugs in the thalidomide family have also shown success in the frontline treatment of MM. Although the effect of thalidomide was originally thought to be related to angiogenesis, it is most likely acting through direct inhibitory effects on plasma cells, regulation of important pathways involving cell growth and adhesion to bone marrow, and immunomodulatory effects. Second-generation drugs in the thalidomide family include lenalidomide, which is reported to be strongly antiangiogenic and up to 50,000 times more potent than thalidomide in selected immunomodulatory effects. Another thalidomide family drug, pomalidomide, is currently still undergoing clinical trials. Preliminary data suggest that it may work in patients who have been treated unsuccessfully with thalidomide or lenalidomide.

In the most recent cancer treatment guidelines from the National Comprehensive Cancer Network (NCCN), all category 1 recommendations for primary therapy in patients with MM, whether or not they are candidates for ASCT, contain bortezomib, thalidomide, and/or lenalidomide, in combination with dexamethasone or prednisone.

ASCT has also seen significant improvements since its inception in the 1990s. Although the general therapeutic approach has not changed significantly over the past 20 years, improved supportive therapies have made the procedure safer. It is now frequently performed on an outpatient basis, and recovery is much quicker. There are better techniques available to mobilize stem cells and more effective approaches for preventing infection. Allogeneic SCT, which has not seen wide use because of the high morbidity rate associated with it, can now be performed more safely, using less aggressive conditioning regimens that allow its use in older patients or those with kidney problems.

The introduction of ASCT and newer systemic therapies has improved outcomes for patients with MM, as reflected in data from the Surveillance, Epidemiology, and End Results database. Compared with the period from 1975 to 1994, when the annual percentage change in mortality from MM showed an increase of 1.4% per year, the period from 1994 to 2002 (after the introduction of ASCT) showed a decrease of 0.8% a year, and the period from 2002 to 2007 (after the introduction of newer systemic therapies) showed a decrease of 1.8% per year. This trend is mirrored in data from the Texas Cancer Registry, which showed that the age-adjusted mortality rate for MM decreased from 4.1 deaths per 100,000 individuals in the period from 1995 to 1999 to 3.5 deaths per 100,000 individuals in the period from 2004 to 2008.

Controversy: Is ASCT Necessary in Frontline Therapy?

Current NCCN treatment recommendations call for ASCT to occur after induction therapy as part of the initial treatment for MM, possibly followed by maintenance therapy with single-agent thalidomide (category 1 recommendation), lenalidomide, or bortezomib. Recently, however, the role of ASCT in frontline therapy has been the subject of debate. Some suggest that the addition of ASCT to the primary treat-
ment regimen may offer no additional advantage for patients who achieve a complete response (CR) or very good partial response (VGPR) after initial chemotherapy alone. Would it be preferable for such patients to move directly to maintenance therapy, reserving ASCT as a postrecurrence treatment option? The advantage would be that the potential expense and morbidities associated with ASCT could be avoided for as long as possible, to be replaced by a long-term drug regimen. Important to note in this assessment is that two of the drugs recommended for maintenance therapy, thalidomide and lenalidomide, are oral agents and would not require clinic visits for administration. Bortezomib is administered intravenously or subcutaneously.

A related question is whether ASCT could be postponed in specific groups of patients based on delineation of risk groups defined by chromosomal or genomic factors. Several treatment algorithms based on this concept have been developed (Mayo Clinic, University of Arkansas).

Two clinicians on the medical staff at Baylor University Medical Center at Dallas who are involved in the care of patients with MM were asked to address these questions from their different professional perspectives.

Christopher Maisel, MD, is a medical oncologist/hematologist who has been involved in a series of clinical trials involving new agents for the systemic treatment of MM. Dr. Maisel pointed out that patients who can achieve a CR or VGPR tend to live longer and do better, and that, until fairly recently, ASCT was essential in order to get patients into remission. This picture may be changing with the introduction of newer agents that show a marked increase in good response rates. He said that, although existing studies have yielded conflicting results, it is beginning to appear that patients who have a disease with high risk features and/or who can achieve a CR or VGPR without frontline ASCT may do better receiving induction therapy followed by maintenance. ASCT could then be reserved for the time of disease progression or relapse. This possibility may become even stronger with the introduction of next-generation agents now undergoing clinical trials and with the almost 200 drugs now reported in preclinical studies. He cautioned that we do not yet have definitive support for this idea from randomized prospective data and that, at any rate, ASCT will almost certainly remain part of the treatment armamentarium against MM for the foreseeable future.

Brian Berryman, MD, is a medical oncologist/hematologist with over 13 years experience in blood and marrow transplantation. He is an attending physician for the Blood and Marrow Transplantation Program at Baylor Dallas, one of the largest multispecialty transplant centers in the country. Dr. Berryman began by proposing that many existing debates in MM treatment derive from a central issue: Is the goal in myeloma treatment cure or control? Most believe it is a control issue and that we need to consider treatment regimens in terms of long-term control while optimizing quality of life. He contrasted potential scenarios with the induction chemotherapy/ASCT treatment standard versus the induction/maintenance model. In the first case, patients may achieve a remission that could last as long as 3 to 4 years, without maintenance. While the second scenario, with the inclusion of long-term maintenance, might offer similar disease outcomes, cost and quality of life issues become important. The agents used for maintenance therapy have side effects that are sometimes significant, some agents must be administered intravenously once or twice a week, and newer agents can be very expensive, often thousands of dollars a month. He suggested that doing a transplant, in the long run, may be cheaper and much more convenient than medical therapy for years on end.

Dr. Berryman believes that at some point, with increasingly more effective therapies, ASCT will gradually fall into disuse. The possibility of triaging patients with risk assessment algorithms based on cytogenetic and genomic information may distinguish those patients most likely to respond well to chemotherapy alone. That same genomic information may lead to the discovery of molecular targets that will allow a precision medicine approach to treating MM. For now, however, Dr. Berryman comes to the same conclusion as Dr. Maisel: We are not yet at the point where we can answer these questions and, for the foreseeable future, regimens combining both chemotherapy and ASCT will remain the treatment standard.
Baylor Cancer Hospital, the first dedicated cancer hospital in North Texas, is set to begin a staged opening as part of the cancer services expansion of Baylor University Medical Center at Dallas. The new inpatient hospital is a major renovation of the existing Collins building and part of the adjacent Sammons building on the Baylor Dallas campus. It will house 120 beds and a pharmacy, as well as patient and family support areas and the bone marrow transplant unit. The hospital will be connected to the recently opened outpatient facility by the Collins Family “Bridge of Hope” skybridge.

The timeline for the opening of the new Baylor Cancer Hospital is as follows:

<table>
<thead>
<tr>
<th>Location</th>
<th>Unit/Service</th>
<th>Estimated Opening Date*</th>
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<tbody>
<tr>
<td>Basement</td>
<td>Medical equipment maintenance</td>
<td>January 2012</td>
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<tr>
<td>1st floor</td>
<td>Apheresis unit, evaluation and treatment center</td>
<td>February 2012</td>
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<tr>
<td></td>
<td>Infusion center</td>
<td>March 2012</td>
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<tr>
<td></td>
<td>Interventional radiology</td>
<td>December 2012</td>
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<td></td>
<td>Food services</td>
<td>December 2012</td>
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<tr>
<td>2nd floor</td>
<td>Blood and marrow transplant processing lab</td>
<td>January 2012</td>
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<tr>
<td></td>
<td>Nursing unit</td>
<td>December 2012</td>
</tr>
<tr>
<td>3rd floor</td>
<td>Pharmacy</td>
<td>January 2012</td>
</tr>
<tr>
<td>4th floor</td>
<td>Nursing unit</td>
<td>December 2012</td>
</tr>
<tr>
<td>5th floor</td>
<td>Nursing unit</td>
<td>December 2012</td>
</tr>
<tr>
<td>6th floor</td>
<td>Nursing unit for leukemias and lymphomas</td>
<td>January 2012</td>
</tr>
<tr>
<td>7th floor</td>
<td>Blood and marrow transplant nursing unit</td>
<td>January 2012</td>
</tr>
<tr>
<td>Various floors</td>
<td>Family support areas, care coordination, nutrition, and social work</td>
<td>January 2012</td>
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*Estimated opening dates may change without notice.

The new Baylor Cancer Hospital will have many of the features that patients and their families want. Donna Bowers, vice president of the oncology program for Baylor Health Care System, said: “We will have larger patient rooms with expanded access for family members, more eating places, and special places like the healing gardens. We want to provide a place for healing, calming, and spirituality for everyone involved in the cancer journey.”
On Thursday, June 30, 2011, the Charlotte Johnson Barrett Lectureship was given by Joan Borysenko, PhD, to a standing room-only crowd in the Tom Hunt Auditorium at Baylor Charles A. Sammons Cancer Center at Dallas. Her talk, “The Art of Resilience: From Surviving to Thriving,” spoke to the cancer patient, but her message was for anyone undergoing change in their lives. Using the cancer patient as her example, she said that being diagnosed with cancer means that you must learn to be comfortable in a place of not knowing. In a sense, it all becomes a rite of passage, comparing life before and after cancer. This is analogous to what many are experiencing today, with the uncertainties in our economy. Her talk was one of learning how to cope, a process that requires realism, a sense of humor, and radical creativity. Whether it relates to the uncertainty of a diagnosis of cancer or to a difficult job situation, we all have to learn the art of resilience.

Dr. Borysenko is a pioneer in integrative medicine, specializing in the connection between mind and body. Her background is in the basic sciences, with a doctorate in medical sciences from Harvard Medical School. She specialized in the area of cancer cell biology in her first postdoctoral fellowship. However, her father’s death from cancer during her first faculty position at Tufts University College of Medicine made her rethink her career path, focusing more on the patient than on the cancer. She went on to complete two additional postdoctoral fellowships and became a licensed psychologist. Dr. Borysenko is the author or coauthor of numerous books on the mind-body connection.

The Charlotte Johnson Barrett Lectureship was established to address psychosocial issues and concerns of cancer survivors and their families. Charlotte Barrett was a cancer patient who helped establish the first patient support group at Baylor Sammons Cancer Center. After her death in 1982, her family and friends generously established an endowment to support annual programs and seminars relating to cancer patient education and support.

Left to right: Pam Carnevale, MHSA, manager of the Cvetko Center, C. Alan Stringer, Jr., MD, medical director of the Cvetko Center, Alan M. Miller, MD, PhD, chief of oncology, Baylor Health Care System and medical director, Baylor Sammons Cancer Center, Joan Borysenko, PhD, and Donna Bowers, JD, RHIA, CHP, BHCS vice president/COO, Baylor Sammons Cancer Center.
Site-Specific Tumor Conferences at Baylor Sammons Cancer Center

At Baylor Sammons Cancer Center, a key element at the heart of our approach to patient care and education is the site-specific tumor conference program. Rather than focusing solely on recommendations for patient care, the site-specific conferences also aim at educating the medical professionals attending the conference. Unlike tumor boards, continuing medical education credit is available for physicians who attend. Because several patients with the same diagnosis are presented at each conference, attendees are provided with an in-depth view from specialists, accompanied by lively discussion.

Most of the site-specific tumor conferences have been relocated to the 10th floor conference center in the new outpatient cancer center. The gynecology and skull base conferences currently remain at their former locations. For more information about site-specific tumor conferences at Baylor Sammons Cancer Center, please call 214.820.4073.

Conference schedule:

<table>
<thead>
<tr>
<th>Conference</th>
<th>Date</th>
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<tbody>
<tr>
<td>Bone and Soft Tissue</td>
<td>1st Tuesday</td>
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<tr>
<td>Breast</td>
<td>Thursdays</td>
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<tr>
<td>Chest</td>
<td>1st, 2nd and 4th Wednesday</td>
</tr>
<tr>
<td>Endocrine</td>
<td>3rd Tuesday</td>
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<tr>
<td>Gastrointestinal</td>
<td>Alternating Thursdays</td>
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<tr>
<td>Gynecology</td>
<td>Wednesdays</td>
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<tr>
<td>Head and Neck</td>
<td>2nd and 4th Tuesday</td>
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<tr>
<td>Head and Neck Journal Club</td>
<td>5th Tuesdays</td>
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<tr>
<td>Hematology/Oncology Journal Club*</td>
<td>Rotating Wednesdays</td>
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<tr>
<td>Hematology*</td>
<td>Rotating Wednesdays</td>
</tr>
<tr>
<td>Liver</td>
<td>2nd Tuesday</td>
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<tr>
<td>Lymphoma*</td>
<td>Rotating Wednesdays</td>
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<tr>
<td>Neuro-oncology</td>
<td>2nd and 4th Wednesday</td>
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<tr>
<td>Skin</td>
<td>1st and 3rd Wednesday</td>
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<tr>
<td>Skull Base</td>
<td>1st Wednesday</td>
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<tr>
<td>Stem Cell Transplant*</td>
<td>Rotating Wednesdays</td>
</tr>
<tr>
<td>Urology</td>
<td>3rd Wednesday</td>
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*Rotate during the month
Baylor Dallas Joins Forces with Texas A&M Health Science Center to Expand Medical Education Opportunities in Dallas

Baylor University Medical Center at Dallas is joining forces with Texas A&M Health Science Center (TAMHSC) to establish a clinical training program in Dallas. Students will complete their first 2 years of medical education at the TAMHSC-College of Medicine campus in either Bryan/College Station or Temple. For their last 2 years of medical school, they will complete clinical rotations in surgery, internal medicine, family medicine, psychiatry, pediatrics, and obstetrics/gynecology at Baylor Dallas and other clinical affiliates. Elective rotations under the supervision of a select group of Baylor Dallas medical staff physicians will also be available.

The program will welcome its first cohort of 24 third-year students in December 2011. The following academic year, a comparable number of new third-year students will arrive in Dallas to join the inaugural cohort as they enter their fourth year of medical school. Patient volume and faculty are adequate to gradually increase enrollment to 40 third-year and 40 fourth-year students, pending available funding to meet accreditation requirements.

Cristie Columbus, MD, will serve as vice dean for the clinical training program. Dr. Columbus is the assistant director of medical education at Baylor Dallas. She serves as vice chair of the Graduate Medical Education Committee, chair of the Graduate Medical Education Subcommittee on Internal Review, and vice chair of the Institutional Review Board. Since 2010, she has served as the program director of the infectious diseases fellowship at Baylor Dallas and is currently the president of the medical staff.

"Baylor University Medical Center is looking forward to the opportunity of serving as a clinical training site for the Texas A&M Health Science Center College of Medicine," Dr. Columbus said. "The affiliation with the College of Medicine builds upon the longstanding relationship between Baylor and the Texas A&M Health Science Center, as the Health Science Center’s Baylor College of Dentistry has been located on the Baylor campus for many years. The College of Medicine is committed to addressing the Texas physician shortage and the health care needs of all Texans, and Baylor provides an excellent clinical training opportunity for the North Texas area."

Alan M. Miller, MD, PhD, chief of oncology, Baylor Health Care System, and medical director, Baylor Charles A. Sammons Cancer Center at Dallas, also expressed excitement about this new affiliation. "It will be a great opportunity to provide experience for the students in oncology, with the hope that some of them may become interested in pursuing it as a career path. The affiliation will also help to open doors to cancer research collaboration with faculty at the Texas A&M Health Science Center."

Third-year medical students will have contact with hematology and medical oncology patients that are placed on the internal medicine teaching service, as well as surgical and gynecologic oncology patients on their general surgery rotations and obstetrics/gynecology rotations. Fourth-year electives are likely, although still in development, in surgical oncology, gynecologic oncology, and bone marrow transplantation.

Marvin J. Stone, MD, MACP, director of Oncology Medical Education and clerkship director for internal medicine, looks forward to having medical students participating in the patient care activities at Baylor: "Having medical students, as well as residents and fellows, contributes to the clinical excellence of patient care and will benefit all those patients who come to Baylor."

"It will be a great opportunity to provide experience for the students in oncology, with the hope that some of them may become interested in pursuing it as a career path. The affiliation will also help to open doors to cancer research collaboration with faculty at the Texas A&M Health Science Center."

Alan M. Miller, MD, PhD
Clinical Trials on the Baylor Dallas Campus: Multiple Myeloma

You can now access information about open oncology clinical trials at Baylor Sammons Cancer Center at Dallas by following these steps:

- Go to BaylorHealth.edu/Sammons.
- Click on “Cancer Clinical Trials” on the right-hand menu.
- From the list of studies that appears, click on the study that is of interest to you to view details such as the inclusion/exclusion criteria.

For additional details or questions about the studies, please contact the Office of Clinical Oncology Research Coordination at 214.818.8472 or via e-mail at cancer.trials@baylorhealth.edu.

The following clinical trials at Baylor Dallas are currently open and recruiting patients:

**Study title:** A randomized, multicenter, phase III study comparing carfilzomib, lenalidomide, and dexamethasone versus lenalidomide and dexamethasone in subjects with relapsed multiple myeloma  
**Study ID number:** BRI IRB# 010-175  
**Principal investigator:** Edward Agura, MD, medical director of Blood and Marrow Transplantation  
**Sponsor:** Onyx Therapeutics, Inc.  
**Participating site:** Baylor Sammons Cancer Center  
**Study description:** Eligible subjects will be randomized in a 1:1 ratio to receive the control or treatment regimen. Randomization will be stratified by beta-2 microglobulin levels, prior bortezomib use, and prior lenalidomide use.  
**Study outcomes:** Progression-free survival (primary); overall survival, overall response rate, duration of response, disease control rate, safety, time to progression, time to next treatment (secondary).  

**Volunteers needed:** Patients with symptomatic, measurable multiple myeloma who have had prior treatment with one to three regimens for multiple myeloma, have documented relapse or progressive disease on or after any regimen, and who achieved a response with at least one prior regimen.

**Study title:** An open-label, multicenter, phase I trial of the safety and pharmacokinetics of escalating doses of MFGR1877S in patients with relapsed or refractory t(4;14)-positive multiple myeloma.  
**Study ID number:** BRI IRB# 010-139  
**Principal investigator:** Edward Agura, MD  
**Sponsor:** Genentech  
**Participating site:** Baylor Sammons Cancer Center  
**Study description:** This is an interventional open-label study with single group assignment.  
**Study outcomes:** Dose-limiting toxicities (primary); adverse events, objective response, duration of response, progression-free survival, pharmacodynamics (secondary)  
**Volunteers needed:** Patients with histologically documented, previously treated t(4;14)-positive multiple myeloma with an Eastern Cooperative Oncology Group performance status of 0, 1, or 2.

**Study title:** A study of siltuximab effects on the QT interval in subjects with monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or indolent multiple myeloma (IMM).  
**Study ID number:** BRI IRB# 011-062  
**Principal investigator:** Joseph Fay, MD, medical director, Division of Immunologic Therapy for Cancer  
**Sponsor:** Centocor, Inc.  
**Participating site:** Baylor Sammons Cancer Center in collaboration with the Multiple Myeloma Research Consortium  
**Study description:** Siltuximab is a chimeric antibody against interleukin 6 (IL-6). High levels of IL-6 can stimulate cancer cell growth, reduce the efficacy of chemotherapy drugs, and contribute to cancer-related sicknesses such
as weight loss and bone weakening. This study examines whether siltuximab has an effect on heart function measured by electrocardiographic recordings. All patients will receive siltuximab four times every 3 weeks for 6 months.

**Study outcomes:** QT interval (primary); safety, efficacy, pharmacokinetic and pharmacodynamic evaluations (secondary)

**Volunteers needed:** Patients with a diagnosis of MGUS, SMM, or IMM, no diagnosis of symptomatic multiple myeloma, with no prior exposure to myeloma treatments or to agents targeting IL-6 or IL-6 receptor and no significant cardiac disease.

**Study title:** An open label, dose escalation, phase 1-2 study of the oral formulation of MLN9708 administered twice weekly in combination with lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma requiring systemic treatment.

**Study ID number:** BRI IRB# 011-093

**Principal investigator:** Joseph Fay, MD

**Sponsor:** Millennium Pharmaceuticals, Inc.

**Participating site:** Baylor Sammons Cancer Center in collaboration with the Multiple Myeloma Research Consortium

**Study description:** Both the phase 1 and the phase 2 portions of the study will have 1 year of induction therapy with MLN9708 in combination with lenalidomide and dexamethasone followed by maintenance therapy with MLN9708 alone until progressive disease or unacceptable toxicity.

**Study outcomes:** Maximum tolerated disease, response rate, adverse events (primary); response rate (phase 1), time to response (phase 2), duration of response (phase 2), time to progression (phase 2), progression-free survival (phase 2), overall survival (phase 2) (secondary).

**Volunteers needed:** Patients with newly diagnosed asymptomatic multiple myeloma or asymptomatic myeloma with myeloma-related organ damage.

**Study title:** Ancillary tissue collection and use of multiple myeloma blood and bone marrow samples

**Study ID number:** BRI IRB# 011-174

**Principal investigator:** Joseph Fay, MD

**Sponsor:** The Multiple Myeloma Research Consortium

**Participating site:** Baylor Sammons Cancer Center

**Study description:** Peripheral blood and bone marrow samples will be collected, stored, and cataloged from patients with multiple myeloma and other related disorders including, without limitation to, smoldering myeloma, monoclonal gammopathy of undetermined significance (MGUS), primary plasma cell leukemia, solitary plasmacytoma, and amyloidosis (Myeloma Related Disorders) for myeloma research.

**Study outcomes:** The samples will be used to study those genes and proteins already known to play a role in multiple myeloma and myeloma related disorders and to identify new genes and proteins that may lead to a better understanding of how to prevent and better treat these diseases.

**Volunteers needed:** Patients with newly diagnosed or relapsed/refractory multiple myeloma and myeloma related disorders (see above definition).

**Study title:** A prospective, longitudinal, observational study in newly diagnosed multiple myeloma patients to assess the relationship between patient outcomes, treatment regimens and molecular profiles

**Study ID number:** BRI IRB# 011-169

**Principal investigator:** Joseph Fay, MD

**Sponsor:** The Multiple Myeloma Research Foundation

**Participating site:** Baylor Sammons Cancer Center

**Study description:** This is a long-term, prospective, observational study of newly diagnosed myeloma patients that will include serial clinical and molecular profiling assessments.

**Study outcomes:** Response rate (as defined by International Myeloma Working Group criteria), progression-free survival, overall survival, health-related quality of life assessment, and biologic profiling and genomic marker studies on bone marrow tumor cells and peripheral blood at baseline pretreatment and at first and subsequent relapse.

**Volunteers needed:** Diagnosis of symptomatic multiple myeloma with measurable disease, candidate for systemic therapy that includes an immunomodulatory drug (lenalidomide, pomalidomide, or thalidomide) and/or a proteasome inhibitor as part of the initial regimen, no more than 30 days from baseline bone marrow evaluation to initiation of therapy.
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Scientific Publications

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