SPRING 2017

WELCOME

We began 2017 welcoming Charles S. Fuchs, MD, MPH, the new Director of Yale Cancer Center and Physician-in-Chief of Smilow Cancer Hospital. Dr. Fuchs has shared his vision to strengthen patient care across all Smilow Centers. We look forward to his leadership and further pursuit of our mission.

As part of the Oncology Care Model (OCM) initiative, and our commitment toward Value-Based care, Smilow Cancer Hospital recently launched the Extended Care Clinic, where patients can be seen by a team of APPs and an Attending Physician who are experts in the urgent care of oncology patients. The Extended Care Clinic is open from 7am to 11pm 7 days a week.

Ribbon cutting ceremony for our new Extended Care Clinic
As Smilow Cancer Hospital continues to evolve in the community, I hope that we are providing the right access for your patients. Clinical trials are available in each of our care centers, and referrals can be made to our main campus for more complex management and early stage trials. I welcome the opportunity to discuss ideas or concerns you may have. Please contact my office directly at (203) 200-1344 with your feedback.

Rogerio Lilenbaum, MD
Professor of Medicine
Yale Cancer Center
Chief Medical Officer
Smilow Cancer Hospital

PROGRAM HIGHLIGHTS

Liver Cancer Program
Smilow Cancer Hospital now has a dedicated Liver Cancer Program. The incidence of liver cancer continues to rise in the United States, and we recognize the need for a dedicated team of experts to care for patients with liver cancer. The Multidisciplinary program includes Hepatology; Medical Oncology; Surgical Oncology; Transplant; and Interventional Radiology. Well known to Yale, Mario Strazzabosco, MD, PhD has returned to campus full time to lead the program. To refer a patient, please contact our intake coordinator, Jessica.

Contact:
(203) 200-LIVR (5487)
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Integrative Medicine Consultations
We are proud to announce that Smilow Cancer Hospital now has an Integrative Medicine Program. Led by Ather Ali, ND, MPH, MHS, the program provides guidance on the risks and benefits of using dietary supplements/natural products, acupuncture, massage, meditation, and other complementary therapies. The Smilow Integrative Medicine Program provides an evidence-based and conservative approach, working in conjunction with mainstream care, to promote safe and effective patient care.

Contact:
(203) 200-HEAL (4325)
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Harold Tara, Jr., MD
Medical Director, Smilow Cancer Hospital Care Centers - Trumbull and Fairfield

Harold H. Tara, Jr., MD has been appointed Medical Director of the Smilow Cancer Hospital Care Centers in Trumbull and Fairfield, Connecticut. A member of the Yale community for 20 years, Dr. Tara's leadership will ensure that the centers continue to offer our patients the best care available, along with the latest treatment options through clinical trials.

Dr. Tara will continue his specialty clinics in Head and Neck Cancers and Urologic Oncology at Smilow Cancer Hospital. Please join us in welcoming Dr. Tara to Trumbull and Fairfield and contact him for any patient-related questions and referrals at the Trumbull office at (203) 502-8400.
**Cardio-Oncology Program**

The Cardio-Oncology Program at Smilow Cancer Hospital is designed to help address the cardio-toxic side effects of treatment, as well as the management of co-existing cardiac disease and cancer. Led by Dr. Lauren Baldassarre, the Program provides pre-surgical and pre-treatment cardiac evaluation for patients with cancer.

Several drugs used in the treatment of cancer have unanticipated cardiac side effects. Radiation is also known to cause cardiotoxicity. Prior to, during, or after treatment, the Cardio-Oncology Program is available to work with you on the prevention and management of this dire complication.

Contact:
(203) 785-7867
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**Fertility Clinic**

Dr. Pasquale Patrizio, Director of the Yale Fertility Center and Fertility Preservation Program, has a weekly clinic in Smilow Cancer Hospital for patients with cancer and cancer survivors. Dr. Patrizio’s expertise helps young men needing sperm banking and premenopausal women with a new diagnosis of cancer. Referrals should be made for consultation prior to treatment beginning. He is available to consult with both adult patients and young male and female patients that could benefit from fertility preservation. Dr. Patrizio closely collaborates with the referring team to coordinate all care.

Contact:
(203) 785-4708

**Onco-Dermatology Program**

The Yale Onco-dermatology Clinic at Smilow Cancer Hospital serves the dermatologic needs of cancer patients. Such issues include very dry skin, itching, skin changes as side effects from chemotherapy including rashes, nail and hair changes, skin infections, cancer involvement of the skin, radiation dermatitis, and other changes due to radiation. Physicians can refer a patient to the program for consultation with Dr. Jonathan Leventhal, director of the program.

Contact:
(203) 200-6622
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Andrea Silber, MD
2016 Connecticut Cancer Partnership Cancer Champion Award Recipient

Dr. Andrea Silber, Associate Clinical Professor of Medicine (Medical Oncology) at Yale School of Medicine, was recently awarded The CT Cancer Partnership 2016 Cancer Champion Award. The award recognizes contributions to cancer prevention and control in the state of Connecticut.

Dr. Silber specializes in breast cancer and leads a program called OWN-IT (Oncologists Welcome New Haven Into Trials). OWN IT’s purpose is to get more minorities from inner city New Haven into clinical trials being conducted at Smilow Cancer Hospital. For over 30 years Dr. Silber has worked towards decreasing cancer health disparities in New Haven and surrounding communities.
CLINICAL TRIAL SUMMARIES

A full list of all clinical trials available through Yale Cancer Center is updated daily and available online by disease type. In addition, a list of Phase I trials for patients through our Phase I Clinical Trial Program can be accessed at any time.

HIC# 1509016502
Principal Investigator: Jennifer Moliterno, MD

**A Phase II/III Randomized, Open-Label Study of Toca 511, a Retroviral Replicating Vector, Combined With Toca FC Versus Standard of Care in Subjects Undergoing Planned Resection for Recurrent Glioblastoma or Anaplastic Astrocytoma**

The Toca 5 trial is for patients who are planning to undergo removal of a recurrent glioblastoma or anaplastic astrocytoma tumor. Toca 511 is an investigational retroviral replicating vector that encodes the transgene cytosine deaminase (CD). Toca 511 selectively infects, persists and spreads in actively proliferating cancer cells. Subsequent oral administration of extended-release 5-fluorocytosine (Toca FC) results in production of 5-fluorouracil (5-FU) by the CD protein produced within infected cells. As a result, within the tumor microenvironment infected cancer cells are selectively killed along with myeloid derived suppressor cells which help shield tumors from the immune system. Subsequently, the immune system is activated against the cancer through a combination of mechanisms while leaving healthy cells unharmed. Clinical data from phase 1 trials show a favorable safety profile and extended survival compared to historical controls.

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HIC# 1607018037
Principal Investigator: Tara Sanft, MD

**Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer**

This randomized phase III trial studies whether weight loss in overweight and obese women may prevent breast cancer from recurrence. Previous studies have found that women who are overweight or obese when their breast cancer is diagnosed have a greater risk of their breast cancer recurring, as compared to women who were thinner when their cancer was diagnosed. This study aims to test whether overweight or obese women who take part in a weight loss program after being diagnosed with breast cancer have a lower rate of cancer recurrence as compared to women who do not take part in the weight loss program. This study will help to show whether weight loss programs should be a part of breast cancer treatment.

**SMILOW CANCER HOSPITAL CLINICAL PROGRAMS**

- Brain Tumor
  (203) 200-1638

- Breast Center
  (203) 200-2328

- Endocrine Cancers
  (203) 200-3636
HIC# 1507016120  
**Principal Investigator:** Roy Herbst, MD  
**An Open-Label, Multicenter, Phase I Study of Ramucirumab Plus Pembrolizumab in Patients With Locally Advanced and Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, or Transitional Cell Carcinoma of the Urothelium**

The main purpose of this study is to evaluate the safety and preliminary efficacy of the combination of the study drug known as ramucirumab plus pembrolizumab in participants with locally advanced and unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma, non-small cell lung cancer (NSCLC), or transitional cell carcinoma of the urothelium. Ramucirumab is a human IgG1 monoclonal antibody VEGFR-2 antagonist. Pembrolizumab is a humanized IgG4 monoclonal antibody against PD-1.  

[HIC# 1603017493](#)  
**Principal Investigator:** Paul Eder, MD  
**An Open-Label, Multicenter, Dose Escalation and Expansion Phase 1B Study to Evaluate the Safety, Pharmacokinetics and Therapeutic Activity of RO6958688 in Combination with Atezolizumab in Patients with Locally Advanced and/or Metastatic CEA-Positive Solid Tumors**

[HIC# 1511016798](#)  
**Principal Investigator:** Patricia LoRusso, DO  
**A Phase 1 Trial of SL-801, a Novel Inhibitor of XPO1 Nuclear Export, in Patients With Advanced Solid Tumors**

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**RESEARCH IN THE NEWS**

**Yale scientists identify key defect in brain tumor cells**

In a new study, Yale Cancer Center researchers identified a novel genetic defect that prevents brain tumor cells from repairing damaged DNA. They found that the defect is highly sensitive to an
existing FDA-approved drug used to treat ovarian cancer - a discovery that challenges current practice for treatment of brain tumors and other cancers with the same genetic defect, said the scientists.

The researchers tested several existing cancer drugs on the mutated cell lines. They found that tumor cells with the mutant genes were particularly sensitive to a drug, olaparib, recently approved for the treatment of hereditary ovarian cancer. The drug caused a 50-fold increase in brain tumor cell death.

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Clue to how cancer cells spread
In a second human case, a Yale-led research team has found that a melanoma cell and a white blood cell can fuse to form a hybrid with the ability to metastasize. The finding provides further insight into how melanoma and other cancers spread from solid tumors with implications for future treatment.

The research team analyzed tumor biopsies from a patient with malignant melanoma who had received a bone-marrow transplant before developing cancer. They compared DNA from the primary melanoma and from lymph nodes where the cancer had spread. In both sites, they found a mixture of patient and donor DNA.

The presence of the mixed patient-donor DNA strongly suggests that white blood cells that normally attack cancer cells instead fused with them, forming a genetic hybrid that then spread.

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Lung cancer patients may benefit from delayed chemotherapy after surgery
A new Yale study suggests that patients with a common form of lung cancer may still benefit from delayed chemotherapy started up to four months after surgery, according to the researchers.

While there is consensus regarding the use of chemotherapy after cancer surgery, the optimal timing is poorly defined. Many clinicians support starting chemotherapy within six to nine weeks after surgery. But factors such as postoperative complications may affect a patient's ability to tolerate chemotherapy following surgery.

The study of 12,473 patients with stage I, II, or III disease who received chemotherapy suggests that the initiation of chemotherapy between 57 and 127 days postoperatively led to similar outcomes as patients who started closer to the currently recommended six-to-nine-week window, report the researchers. Furthermore, delayed chemotherapy was associated with a lower risk of death compared to those patients treated only with surgery.

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Subtype of triple negative breast cancer responds better to chemotherapy

Researchers at Yale Cancer Center have identified a new subtype of triple negative breast cancer that shows significantly improved response to chemotherapy. Patients with the newly defined subtype - BRCA-deficient triple negative breast cancer - had significantly higher survival rates with chemotherapy.

The researchers in the Yale-led study performed whole exome sequencing - a technique for sequencing all the expressed genes in a genome - on TNBC tumors. They used the technique to identify mutations in specific genes, or pathways, that might indicate response or resistance to the standard of care, which is anthracycline/taxane (ACT) chemotherapy.

The research team found that TNBC tumors carrying mutations in the AR and FOXA1 pathways had a significantly higher response rate - 94.1% compared to 16.6% in tumors without the mutations.

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New Haven cancer doctors working to draw people of color into clinical trials

Wendy Ormond was fortunate. As a patient of Dr. Andrea Silber, she was offered a chance to take part in a clinical trial of a new chemotherapy drug.

Long mistrustful of doctors, Ormond, 61, went to see Silber when she felt a lump in her breast. It turned out she had stage 3 breast cancer. She began traditional chemotherapy with Herceptin.

Then Silber offered to enroll Ormond in a nationwide clinical trial of a drug called TDM1.

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New drug available for patients with late-stage lung cancer

A new drug has been approved by the FDA in the fight against lung cancer. Tecentriq is an immunotherapy medication, and the focus of an international clinical trial.

Lead investigator Dr. Roy Herbst at Smilow Cancer Hospital and Yale Cancer Center touted the drug's ability. "Tumors are very smart," Dr. Herbst explained, "And they
Immunotherapy may need its own value model

Immunotherapy has been a game changer for the oncology field, but typical models used to assess the value of cancer treatments don’t take into account the unique characteristics of this therapy. There are multiple models to assess the value of a cancer treatment, and while they all look at cost, effectiveness and population health impact, none are perfect to apply to immunotherapy.

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