WINTER 2015

Welcome to DirectMD

The Cancer Center

Immunotherapy Drug

Protein Predicts Response to New

Immunotherapy Drug

Research in the News

New Drug Combination for Advanced

Progression

New Agents for Cancer Treatment CME Dinner

March 5; 5:30 PM  |  Smilow Cancer Hospital

New Investigators Honoring Thomas Duffy

March 6; 9:00 AM  |  Smilow Cancer Hospital

Breast Cancer CME Symposium

May 7; 7:00 AM  |  Courtyard by Marriott New Haven!

Smilow Cancer Hospital at Yale-New Haven

333 Cedar Street
P.O. Box 208028
New Haven, CT 06520-8028

If you need help with an inpatient transfer to Smilow Cancer Hospital, you can call the Y Access Line for direct access to an attending for transfer at 888-YNHH-BED. If you would like information on clinical trials for your patients, we have them available online, or you can call (203) 785-5702. Our nurses are here to partner with you in the care of your patients.

As always, we are here to partner with you in the care of your patients. Please remember that we are committed to making these trials available in the community at our cancer center, also ensuring we are continually pushing to make innovative treatments available to our patients. Since 2009, the number of patients participating in clinical trials has doubled, and we are proud to be making these trials available in the community at our cancer center designated comprehensive cancer center, Connecticut’s only National Cancer Institute designated comprehensive cancer center.

Yale Cancer Center, Connecticut’s only National Cancer Institute designated comprehensive cancer center, also ensures we are continually pushing to make innovative treatments available to our patients. Since 2009, the number of patients participating in clinical trials has doubled, and we are proud to be making these trials available in the community at our cancer center designated comprehensive cancer center, Connecticut’s only National Cancer Institute designated comprehensive cancer center, also ensuring we are continually pushing to make innovative treatments available to our patients. Since 2009, the number of patients participating in clinical trials has doubled, and we are proud to be making these trials available in the community at our cancer center designated comprehensive cancer center, Connecticut’s only National Cancer Institute designated comprehensive cancer center, also ensuring we are continually pushing to make innovative treatments available to our patients. 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Yale Cancer Center, Smilow Cancer Hospital at Yale-New Haven
Chief Medical Officer
Yale School of Medicine
Professor of Medicine
Rogerio Lilenbaum, MD

trial summaries, and research in the news below.
Throughout the year, beginning with new program highlights, clinical
progress and highlights from Smilow’s 5th anniversary with you
my office at (203) 200-1344 at any time. I look forward to sharing
patients, or Smilow Cancer Hospital, please feel free to reach out to
If you have any questions or concerns regarding the care of your
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Research in the News

Research in the News

\( \begin{align*}
\text{WINTER 2015}
\end{align*} \)
Smilow Cancer Hospital at Yale-New Haven is celebrating an important milestone - 5 years since we opened our doors to our patients in November 2009! In addition to the collaboration of cancer services at Smilow Cancer Hospital in New Haven, the last 5 years have brought tremendous growth to our Network, with the addition of 11 Care Centers throughout our region. Our partnership with Yale Cancer Center, Connecticut’s only National Cancer Institute designated comprehensive cancer center, also ensures we are continually pushing to make innovative treatments available to our patients. Since 2009, the number of patients participating in clinical trials has doubled, and we are proud to be making these trials available in the community at our Care Centers.

As always, we are here to partner with you in the care of your patients. If you need help with an inpatient transfer to Smilow Cancer Hospital, you can call the Y Access Line for direct access to an attending for transfer at 888-YNHH-BED. If you would like information on clinical trials for your patients, we have them available online, or you can call (203) 785-5702.

If you have any questions or concerns regarding the care of your patients, or Smilow Cancer Hospital, please feel free to reach out to my office at (203) 200-1344 at any time. I look forward to sharing the progress and highlights from Smilow’s 5th anniversary with you throughout the year, beginning with new program highlights, clinical trial summaries, and research in the news below.

Rogerio Lilenbaum, MD
Professor of Medicine
Yale School of Medicine
Chief Medical Officer
Smilow Cancer Hospital at Yale-New Haven
Yale Cancer Center

Welcome to DirectMD!

New Drug Combination for Advanced Breast Cancer Delays Disease Progression

A new combination of cancer drugs delayed disease progression for patients with hormone-receptor-positive metastatic breast cancer, according to a multi-center phase II trial presented by Dr. Roy S. Herbst, MD, PhD at Yale Cancer Center. The trial enrolled 118 post-menopausal women with metastatic hormone-receptor-positive breast cancer whose cancer continued to progress after being treated with an aromatase inhibitor. The study found that the combination of the drugs bortezomib and fulvestrant – versus fulvestrant alone – doubled the rate of survival at 12 months and reduced the chance of cancer progression overall.


Protein Predicts Response to New Immunotherapy Drug

The presence of an immune-suppressing protein in non-cancerous immune cells may predict how patients with different types of cancer respond to treatment, a multi-center phase i study using an investigational immune therapy drug has found. The study, led by Roy S. Herbst, MD, PhD at Yale Cancer Center, was described in the Journal Nature.

The trial included patients with melanoma or cancers of the lung, kidney, colon, GI tract, or head and neck, whose tumors were evaluated for PD-L1 expression by a novel assay. PD-L1 is a protein expressed by many tumor types that is believed to act as a stop sign that prevents the immune system from attacking cancer cells. Patients were treated with MPDL3280A, a drug that blocks PD-L1 and is being developed by Genentech, a member of the Roche group. Of the 175 patients enrolled, 21% showed partial or complete response to MPDL3280A, with some being rapid and durable. Across all tumor types, 46% of patients with high PD-L1 expression on non-tumor cells showed a partial or complete response.


Yale Team Devises Ingenious Method to Attack Cancer at its Genetic Source

MicroRNAs may be tiny - as few as 20 genetic letters, compared to 3 billion in the DNA of a human - but they play a major role in biology, helping to determine which genes are expressed or silenced. In the last 10 years, researchers at Yale and elsewhere have shown they play a major role in formation and spread of tumors.

However, their potential as a target for cancer therapy has not been realized because of a daunting problem that has held back clinical applications of gene therapy: how can you target minute pieces of genetic material locked safely inside the membranes of billions of cells?

A multi-disciplinary team of Yale researchers has solved the problem by designing a therapeutical molecule that both targets the acidic microenvironments of tumors and penetrates cells to deliver a therapeutic cargo. The new delivery system effectively killed advanced tumors in mice, the team reported in the journal Nature.

Visit http://bit.ly/1AcYwY4 to learn more.

RESEARCH IN THE NEWS

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EVENTS

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March 6, 9:00 AM | Smilow Cancer Hospital

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**NEW FACES**

Smillow Cancer Hospital was pleased to announce two new Cancer Care Centers this fall with the addition of physicians and staff of Oncology Associates of Bridgeport to Fairfield and the New Haven locations. The two office locations have undergone renovations and expanded to provide on-site pharmacy services, upgraded facilities for infusion services, and improved safety standards. This addition allows us to provide Smillow care in Fairfield County Community Health Centers to eleven locations.

**Location Addresses**

111 Beach Road
Fairfield, CT 06430
Phone: (203) 255-2766

5520 Park Avenue
Trumbull, CT 06611
Phone: (203) 502-8400

**NEW FACES**

Dr. Robert S. Solman

Dr. Robert S. Solman received his medical degree from the State University of New York at Buffalo and completed his fellowship at Memorial Sloan Kettering. He served as Partner and President of the former Oncology Associates of Bridgeport, P.C. for nearly 40 years.

Dr. Neal Fischbach

Dr. Neal Fischbach cares for patients with genitourinary, gynecologic, and endocrine tumors.

Dr. Jerry Malefatto

Dr. Jerry Malefatto received his medical degree at the University of Pennsylvania and Harvard Medical School and completed his fellowship at the University of California, San Francisco.

Dr. David H. Witt

Dr. David H. Witt attended the New York University School of Medicine and completed his fellowship in Hematology/Oncology at Coney Island Hospital. He served as Partner in Oncology Associates of Bridgeport, P.C. for 20 years.

Dr. Justin Persico

Dr. Justin Persico attended Tufts University School of Medicine where he also completed his fellowship in Gastroenterology/ Oncology at Beth Israel Medical Center in New York. He has published several publications in the American Journal of Gastroenterology regarding both leukemia and solid tumors.

Dr. Persico has also been involved with several studies including one looking at colon cancer metastases of solid tumors.

**CLINICAL TRIAL SUMMARIES**

**HIC# 1404013690**

**Principal Investigator:** Howard Hochster, MD

**Phase II/II study of LX818 and Celecoxib or LX818, BYL719 andCelecoxib in BRCA Positive and Non-BRCA Mutated Advanced Colorectal Cancer**

Seeking Colorectal Cancer Patients with BRCA Mutations: Patients with BRCA mutant metastatic colorectal cancer may be eligible to receive investigational drugs LX818 and BYL719 (Novartis) in combination with the anti-EGFR antibody in this study designed to determine their safety and efficacy. LX818 is a highly active inhibitor of the mutated BRAF gene, and has shown promise in stopping cancers in laboratory and animal studies. BYL719 binds and blocks PI3Kalpha and AKT signaling, which is also key to bypassing RAF blockade. Both the Celecoxib and the triplet have shown extremely promising activity in the phase 1 trial. Yale is participating in the Phase 2 portion of this trial. Participants undergo genetic testing to determine eligibility to receive either daily doses of LX818 and weekly infusions of celecoxib (2 drug combination), or daily doses of LX818 and BYL719 (3 drug combination).


**HIC# 1407014356**

**Principal Investigator:** Howard Hochster, MD

**A Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of EVEROLIMUS in Patients with High-Risk, Hormone Receptor-Positive AND HER2/neu Negative Breast Cancer Seeking Familial BRCA Patients with Pancreatic Cancer**

BRCA families are predisposed to breast and ovarian cancer, but also may develop Pancreatic Cancer (especially those with BRCA-2 mutations). Participants with germline mutated BRCA and metastatic pancreatic cancer will receive induction platinum-based chemotherapy and then be randomized to Olaparib or placebo. Olaparib is a PARP inhibitor and previous trials have shown promise in halting or even reversing cancer progression. The drug was approved in Europe last week for maintenance of ovarian cancer, using the same design as in this trial. Please consider referring such patients and monitoring this trial with those familial BRCA mutations, who may know a candidate.


**HIC# 1203009900**

**Principal Investigator:** Ray Herbst, MD, PhD

**A Phase I, Open-Label, Dose Escalation Study of the Safety and Pharmacokinetics of MPDL3280A Administered Intravenously as a Single Agent or in Combination with Locally Advanced or Metastatic Solid Tumors or Hematologic Malignancies**

MPDL3280A is a humanized monoclonal antibody (mAb) that is designed to target PD-L1 expressed in tumor cells and tumor-infiltrating immune cells, and prevent binding to PD-1 and PD-7 on the surface of T cells. Patients with histologically or cytogenetically documented incurable or metastatic solid tumor or hematologic malignancy may be eligible to receive MPDL3280A in a study designed to determine if treatment.

Participation involves treatment with a single IV dose of MPDL3280A every 21 day cycle, and may also involve screening, blood, urine, and tissue samples, physical examination, CT or MRI of the cancer sites, a bone marrow evaluation (for ML and MM patients), skeletal surveys (for MM patients), and a core needle biopsy of the liver (for HCC patients).


**HIC# 1406014912**

**Principal Investigator:** Scott Gettinger, MD

**A Phase II, Multi-center, Single-arm Study of Op AP2613 in Patients with ALK-positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) Who Have Previously Been Treated with Crizotinib**

Patient with advanced ALK-rearranged lung cancer with progression after treatment with crizotinib will receive AP-2613. AP-2613 has shown high response rates in this population in a phase I trial with excellent tolerance.


**Smillow Cancer Hospital**

**CLINICAL PROGRAMS**

Brain Tumor

Breast Cancer

Endocrine Cancers

Gastrointestinal Cancers

Gynecologic Cancers

Hematology

Melanoma

Pediatric Hematology & Oncology

Prostate & Urologic Cancers

Sarcoma

Thoracic Oncology

**SMILOW CANCER HOSPITAL CARE CENTERS**

At Smillow Cancer Hospital Care Centers, we offer state of the art cancer care services at several convenient locations throughout the region. In addition to the flagship Smillow Cancer Hospital in New Haven, we have 11 care centers across the region, including Smillow Cancer Hospital’s Greenwich Campus.

**Program Co-Directors**

Enri Hoffstatter, MD  
Xavier Llor, MD  
Visit [bit.ly/1A2Yve](http://bit.ly/1A2Yve) to learn more.

**Cancer Genetics and Prevention Program**

The Smillow Cancer Genetics and Prevention Program is comprised of an interdisciplinary team that includes geneticists, genetic counselors, physicians, and nurses who work together with the goal of providing cancer risk assessment and taking steps to prevent the development of cancer.

Patients that are considered at risk for a familial or hereditary cancer receive genetic counseling and testing at no charge.

**Smillow Cancer Research Institute**

**Visit bit.ly/1DGM624 to learn more.**