2015 Chabner Colloquium
Collaboration in Cancer Trials

Featuring a thoughtful look at the potential for collaborative drug development, utilizing the resources of government and academic centers

October 26-27, 2015
The Liberty Hotel
215 Charles Street
Boston, Massachusetts
### 2015 Chabner Colloquium: Collaboration in Cancer Trials

**Meeting Agenda**

**Monday, October 26, 2015**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 1: New Therapeutic Approaches: Immunotherapy and Cancer Sanctuaries</th>
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<tbody>
<tr>
<td>7:45AM</td>
<td>Welcome and Introduction</td>
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<tr>
<td></td>
<td>Martin J. Murphy, DMedSc, PhD, Convener, Society for Translational Oncology</td>
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<tr>
<td></td>
<td>Bruce A. Chabner, MD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>8:00-8:40AM</td>
<td>CAR Therapy – The CD19 Paradigm</td>
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<td></td>
<td>Michel Sadelain, MD, PhD, Memorial Sloan Kettering Cancer Center</td>
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<td>8:40-9:20AM</td>
<td>Cancer Vaccines and Immunomodulatory Therapy</td>
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<td>David E. Avigan, MD, Beth Israel Deaconess Medical Center, Harvard Medical School</td>
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<tr>
<td>9:20-10:00AM</td>
<td>Genomic Characterization of CNS Metastases: Implications for Precision Medicine</td>
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<td></td>
<td>Priscilla K. Brastianos, MD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>10:00-10:20AM</td>
<td>Break/Exhibits</td>
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<tr>
<th>Time</th>
<th>Session 2: Exploiting Defective DNA Repair</th>
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<tr>
<td>10:20-11:00AM</td>
<td>The BRCA-Like Phenotype in Cancer</td>
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<td>Leif W. Ellisen, MD, PhD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>11:00-11:40AM</td>
<td>Targeting DNA Repair in Cancer Therapy</td>
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<td>Alan D. D’Andrea, MD, Dana-Farber Cancer Institute, Harvard Medical School</td>
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<tr>
<td>11:40-12:15PM</td>
<td>Alternative Lengthening of Telomeres Renders Cancer Cells Hypersensitive to ATR Inhibitors</td>
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<td>Lee Zou, PhD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>12:15-1:00PM</td>
<td>Lunch Buffet and Exhibits</td>
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<tr>
<th>Time</th>
<th>Session 3: New Concepts in Cancer Biology</th>
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<tr>
<td>1:00-1:45PM</td>
<td>Reengineering the Tumor Stroma to Improve Cancer Treatment: Bench to Bedside</td>
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<td>Rakesh K. Jain, PhD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>1:45-2:30PM</td>
<td>Targeting Sleeping Cancer Cells</td>
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<td>Sridhar Ramaswamy, MD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<td>2:30-3:15PM</td>
<td>Deconstructing Breast Cancer from a Developmental Perspective</td>
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<td>Geoffrey M. Wahl, PhD, The Salk Institute for Biological Studies</td>
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<td>3:15-3:30PM</td>
<td>Break/Exhibits</td>
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<tr>
<th>Time</th>
<th>Session 4: Rising Stars Forum</th>
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<tr>
<td>3:30-3:50PM</td>
<td>The Lazarex-MGH Cancer Care Equity Program</td>
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<td>Ryan D. Nipp, MD, Dana-Farber Cancer Institute, Harvard Medical School</td>
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<td>3:50-4:10PM</td>
<td>Preferentially Targeting the Malignant Hematopoietic Clone in Myeloproliferative Neoplasms (MPN)</td>
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<td>Ann Mullally, MD, Dana-Farber/Brigham and Women’s Cancer Center, Harvard Medical School</td>
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<td>4:10-4:30PM</td>
<td>Molecular Analysis of CTCs in Prostate Cancer</td>
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<td>David T. Miyamoto, MD, PhD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<td>4:30-4:50PM</td>
<td>Loss of SIRT6 Reactivates the Oncofetal Protein Lin28b to Drive Pancreatic Cancer</td>
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<td>Sita Kugel, PhD, Massachusetts General Hospital Cancer Center, Harvard Medical School</td>
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<tr>
<td>5:00PM</td>
<td>Adjourn Day 1</td>
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<tr>
<td>Time</td>
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<tr>
<td>7:50-8:00AM</td>
<td>Welcome and Introduction</td>
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<tr>
<td>8:00-8:40AM</td>
<td>Session 5: Metabolic and Signaling Pathways</td>
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<td>Serine Biosynthesis Regulates Folate Availability in Cancer Cells</td>
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<td>8:40-9:20AM</td>
<td>Dissecting Metastasis Through Circulating Tumor Cells</td>
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<tr>
<td>9:20-10:00AM</td>
<td>Emerging Therapies to Optimize MAP Kinase Blockade and Intercept Compensatory Signaling</td>
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<td>10:00-10:20AM</td>
<td>Break/Exhibits</td>
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<tr>
<td>10:20-11:00AM</td>
<td>Session 6: Clinical Drug Development</td>
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<td>Accelerate the Development of Highly Effective and Safe Anti-Cancer Agents in the Era of Precision Medicine</td>
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<td>11:00-11:40AM</td>
<td>The Changing Nature of Phase I Trials</td>
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<td>11:40-12:20PM</td>
<td>How Financial Engineering Can Cure Cancer</td>
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<tr>
<td>12:20PM</td>
<td>Closing Remarks and Adjourn Day 2 Lunch Buffet</td>
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The content of each presentation does not necessarily reflect the views of the Society for Translational Oncology, *The Oncologist*, or The Massachusetts General Hospital or any of its affiliates.

Slides will not be printed for the meeting in an effort to protect the environment. Any requests for slides should be directed to the specific presenter as STO does not have permission to distribute slides on their behalf.
Overview

In the field of oncology, the rapid pace of discovery and a better understanding of prevention, detection, the microenvironment, and treatment of cancer will lead to improved patient outcomes. Accurately tailored cancer treatment and individualized therapy will focus on tumor biology and host factors. The healthcare provider will need to be well informed in order to provide the most effective therapy for a particular patient with the fewest associated risks and toxicities. In oncology, our understanding of the complexity of the disease is expanding at an exponential rate.

Target Audience

This activity is designed to meet the educational needs of physicians and scientists in academic and practice settings who wish to advance their knowledge of the research into new treatments and improve their competence in the care of patients with cancer.

Accreditation

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Society for Translational Oncology and The Massachusetts General Hospital. The Society for Translational Oncology is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation

The Society for Translational oncology designates this live activity for a maximum of 10 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CME Credit

In order to receive CME credit, learners must sign in, review the CME information (accreditation, learning objectives, faculty disclosures, etc.) and attend the CME activity. Learners will be asked to complete an electronic activity evaluation following the meeting to indicate the number of credit hours claimed. Certificates will be provided upon completion of the evaluation.

To obtain CME credit, please visit: http://bit.ly/2015ChabnerCMECredit.

ACKNOWLEDGEMENTS

STO gratefully acknowledges educational grants in partial support of this activity from:

- AbbVie Inc.
- Chugai Academy for Advanced Oncology (CHAAO)
- Epizyme, Inc.
- Incyte Corporation
- Lilly USA, LLC
- Merrimack Pharmaceuticals, Inc.
- Novartis Pharmaceuticals Corporation
- Otsuka America Pharmaceutical, Inc.
- Pfizer Inc.

THE PHYSICIAN PAYMENTS SUNSHINE ACT (SUNSHINE ACT) COMPLIANCE

Effective August 1, 2013, The Centers for Medicare & Medicaid Services (CMS) required reporting of any direct or indirect payments made to any US Healthcare Professional by pharmaceutical and device manufacturers and applicable group purchasing organizations (GPOs) under its Open Payments program.

STO will comply with the requirements of those companies who have provided support for this CME activity regarding the appropriate reporting of all direct and indirect payments to healthcare professionals.
In accordance with ACCME Standards for Commercial Support and the policies of the Society for Translational Oncology (STO), persons participating in this activity who are in a position to control the content have disclosed all relevant relationships with any commercial interest. On the basis of disclosed information, STO identifies and resolves all conflicts of interest before delivery of content.

**STO staff involved in the development of this activity have nothing to disclose.**

The following faculty have indicated that they have had relevant financial relationship(s) with a commercial interest within the past 12 months or that they have nothing to disclose.

- **David E. Avigan, MD**  
  Nothing to disclose

- **Susan Bates, MD**  
  **Intellectual property rights/Inventor or patent holder:** Romidepsin: Method of Administration  
  **Research Funding:** CRADA research funding from Celgene, Inc.

- **Joseph R. Bertino, MD**  
  Nothing to disclose

- **Gideon M. Blumenthal, MD**  
  Nothing to disclose

- **Priscilla K. Brastianos, MD**  
  Nothing to disclose

- **George P. Canellos, MD**  
  **Consultant/advisory role:** Celgene

- **Bruce A. Chabner, MD**  
  **Consultant/advisory role:** Epizyme, Inc., Midatech  
  **Leadership role:** PharmaMar (Board of Directors)  
  **Expert testimony:** Eli Lilly  
  **Ownership interests:** Agios, BioMarin, Celgene, Epizyme, Inc., PharmaMar, and Regeneron

- **Alan D. D’Andrea, MD**  
  Nothing to disclose

- **Leif W. Ellisen, MD, PhD**  
  **Consultant/advisory role:** Vertex Pharma and Bioreference Laboratory

- **Keith T. Flaherty, MD**  
  **Consultant/advisory role:** GSK, Novartis, Roche, Sanofi, Merck, Momenta, and Raze  
  **Ownership interests:** Clovis and Loxo

- **Antonio “Tito” Fojo, MD, PhD**  
  Nothing to disclose

- **Daniel A. Haber, MD, PhD**  
  Nothing to disclose

- **Rakesh K. Jain, PhD**  
  **Intellectual property rights/Inventor or patent holder:** XTuit  
  **Consultant/advisory role:** XTuit, Ophthotech, PureTech, SPARC, SynDevRx  
  **Ownership interests:** Enlight, Ophthotech, SynDevRx, and XTuit  
  **Other:** Board of Trustees-Tekla Healthcare Investors, Tekla Life Sciences Investors, and Tekla Healthcare Opportunities Funds

- **Sita Kugel, PhD**  
  Nothing to disclose

- **Andrew W. Lo, PhD**  
  **Consultant/advisory role:** BridgeBio Capital, LLC  
  **Ownership interests:** Investor in ImmuneXcite, KEW, MPM, Novalere, Royalty Pharma, and VisionScope

- **David T. Miyamoto, MD, PhD**  
  Nothing to disclose

- **Ann Mullally, MD**  
  Nothing to disclose

- **Charles “Snuffy” Myers, MD**  
  To be announced

- **Ryan D. Nipp, MD**  
  Nothing to disclose

- **Sridhar Ramaswamy, MD, FACP**  
  Nothing to disclose

- **Michel Sadelain, MD, PhD**  
  **Intellectual property rights/Inventor or patent holder:** Memorial Sloan Kettering Cancer Center - Chimeric Antigen Receptor (CAR)  
  **Consultant/advisory role:** Juno Therapeutics  
  **Ownership interest:** Juno Therapeutics

- **Lillian Siu, MD, FRCRC**  
  **Consultant/advisory role:** Boehringer-Ingelheim (uncompensated), Regeneron (uncompensated), Merck (uncompensated), and Novartis (compensated – Institution)  
  **Research Funding:** Novartis, Bristol-Myers Squibb, Pfizer, Boehringer-Ingelheim, Regeneron, GlaxoSmithKline, Roche, Karyopharm, AstraZeneca, Merck, and Celgene  
  **Ownership interests:** Agios (spouse) and Entremed (spouse)

- **Matthew Vander Heiden, MD, PhD**  
  **Consultant/advisory role:** Agios Pharmaceuticals  
  **Ownership interest:** Agios Pharmaceuticals

- **Geoffrey M. Wahl, PhD**  
  Nothing to disclose

- **Lee Zou, PhD**  
  Nothing to disclose
After successful completion of this educational activity, participants should be able to:

- Explain the principle of CAR design and CAR therapy.
- Cite current results obtained with CAR therapy targeting CD19 in patients with B cell malignancies.
- Discuss the unique opportunity that alternative lengthening of telomeres offers for targeted cancer therapy.
- Describe the therapeutic value of newly developed ATR inhibitors in targeted cancer therapy.
- Describe the immunologic milieu in the tumor microenvironment.
- Discuss vaccine therapy-engineered T cells and checkpoint inhibitors as therapeutic strategies for cancer.
- Explain how underlying DNA repair deficiencies in human cancers can predict drug sensitivities.
- Describe the mechanism of PARP inhibitors in ovarian, breast, and prostate cancers.
- Describe the genomic evolution of CNS metastases.
- Compare genetic changes in brain metastases with those of primary tumors and extracranial metastases.
- Explain how metabolism supports cancer progression and how drugs targeting folate metabolism work to treat cancer.
- Explain the clinical importance of developing a biomarker of the BRCA1/2 pathway.
- Discuss the current state of assays to test the BRCA1/2 pathway in tumors.
- Explain the molecular basis of cancer cell quiescence.
- Describe the role that quiescence plays in cancer treatment resistance.
- Explain how identification of fetal antigens may be useful for immunotherapy approaches to breast cancer.
- Discuss the application of single cell transcriptional analyses to discern the regulatory pathways that control the stem-cell state of embryonic and adult cells.
- Discuss the impact of the Lazarex-MGH Cancer Care Equity Program on clinical trial enrollment.
- Describe the financial burden experienced by cancer clinical trial participants and the role that financial barriers may play in the poor accrual to cancer clinical trials.
- Discuss the clinical and biological effects of MPN therapies such as JAK inhibitors and interferon.
- Cite and discuss novel therapeutic approaches in MPN.
- Describe circulating tumor cells (CTCs) and potential applications of CTC analyses in the clinical management of cancer patients.
- Describe emerging technologies for the efficient and sensitive isolation of CTCs from peripheral blood.
- Explain the tumor suppressive role of SIRT6 in pancreatic adenocarcinoma.
- Discuss the hostile metabolic and mechanical tumor microenvironment created by abnormal vessels and matrix.
- Describe two strategies to reengineer the tumor environment and improve the treatment outcome of cancer and various non-neoplastic diseases.
- Describe the expedited review programs at the FDA and how the Office of Hematology and Oncology Products has utilized these programs.
- Discuss drug development challenges in the era of molecularly targeted medicine.
- Describe features related to the changing nature of phase I clinical trials in the era of novel oncotherapeutics.
- List the reasons for these changes in phase I trials and their implications in the drug development process.
- Describe the clinical benefit associated with BRAF and MEK inhibitor therapy in BRAF and RAS mutated cancers.
- Explain the mechanisms of resistance to BRAF and MEK inhibitors and the rationale for novel RAF and ERK inhibitors.
- Explain the key factors and trends driving funding and business models in the biopharmaceutical industry.
- Use financial engineering to develop a more efficient method for funding translational medical innovation.
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In 2001, former President George H.W. Bush founded the CEO Roundtable on Cancer that enables business leaders to play a key role in eliminating cancer as a health threat. CEOs responded by creating the following initiatives:

- **CEO Cancer Gold Standard™**
  An employer-led wellness program addressing prevention, diagnosis, and quality treatment

- **Life Sciences Consortium**
  A collaboration of research organizations addressing grand challenges that cannot be solved by any one entity. One of these is:
  - Project Data Sphere, LLC (www.projectdatasphere.org)
    An independent initiative providing a digital library-laboratory to share, integrate, and analyze clinical trial data

- **CEO Roundtable on Cancer-China**
  An invited non-governmental organization (NGO), bringing this employer-led health and wellness model to China.

Mass General Cancer Center is among the leading cancer care providers in the U.S., and is consistently ranked on U.S. News & World Report’s top ten list.

The Cancer Center comprises more than 37 treatment programs within 29 fully integrated, multidisciplinary disease centers and a vast array of support and educational services.

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