## Clinical Cancer Research

### Table of Contents

March 1, 2015 • Volume 21 • Number 5

### Highlights of This Issue 937

### SPECIAL FEATURES

#### CCR 20th Anniversary Commentary

- **939**  
  CCR 20th Anniversary Commentary: In the Beginning, There Was PS-341  
  Beverly A. Teicher and Kenneth C. Anderson

- **942**  
  CCR 20th Anniversary Commentary: Preclinical Study of Proteasome Inhibitor Bortezomib in Head and Neck Cancer  
  Clint T. Allen, Barbara Conley, John B. Sunwoo, and Carter Van Waes

#### CCR Translations

- **944**  
  Immunomodulatory Antibody Therapy of Cancer: The Closer, the Better  
  Roxana S. Dronca and Haidong Dong  
  See related articles, p. 1115 and p. 1127

- **947**  
  Moving from Evaluation to Value in Cancer Care  
  Richard L. Schilsky  
  See related article, p. 1036

#### CCR Perspectives in Drug Approval

- **950**  
  FDA Approval: Siltuximab for the Treatment of Patients with Multicentric Castleman Disease  
  Albert Deisseroth, Chia-Wen Ko, Lei Nie, Jeanne F. Zirkelbach, Liang Zhao, Julie Bullock, Nitin Mehrotra, Pedro Del Valle, Haleh Saber, Christopher Sheth, Brenda Gehrze, Robert Justice, Ann Farrell, and Richard Pazdur

### Molecular Pathways

- **955**  
  Molecular Pathways: Translational and Therapeutic Implications of the Notch Signaling Pathway in Cancer  
  Rebecca A. Preevis, Robert L. Coleman, Adrian L. Harris, and Anil K. Sood

- **962**  
  Molecular Pathways: Linking Tumor Microenvironment to Epithelial–Mesenchymal Transition in Metastasis  
  Hae-Yun Jung, Laurent Fattet, and Jing Yang

### Reviews

- **969**  
  Zebrfish: A New Companion for Translational Research in Oncology  
  Jorge Barrios, Raghavendra Nagaraju, and Adam Hurwitz

- **976**  
  Cancer Immunotherapy: A Future Paradigm Shift in the Treatment of Non–Small Cell Lung Cancer  
  Valsamo K. Anagnostou and Julie R. Brahmer

### CANCER THERAPY: CLINICAL

- **985**  
  A Phase I Study of Oral ARRY-614, a p38 MAPK/Tie2 Dual Inhibitor, in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes  

- **995**  
  CDK 4/6 Inhibitor Palbociclib (PD0332991) in Rb+ Advanced Breast Cancer: Phase II Activity, Safety, and Predictive Biomarker Assessment  
  Angela DeMichele, Amy S. Clark, Kay See Tan, Daniel F. Heitjan, Kristi Gramlich, Maryann Gallagher, Priti Lal, Michael Feldman, Paul Zhang, Christopher Colameco, David Lewis, Melissa Langer, Noah Goodman, Susan Domshek, Kerihi Gogineni, Mark Rosen, Kevin Fox, and Peter O’Dwyer

- **1002**  
  Phase I Dose-Escalation Trial of the Oral Investigational Hedgehog Signaling Pathway Inhibitor TAK-441 in Patients with Advanced Solid Tumors  

- **1010**  
  Angiogenic Cytokines Are Antibody Targets During Graft-versus-Leukemia Reactions  
A Pilot Trial Using Lymphocytes Genetically Engineered with an NY-ESO-1–Reactive T-cell Receptor: Long-term Follow-up and Correlates with Response
Paul F. Robbins, Sadik H. Kassim, Thai L.N. Tran, Jessica S. Crystal, Richard A. Morgan, Steven A. Feldman, James C. Yang, Mark E. Dudley, John R. Wunderlich, Richard M. Sherry, Udai S. Kammula, Marybeth S. Hughes, Nicholas P. Restifo, Mark Raffeld, Chyi-Chia R. Lee, Yong F. Li, Mona El-Gamil, and Steven A. Rosenberg

Redifferentiation of Iodine-Refractory BRAF V600E-Mutant Metastatic Papillary Thyroid Cancer with Dabrafenib
S. Michael Rothenberg, David G. McFadden, Edwin L. Palmer, Gilbert H. Daniels, and Lori J. Wirth

Raising the Bar for Antineoplastic Agents: How to Choose Threshold Values for Superiority Trials in Advanced Solid Tumors
Alberto F. Sobrero, Alessandro Pastorino, Daniel J. Sargent, and Paolo Bruzzi

A Phase I Study of PF-04449913, an Oral Hedgehog Inhibitor, in Patients with Advanced Solid Tumors
Andrew J. Wagner, Wells A. Messersmith, M. Naveed Shaik, Sherry Li, Xianxian Zheng, Karen R. McLachlan, Rossano Cesari, Rachel Courtney, Wendy J. Levin, and Anthony B. El-Khoueiry

Nottingham Clinico-Pathological Response Index (NPRI) after Neoadjuvant Chemotherapy (Neo-ACT) Accurately Predicts Clinical Outcome in Locally Advanced Breast Cancer

Longitudinal Noninvasive Imaging of Progesterone Receptor as a Predictive Biomarker of Tumor Responsiveness to Estrogen Deprivation Therapy
Szeman Ruby Chan, Amy M. Fowler, Julie A. Allen, Dong Zhou, Carmen S. Dence, Terry L. Sharp, Nicole M. Fettig, Farrokh Dehdashii, and John A. Katzenellenbogen

Correlation of PD-L1 Tumor Expression and Treatment Outcomes in Patients with Renal Cell Carcinoma Receiving Sunitinib or Pazopanib: Results from COMPARZ, a Randomized Controlled Trial
Toni K. Choueiri, David J. Figueredo, André P. Fay, Sabina Signoretti, Yuan Liu, Robert Gagnon, Keith Deen, Christopher Carpenter, Peter Benson, Thai H. Ho, Lini Pandite, Paul de Souza, Thomas Powles, and Robert J. Motzer

Gene Expression Markers of Efficacy and Resistance to Cetuximab Treatment in Metastatic Colorectal Cancer: Results from CALGB 80203 (Alliance)
Stephanie M. Cushman, Chen Jiang, Ace I. Hatch, Ivo Shterev, Alexander B. Sibley, Donna Niedzwiecki, Alan P. Venook, Kouros Owzar, Herbert I. Hurwitz, and Andrew B. Nixon

Clinical Relevance of KRAS-Mutated Subclones Detected with Picodroplet Digital PCR in Advanced Colorectal Cancer Treated with Anti-EGFR Therapy
Pierre Laurent-Puig, Deniz Pekin, Corinne Normand, Steve K. Kastopoulos, Philippe Nizard, Karla Perez-Toralla, Rachel Rowell, Jeff Olson, Preethi Srinivasan, Delphine Le Corre, Theyy Hor, Zakaria El Harrak, Xinyu Li, Darren R. Link, Olivier Bouché, Jean-François Emile, Bruno Landi, Valérie Boige, J. Brian Hutchison, and Valerie Taly

Circulating Tumor Cell Analysis in Metastatic Triple-Negative Breast Cancers

Neuregulin 1 Expression Is a Predictive Biomarker for Response to AV-203, an ERBB3 Inhibitory Antibody, in Human Tumor Models
Kristan Meetze, Sylvie Vincent, Steven Tyler, Elizabeth K. Maza, Andrea R. Delpero, Steve Boteja, Donna McIntosh, Richard Nicoletti, William M. Winston, Sally Weiler, Bin Feng, Jeno Gyuris, and Zhiqiang Weng

The Human Agonistic CD40 Antibody ADC-1013 Eradicates Bladder Tumors and Generates T-cell–Dependent Tumor Immunity
Sara M. Mangsbo, Sissela Broos, Erika Fletcher, Niina Veitonmäki, Christina Furebring, Eva Dahlén, Per Norlén, Malin Lindstedt, Thomas H. Tottman, and Peter Ellmark

See related commentary, p. 944

Table of Contents
ABOUT THE COVER

The cover shows a section of a tumor biopsy from mice with the SW1 melanoma, which were treated with an anti-CTLA4/PD-1/CD137 mAb combination. Immunohistochemical staining shows a dramatic decrease of tumor-infiltrating CD19 cells. For details, see the article by Dai and colleagues on page 1127 of this issue.