



Vicki Goodman, M.D.

Vice President Development Lead, Opdivo/Yervoy Melanoma/GU

I am a hematologist/medical oncologist with 12 years of drug development experience in both government and industry. Following my training in internal medicine and hematology/oncology at the University of Michigan, I served as a medical officer at FDA for 2.5 years and subsequently worked at GSK for 8 years. While at GSK, I took on roles of increasing responsibility, from medical monitor and Project Physician Leader, to Early Development Leader and finally Medicine Development Leader. I worked on a range of projects including pazopanib (Votrient), and dabrafenib (Tafinlar), alone and in combination with trametinib (Mekinist). I also led the development of several epigenetic early phase assets (BET, EZH2 and LSD1), and a signal transduction asset (AKT). Leveraging my regulatory experience, I led the safety subteam of the clinical submission team for Votrient in renal cell carcinoma (RCC) and subsequently led the clinical submission teams for Tafinlar and Tafinlar/Mekinist in melanoma. I joined BMS in January 2015 in my current role as Development Leader for Opdivo/Yervoy in melanoma/RCC. After launching the new development team just over a year ago, I oversaw the US/EU approval of the first I-O combination (Opdivo and Yervoy) in advanced melanoma, approval of Opdivo in RCC and the initiation of several registrational trials.

Board Certification/Licensure

2004	Diplomate in Medical Oncology
2004	Diplomate in Hematology
2001-2011	Diplomate, American Board of Internal Medicine
2004	Maryland License #D 61760

Lectures

June 2013	“Cancer Epigenetics—Everything You Wanted to Know but were Afraid to Ask”
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Oncology Lecture Series, GlaxoSmithKline
Collegeville, PA

May 2013 “BET Inhibitors and Cancer – Realizing Emerging Clinical Opportunities”
Symposium: Targeting Epigenetic Regulators for Cancer Therapy
New York Academy of Sciences, New York, NY

October 2009 “Clinical Assessment of Progression-Free Survival”
DIA Progression-Free Survival Oncology Workshop
Bethesda, MD

March 2009 “Carcinoma of Unknown Primary”
Oncology Lecture Series, GlaxoSmithKline
Collegeville, PA

August 2006 “Clinical Trial Design in Oncology—FDA Perspective”
ASCO Development of Molecular Therapeutics in Breast Cancer Conference
Aspen, CO

June 2006 “FDA Perspective on Innovative Clinical Trial Designs in Oncology”
Drug Information Association Annual Meeting
Philadelphia, PA

April 2006 “Clinical Trials and the Drug Approval Process”
National Breast Cancer Coalition Fund Annual Meeting
Washington, DC

March 2006 “A Primer on Regulation of Oncology Drugs:
Regulatory Issues and Scientific Objectives”
CDRH/CDER Best Practices Workshop

January 2006 “Challenges in Oncology Drug Development and Regulation”
Pharmaceutical Education and Research Institute
“Changing the Paradigm in Oncology Drug Development” course
Arlington, VA

November 2005 “Defining Success of Oncology Drugs”
Chemotherapy Foundation Symposium XXIII
New York, NY

June 2005 "FDA Review of Criteria for Approvability of New Agents in Pancreatic Cancer"
Pancreas Cancer 2005: State of the Art Conference
The Lustgarten Foundation for Pancreatic Cancer Research
New York, NY

May 2005 "Postmarketing Drug Safety Surveillance"
Project LEAD 10th Anniversary Symposium
National Breast Cancer Coalition Fund

Washington, D.C.

Publications/Presentations

“Correlation of BRAF Mutation Status in Circulating-Free DNA and Tumor and Association with Clinical Outcome across Four BRAFi and MEKi Clinical Trials” Santiago-Walker A, Gagnon R, Mazumdar J, Casey M, Long GV, Schadendorf D, Flaherty K, Kefford R, Hauschild A, Hwu P, Haney P, O'Hagan A, Carver J, **Goodman V**, Legos J, Martin AM . ¹ *Clin Cancer Res.* 2016 Feb 1;22(3):567-74

“BRAF inhibitor dabrafenib in patients with metastatic BRAF-mutant thyroid cancer” Falchook GS, Millward M, Hong D, Naing A, Piha-Paul S, Waguespack SG, Cabanillas ME, Sherman SI, Ma B, Curtis M, **Goodman V**, Kurzrock R *Thyroid.* 2015 Jan;25(1):71-7

“Patient Perception of the Benefit of a BRAF Inhibitor in Metastatic Melanoma: Quality of Life Analyses of the BREAK-3 Study Comparing Dabrafenib With DTIC” J.-J. Grob, M. M. Amonkar, S. Martin-Algarra, L. V. Demidov, **V. Goodman**, K. Grotzinger, P. Haney, E. Kämpgen, B. Karaszewska, C. Mauch, W. H. Miller Jr., M. Millward, B. Mirakhur, P. Rutkowski, V. Chiarion-Sileni, S. Swann, A. Hauschild *Annals of Oncology* 2014 (published online Apr 25)

“Population Pharmacokinetics of Dabrafenib, a BRAF Inhibitor: Effect of Dose, Time, Covariates, and Relationship With Its Metabolites” Daniele Ouellet, Ekaterina Gibiansky, Cathrine Leonowens, Anne O'Hagan, Patricia Haney, Julie Switzky, and **Vicki L. Goodman** *J Clin Pharm* 2014
doi: 10.1002/jcph.263

“Correlation of BRAF mutation status in cfDNA and tumor and association with clinical outcome across four BRAFi and MEKi clinical trials” Ademi Santiago-Walker, Bob Gagnon, Jolly Mazumdar, Michelle Casey, Patricia Haney, Anne O'Hagan, Jennifer Carver, **Vicki Goodman**, Jeff Legos, and Anne-Marie Martin *Pigment Cell and Melanoma Research* 2013; 26: 997

“An update on BREAK-3, a phase 3 randomized trial: dabrafenib vs. dacarbazine (DTIC) in patients with BRAF V600E mutation-positive melanoma” A. Hauschild, J-J Grob, L. V. Demidov, T. Jouary, R. Gutzmer, M. Millward, P. Rutkowski, C. U. Blank, W.H. Miller, Jr., E. Kampgen, S. Martin-Algarra, B. Karaszewski, C. Mauch, V. Chiarion-Sileni, B. Mirakhur, M. E. Guckert, R. S. Swann, P. Haney, **V. L. Goodman**, P. B. Chapman *J Clin Oncol* 31, 2013 (suppl; abstr 9013)

“Interim results of phase 2 study BRF113928 of dabrafenib in BRAF V600E mutation-positive non-small cell lung cancer (NSCLC) patients” David Planchard, Julien Mazieres, Gregory J. Riely, Charles M. Rudin, Fabrice Barlesi, Elisabeth A. Quoix, Pierre-Jean Souquet, Mark A. Socinski, Julie Switzky, Bo Ma, **Vicki L. Goodman**, Stanley W. Carson, C. Martin Curtis Jr., Michael R. W. Streit, Bruce E. Johnson *J Clin Oncol* 31, 2013 (suppl; abstr 8009)

“A Phase II trial (BREAK-2) of the BRAF inhibitor dabrafenib (GSK2118436) in patients with metastatic melanoma” Paolo Antonio Ascierto, David Minor, Antoni Ribas, Celeste Lebbe, Anne O'Hagan, Niki Arya, Mary Guckert, Dirk Schadendorf, Richard F Kefford, Jean-Jaques Grob, Omid Hamid, Ravi Kumar Amaravadi, Ester Simeone, Tabea Wilhelm, Kevin B Kim, Georgina V Long, Anne-Marie Martin, Jolly Mazumdar, **Vicki L Goodman**, and Uwe Trefzer *Journal Clin Oncol* 2013; 31: 3205-3212

“Dabrafenib in patients with Val600Glu or Val600Lys BRAF-mutant melanoma metastatic to the brain (BREAK-MB): a multicentre, open-label, phase 2 trial” Georgina V. Long, Uwe Trefzer, Michael A. Davies, Richard F. Kefford, Paolo A. Ascierto, Paul B. Chapman, Igor Puzanov, Axel Hauschild, Caroline Robert, Alain Algazi, Laurent Mortier, Hussein Tawbi, Tabea Wilhelm, Lisa Zimmer, Julie Switzky, Suzanne Swann, Anne-Marie Martin, Mary Guckert, **Vicki Goodman**, Michael Streit, John M. Kirkwood, and Dirk Schadendorf *Lancet Oncology* 2012; 13: 1087-1095

“Dabrafenib in BRAF-mutated metastatic melanoma: a multicentre, open-label, phase 3 randomised controlled trial” Axel Hauschild, Jean-Jacques Grob, Lev V Demidov, Thomas Jouary, Ralf Gutzmer, Michael Millward, Piotr Rutkowski, Christian U Blank, Wilson H Miller Jr, Eckhart Kaempgen, Salvador Martin-Algarra, Boguslawa Karaszewska, Cornelia Mauch, Vanna Chiarion-Sileni, Anne-Marie Martin, Suzanne Swann, Patricia Haney, Beloo Mirakhur, Mary E Guckert, **Vicki Goodman**, Paul B Chapman *Lancet* 2012; 380: 358-365

“BRAF(V600) Inhibitor GSK2118436 Targeted Inhibition of Mutant BRAF in Cancer Patients Does Not Impair Overall Immune Competency” David S. Hong, Luis M. Vence, Gerald S Falchook, Laszlo G. Radvanyi, Chengwen Liu, **Vicki L Goodman**, Jeffrey J Legos, Samuel C Blackman, Antonio T Scamardo1, Razelle Kurzrock, Gregory Lizee, and Patrick Hwu *Clin Cancer Res* 2012;18:2326-2335

“Phase III, randomized, open-label, multicenter trial (BREAK-3) comparing the BRAF kinase inhibitor dabrafenib (GSK2118436) with dacarbazine (DTIC) in patients with BRAF^{V600E}-mutated melanoma” Axel Hauschild, Jean Jacques Grob, Lev V. Demidov, Thomas Jouary, Ralf Gutzmer, Michael Millward, Piotr Rutkowski, Christian U. Blank, Beloo Mirakhur, Mary E. Guckert, R. Suzanne Swann, Patricia Haney, Anne-Marie Martin, Danielle Ouellet, Kelly Grotzinger, **Vicki L. Goodman**, Paul B. Chapman *J Clin Oncol* 30, 2012 (suppl; abstr LBA8500)

“BREAK-MB: A phase II study assessing overall intracranial response rate (OIRR) to dabrafenib (GSK2118436) in patients with BRAF V600E/k mutation-positive melanoma with brain metastases” John M. Kirkwood, Georgina V. Long, Uwe Trefzer, Michael A. Davies, Paolo Antonio Ascierto, Paul B. Chapman, Igor Puzanov, Axel Hauschild, Caroline Robert, Richard Kefford, **Vicki L. Goodman**, Julie C. Switzky, R. Suzanne Swann, Anne-Marie Martin, Mary E. Guckert, Michael R. W. Streit, Dirk Schadendorf *J Clin Oncol* 30, 2012 (suppl; abstr 8501)

“Tumor-specific circulating cell-free DNA (cfDNA) BRAF mutations to predict clinical outcome in patients (pts) treated with the BRAF inhibitor dabrafenib (GSK2118436)” Georgina V. Long, Paolo Antonio Ascierto, Jean Jacques Grob, Omid Hamid, Richard Kefford, Celeste Lebbe, David R. Minor, Antoni Ribas, Dirk Schadendorf, Leslie Anne Fecher, Uwe Trefzer, Nikita Arya, Robert C. Gagnon, **Vicki L. Goodman**, Anne Siegfried, Jolly Mazumdar, Anne-Marie Martin *J Clin Oncol* 30, 2012 (suppl; abstr 8518)

“BREAK-2: a Phase IIA trial of the selective BRAF kinase inhibitor GSK2118436 in patients with BRAF (V600E/K) mutation-positive metastatic melanoma” U. Trefzer, D. Minor, A. Ribas, C. Lebbe, A. Siegfried, N. Arya, M. Guckert, D. Schadendorf, R. Kefford, J-J. Grob, O. Hamid, R. Amaravadi, E. Simeone, T. Wilhelm, K. Kim, **V. Goodman** and P.A. Ascierto *Pigment Cell Melanoma Res* 2011; 24: 1020.

“A randomized and open-label trial evaluating the addition of pazopanib to lapatinib as first-line therapy in patients with HER2-positive advanced breast cancer”

Stephen R. D. Johnston, Henry Gomez, Salomon M. Stemmer, Maria Richie, Michael Durante, Lini Pandite, **Vicki Goodman**, Dennis Slamon *Breast Cancer Research and Treatment* 2013; 137: 755

"Association of the Hemochromatosis Gene with Pazopanib-Induced Transaminase Elevation in Renal Cell Carcinoma"

Chun-Fang Xu, Brian H Reck, **Vicki L Goodman**, Zhengyu Xue, Lingfang Huang, Michael Barnes, Colin F Spraggs, Vincent E Mooser, Lon R Cardon, and Lini Pandite *J Hepatol.*54(6):1237-1243 (2011)

“Trough PK concentration, age of patient, and baseline ALT are important factors in predicting ALT elevations in pazopanib treated mRCC patients”

V. Goodman, J. Botbyl, B. Suttle, J. Gauvin, M. Dar, L. Pandite *ESMO 2010 abstract 5094*

“Incidence and management of hepatic toxicity in pazopanib-treated patients”

Goodman, V., Wang, Q., Pandite, L., Watkins, P.B. *ESMO 2010 abstract 5044*

“Association of the hemochromatosis (HFE) gene with pazopanib-induced transaminase elevations in renal cell carcinoma”

Xu, C-F., Reck, B., **Goodman, V.**, Xue, Z., Huang, L., Spraggs, C., Mooser, V., Cardon, L., and Pandite, L. (*J Clin Oncol* 28:15s, 2010 [suppl; abstr 3019])

“Phase 2 study of dual VEGF/HER2 blockade with pazopanib + lapatinib in patients with first-line HER2 positive advanced or metastatic breast cancer”

Slamon, D. Stemmer, S., Johnston, S., Kim, S-B., Durante, M., Pandite, L., Roychowdhury, D., and **Goodman, V.** [SABCS abstract 4114]. *San Antonio Breast Conference Proceedings*. 2008b:29 1s.

“Pazopanib + Lapatinib is more active than Lapatinib alone: Updated results from a randomized study in patients with ErbB2 positive advanced or metastatic breast cancer”

Slamon, D., Gomez, H., Amit, O., Richie, M., Pandite, L., Roychowdhury, D., **Goodman, V.** [ESMO Abstract 139P]. *Ann Oncol.* 2008c; 19 (supp 8):viii 64-65.

“Randomized study of pazopanib + lapatinib vs. lapatinib alone in patients with HER2 positive advanced or metastatic breast cancer” Slamon, D, Gomez, H, Kabbinawar, F, Amit, O, Richie, M, Pandite, L,

Goodman, V *J Clin Onc* 26:2008 (May 20 suppl; abstr 1016)

“Sprycel for Chronic Myeloid Leukemia and Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia Resistant to or Intolerant of Imatinib Mesylate” . Brave, M, **Goodman, V**, Kaminskas, E *et al. Clinical Cancer Research* 14(2): 352-359 (2008)

“Approval Summary: Sunitinib for the Treatment of Imatinib Refractory or Intolerant Gastrointestinal Stromal Tumors and Advanced Renal Cell Carcinoma”. **Goodman, VL**, Rock E, Dagher, R *et al. Clinical Cancer Research* 13(5): 1367-1373 (2007)

“FDA Drug Approval Summary: Sunitinib malate (Sutent[®]) for the Treatment of Gastrointestinal Stromal Tumor and Advanced Renal Cell Carcinoma”. E. Rock, **V. Goodman**, R Dagher, *et al. The Oncologist* 12:107-113 (2007)

“Control of Copper Status for Cancer Therapy” **Goodman VL**, Brewer GJ, and Merajver SD *Current Cancer Drug Targets* 5(7):543-547 (2005)

"Inflammatory Breast Cancer: Advances in Molecular Genetics and Treatment" in Textbook of Breast Cancer, 3rd edition. Ed. Gianni Bonadonna. Informa Healthcare 2005
S.D. Merajver, **V. L. Goodman**, M.S. Sabel

"Copper Deficiency as an Anti-Cancer Strategy". *Endocrine-Related Cancer* 11(2):255-263 (2004). **V.L. Goodman**, G.J. Brewer, S.D. Merajver:

"Tetrathiomolybdate Inhibits Angiogenesis and Metastasis Through Suppression of the NFκB Signaling Cascade". [Abstract]; Susan G. Komen Breast Cancer Foundation 2003 Mission Conference, Washington, D.C. Q. Pan, **V.L. Goodman**, L.W. Bao, S.A. Grove, and S.D. Merajver

"Bilateral Prophylactic Oophorectomy Reduces Risk of Breast and Ovarian Cancers in Women with BRCA Mutations: What Else Do We Need to Know About Long-term Outcomes?" **V. L. Goodman** and S.D. Merajver *Am. J. Oncology Rev.* 1:136-142 (2002)

"Mechanisms of Camptothecin Resistance in Human Leukemia Cells". [Abstract] New Jersey Symposium on Cancer Research May 1998. **V. Goodman**, M. Saleem, X-G Li, and E. Rubin

Professional Memberships

2003 - Present American Society of Clinical Oncology

2014 - Present American Association for Cancer Research