

**Samir E. Witta, M.D., Ph.D.**

**Mountain Blue Cancer Care Center**  
**400 Indiana Street Suite 270**  
**Golden, Colorado 80401**



**Positions and Training:**

- 2009- President, *Hematologist, Medical Oncologist*, Mountain Blue Cancer Care Center, Golden, CO
- 2005- Clinical Assistant Professor, University of Colorado Health Sciences Center, CO
- 2005-2009 *Hematologist, Medical Oncologist*, US Oncology, Rocky Mountain Cancer Centers, Lakewood, Colorado
- 2004-2005 *Assistant Professor*, Thoracic Oncology, Internal Medicine, Division of Oncology, UCHSC
- 2003-2004 Thoracic Oncology Program, University of Colorado Health Sciences Center, CO
- 2002-2003 Developmental Therapeutic Program, University of Colorado Health Sciences Center, CO
- 2001-2004 *Fellow*, Hematology/Medical Oncology, University of Colorado Health Sciences Center
- 1998-2001 *Resident*, Internal Medicine Northeastern Pennsylvania Affiliated Residency Program, PA
- 1996-1998 *Postdoctoral Fellow*, Division of Clinical Pharmacology, University of Colorado
- 1991-1996 *Postdoctoral Fellow*, National Institutes of Health, NIDDK, Bethesda, MD

**Positions:**

- 2011- date President, Global Cancer Research
- 2009- 2013 Medical Oncology Director, Saint Anthony Central Hospital
- 2009- date President Elect. Rocky Mountain Oncology Society
- 2007- 2013 Chairman, Cancer Committee of Centura St. Anthony Hospital
- 2007- date Member of Colorado Cancer Research Program Board of Directors
- 2006- date President and co-founder of AnthioGen-a nonprofit org. to support patients with cancer

**Education:**

- 1992-1998 Ph.D., Genetics, National Institutes of Health, Bethesda, Maryland, USA/  
Charles University, Czech Republic, Ph.D., February 1998  
Thesis: "The role of *XLPOU 2* in early vertebrate development"
- 1983-1990 M.D., First Faculty of Medicine, Charles University, Czech Republic  
Medicinae Universae Doctor (M.D.), June 1990

**Medical Board Exams:**

2005        Medical Oncology  
2001        Internal Medicine

**Clinical trials:**

- 2014    PI, Global Cancer Research: A Phase IIIb/IV Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Progressed During or After Receiving At Least One Prior Systemic Regimen
- 2011    PI, Global Cancer Research: A Phase 1b open-label, expansion study to investigate the safety, efficacy, and pharmacokinetics of intravenous CUDC-101 in subjects with advanced head and neck, gastric, breast, liver and non-small cell lung cancer tumors. Number: CUDC-101-102.
- 2009    PI, US Oncology: A Randomized, Placebo-controlled, Double-blind, Multicenter Phase 2 Study with a Lead in Phase of Erlotinib With or Without SNDX-275 in Patients with Non-small Cell Lung Carcinoma After Failure In Up to Two Prior Chemotherapeutic Regimens for Advanced Disease. SYNDAX Protocol SNDX-275-0401.
- 2008    PI, US oncology: A Study Of AG-013736 (Axitinib) Or Bevacizumab (Avastin) In Combination With Paclitaxel And Carboplatin In Patients With Advanced Lung Cancer.
- 2005    PI, US Oncology: Phase III clinical trial of pemetrexed vs. placebo as consolidation treatment in patients in NSCLC.
- 2006    PI, RMCC: Phase II trial of Carboplatin/Paclitaxel with or without erlotinib as 1<sup>st</sup> line in selected patients with NSCLC.

**Grants and Awards:**

- 7/2004        IASLC Fellowship: Predicting and improving response to EGFR inhibitors in NSCLC
- 7/2004        Colorado Cancer League: Improvement of response to EGFR inhibitors in NSCLC
- 10/1991        Fogarty International Center: National Institutes of Health Visiting Fellowship Award.

**Patents:**

CU1350H: “Histone Deacetylase Inhibitors Sensitize Cancer Cells to Epidermal Growth Factor Inhibitors”

CU1211H: “Gefitinib Sensitivity-Related Gene Expression and Products and Methods Related Thereto”

**Selected Publications/Presentation:**

1. Witta SE, Jotte R, Konduri K, Spira A, et al. Analysis of Cross-Over Portion of ENCORE-401, A Randomized, Double-blind, Placebo-Controlled Phase 2 Study of Erlotinib with and without Entinostat, A Class 1 Isoform Selective Histone Deacetylase Inhibitor (HDAC) In Patients with Advanced Non-Small Cell Lung Cancer. 14<sup>th</sup> World Conference on Lung Cancer on July 2-7, 2011
2. Witta SE, Jotte R, Konduri K, Spira A, et al. Biomarker analysis of a randomized, double-blind, placebo-controlled phase 2 study of erlotinib with and without entinostat, a class 1 isoform selective histone deacetylase inhibitor (HDAC) in patients with advanced non-small cell lung cancer (NSCLC; ENCORE-401), 14<sup>th</sup> World Conference on Lung Cancer on July 2-7, 2011 (Abstract 2988 / MO15.04 ).
3. Dziadziuszko R, Merrick DT, Witta SE, Mendoza AD, Szostakiewicz B, Szymanowska A, Rzyman W, Dziadziuszko K, Jassem J, Bunn PA Jr, Varella-Garcia M, Hirsch FR. Insulin-like growth factor receptor 1 (IGF1R) gene copy number is associated with survival in operable non-small-cell lung cancer: a comparison between IGF1R fluorescent in situ hybridization, protein expression, and mRNA expression. J Clin Oncol. 2010 May 1;28(13):2174-80.
4. K. Konduri, A. I. Spira, R. M. Jotte, T. Boyd, T. Boyd, Y. A. Gaffar, C. Reynolds, S. E. Witta; Results from a phase I safety lead-in study investigating the combination of erlotinib and the histone deacetylase inhibitor entinostat in patients with advanced NSCLC. J Clin Oncol 27, 2009 (suppl; abstr e14545)
5. S. E. Witta , R. Dziadziuszko , K. Yoshida , K. Hedman , M. Varella-Garcia , P. A. Bunn, Jr , and F. R. Hirsch ErbB-3 expression is associated with E-cadherin and their coexpression restores response to gefitinib in non-small-cell lung cancer (NSCLC) Annals of Oncology Advance 2009, Ann Oncol 20: 689-695.
6. Witta SE., Franekova V, Yoshida K., Igoznikov I., Frederick B., Varella-Garcia, M., Bunn P A, Hirsch FR Synergistic effect of SNDX-275 with lapatinib or erlotinib in breast, lung, or head and neck cancer cell lines expressing HER- 2, J Clin Oncol 27, 2009 (suppl; abstr e14566)
7. Witta SE, Gemmill RM, Hirsch FR, Coldren C, Hedman K, Ravdel L, Helfrich B, Dziadziuszko R, Chan DC, Sugita M, Zang C, Baron A, Franklin W, Drabkin HA, Girard L, Gazdar AF, Minna JD, and Bunn PA Jr. Upregulation of E-cadherin by Inhibiting Histone Deacetylases Restores Sensitivity to EGFR Inhibitor in Lung Cancer Cell lines. Cancer Res 2006 66: 944-950
8. Basche M, Gustafson DL, Holden SN, O'Bryant CL, Gore L, Witta S et al. A phase I biological and pharmacologic study of the heparanase inhibitor PI-88 in patients with advanced solid tumors. Clin Cancer Res. 2006 12:5471-80.

9. Bunn PA Jr., Dziadziuszko R, Varella-Garcia M, Franklin WA, Witta SE, Kelly K, and Hirsch FR Biological Markers for Non-Small Cell Lung Cancer Patient Selection for Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy Clin. Cancer Res. 2006 12: 3652-3656.
10. Coldren C, Barbara H, Witta SE, et al. Baseline Gene Expression Predicts Sensitivity to Gefitinib in Non-Small Cell Lung Cancer Cell Lines. Mol Cancer Res 2006 0:1541-7786.MCR-06-0095
11. Ohira T, Kakihana M, Chan D, Witta S, Roche J, Kato H, Drabkin H, Gemmill RM. Induction of E-cadherin and Apoptosis by Histone Deacetylase Inhibitors in Lung Cancer. In submission to J Thoracic Oncology
12. Hirsch F, Varella-Garcia M, Cappuzzo F, McCoy J, Bemis L, Haney J, Xavier A, Gumerlock P, Witta S, West H, Crowley J, Gazdar A, Crino L, Gandara D, Franklin W, Bunn AP Jr. Increased EGFR Copy Number by FISH and EGFR Protein Expression by Immunohistochemistry Can be Used to Select Advanced Non-Small Cell Lung Cancer patients to EGFR Tyrosine Kinase Inhibitor Therapy. Submitted to JAMA.
13. Alvarez E, Zhou W, Witta SE, Freed CR. Characterization of the Bex gene family in humans, mice, and rats. Gene. 2005 357(1):18-28.
14. Cappuzzo F, Hirsch F, Rossi E, Bartolini S, Ceresoli G, Bemis L, Haney J, Witta S, Danenberg K, Domenichini I, Ludovini V, Lombardo L, Gregorc V, Doglioni C, Sidoni A, Tonato M, Franklin W, Crino L, Bunn PA Jr., Varella-Garcia M, Ph.D. Epidermal Growth Factor Receptor Gene Copy Number, Gene Mutations and Protein Level Predict Outcome to Gefitinib Therapy in Advanced Non-Small Cell Lung Cancer J Natl Cancer Inst. 2005 97(9):643-55.
15. Witta S.E., Gustafson D., Pierson S., Menter A., Holden S., Basche M., Persky M., O'Bryant C., Long M., Gibbs A., Kelly K., Bunn P., Chan D., Pallansch P., and Eckhardt S.G. A Phase I and Pharmacokinetic Study of Exisulind and Docetaxel in patients with Advanced Solid Tumors. Clin Cancer Res. 2004 10(21):7229-37.
16. Zawada W. M., Cibelli J. B., Choi P. K., Clarkson E D., Golueke P. J., Witta S. E., Bell K. P., Kane, J., Ponce de Leon, F. A., Jerry D. J., Robl J. M., Freed C. R., and Stice S. L. Somatic cell cloning-produced transgenic bovine neurons for transplantation in parkinsonian rats. 1998 Nat Med. 4:569-74.
17. Clarkson, E. D., La Rosa, F. G., Edward-Prasad, J., Weiland, D. A., Witta, S. E., Freed, C. R. and Prasad, K. N. Relative efficiency of undifferentiated and differentiated immortalized dopamine producing nerve cells in reducing behavioral deficit in 6-Hydroxydopamine lessened rats. 1998 Proc Natl Acad Sci U S A. 3;95:1265-70
18. Witta, S. E. and Sato, S. M. XIPOU 2 is a potential regulator of the head Organizer. 1997 Development. 124: 1179-1189
19. Witta, S. E., Agarwal, V. R. and Sato, S. M. XIPOU 2, a noggin-inducible gene, has direct neuralizing activity. 1995 Development 121: 721-730.