

## **CURRICULUM VITAE**

### **Jonathan D. Cheng, MD**

**NAME:** Jonathan Dean Cheng

**ADDRESS:**

Merck Research Labs  
Oncology Clinical Research  
351 N Sumneytown Pike  
North Wales, PA 19454  
Office: (267) 305-2925  
E-mail: jonathan\_cheng@merck.com

Department of Medicine  
Fox Chase Cancer Center  
333 Cottman Ave  
Philadelphia, PA 19111  
Office: (215) 728-7083  
E-Mail: j\_cheng@fccc.edu

**EDUCATION:**

1988	Marquette University Milwaukee, WI	B.S. Summa cum laude Computer Science
1992	University of Minnesota Minneapolis, MN	M.D

**CLINICAL AND RESEARCH TRAINING:**

1992-1993	University of Minnesota Hospital & Clinic Minneapolis, MN	Intern Dept. of Medicine
1993-1995	University of Minnesota Hospital and Clinic Minneapolis, MN	Resident Dept. of Medicine
1996-1997	Roswell Park Cancer Institute Buffalo, NY	Clinical Fellow Medical Oncology
1997-1998	Roswell Park Cancer Institute Buffalo, NY	Research Fellow GI Oncology Service

1998-1999 Fox Chase Cancer Center Postdoctoral Fellow  
Philadelphia, PA Louis Weiner Lab

**FACULTY POSTS:**

2018-current Vice President  
Therapeutic Area Head  
Late Stage Oncology  
Merck Research Labs  
Merck & Co., Inc.  
Upper Gwynedd, PA

2016-2018 Associate Vice President  
Section Head: Head/neck, GI and New Indications  
Clinical Oncology  
Merck Research Labs  
Merck & Co., Inc.  
Upper Gwynedd, PA

2014-2016 Executive Director  
Product Development Team Lead, Pembrolizumab  
Clinical Oncology, Head and Neck Cancers  
Merck Research Labs  
Merck & Co., Inc.  
Upper Gwynedd, PA

2009-2014 Director  
Clinical Oncology  
Merck Research Labs  
Merck & Co., Inc.  
Upper Gwynedd, PA

2009-current Associate Professor  
Division of Medical Sciences  
Fox Chase Cancer Center  
Philadelphia, PA

2001-2009 Assistant Professor  
Fox Chase Cancer Center  
Philadelphia, PA

1999-2001 Assistant Member, Department of Medical Oncology  
Fox Chase Cancer Center

Philadelphia, PA

1995-1996            Attending Physician, Department of Internal Medicine  
Hennepin County Medical Center  
Minneapolis, MN

1994-1995            Attending Physician, Department of Internal Medicine  
St. Paul Ramsey County Medical Center  
St. Paul, MN

**BOARD CERTIFIED:**

1993            National Board of Medical Examiners  
1995            American Board of Internal Medicine  
1999            ABIM Subspecialty Board on Medical Oncology

**LICENSURE**

Minnesota	1994-1996	37320
New York	1996-1998	P95219
Pennsylvania	1998-	MD-066783-L

**PHARMACEUTICAL EXPERIENCE**

**Merck Sharpe and Dohme [2010-current]**

**Authored and Monitored Clinical Trials**

1. A Phase I Study of MK-4827 in Combination with Temozolomide in Patients with Advanced Cancer (2010-2011)
2. A Phase I Study of MK-0646 in Combination with MK-2206 and MK-0752 in Patients with Advanced Solid Tumors (2010-2011)
3. Phase I Parallel Protocol of MK-8669 (Ridaforolimus) + MK-2206 and MK-8669 (Ridaforolimus) + MK-0752 Doublets (MK-MK) in Patients with Advanced Cancer (2010-2011)
4. A Phase Ib Multi-Cohort Study of MK-3475 in Subjects with Advanced Solid Tumors (KEYNOTE 012) (2012-current)
5. Phase IB Study of MK-3475 in Subjects with Select Advanced Solid Tumors (KEYNOTE 028) (2013-2016)
6. Clinical Trial of Single Agent Pembrolizumab (MK-3475) in Subjects with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) Who Have Failed Platinum and Cetuximab (KEYNOTE 055) (2014-current)

7. A Phase III Randomized Trial of MK-3475 (Pembrolizumab) versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer (KEYNOTE 040) (2014-2016)
8. A Study of Pembrolizumab (MK-3475) for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (MK-3475-048/KEYNOTE-048) (2014-2016)
9. Study of Pembrolizumab (MK-3475) or Placebo With Chemoradiation in Participants With Locally Advanced Head and Neck Squamous Cell Carcinoma (KEYNOTE 412) (2017)
10. A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination With Standard of Care as Adjuvant Therapy for Stage III-IVB Resectable Locoregionally Advanced Head and Neck Squamous Cell Carcinoma (KEYNOTE 689) (2017)

### **Registration Filing Experience**

1. U.S. filing: Ridaforilum for maintenance therapy in metastatic sarcoma (2012)
  - Safety/toxicity lead for ridaforolimus filing (ODAC presentation 3/20/12)
2. EU filing: Vintafolide conditional approval for platinum resistance ovarian cancer (2013-2014)
  - Clinical lead for Vintafolide EU conditional approval BLA (EMA presentation 2/18/14)
3. U.S. Filing: Pembrolizumab accelerated approval for patients with ipilimumab refractory metastatic melanoma (2014)
  - Safety adjudicator for immune related adverse events
4. U.S. Filing: Pembrolizumab accelerated approval for patients with recurrent/metastatic head and neck cancer who had previously progressed on platinum (2016)
  - Clinical and team lead for the sBLA
  - Authored CSR, ISS, and ISE
  - Authored Sections 2.5, 2.7.3, 2.7.4
5. Global Filing: Pembrolizumab for patients with recurrent/metastatic head and neck cancer who had previously progressed on platinum (2016-2017, clinical lead) and 1L recurrent/metastatic head and neck cancer (2019, oncology therapeutic area lead)
6. U.S. Filing: Pembrolizumab accelerated approval for patients with advanced gastric/GE junction cancer with progression after 2 prior lines of therapy (2017, clinical lead)
7. U.S. Filing: Pembrolizumab accelerated approval for patients with advanced cervical cancer with progression after 1 prior lines of therapy (2018, clinical lead)

8. U.S. Filing: Pembrolizumab accelerated approval for adult and pediatric patients with advanced primary mediastinal B-cell lymphoma after 2 prior lines of therapy (2018, oncology therapeutic area lead)
9. US Filing: Lenvima approval for 1L treatment of patients with unresectable hepatocellular carcinoma (2018, oncology therapeutic area lead)
10. Global filing: Pembrolizumab approval in combination with pemetrexed and platinum-based chemotherapy as 1L treatment of patients with metastatic nonsquamous non-small cell lung cancer (2018, oncology therapeutic area lead)
11. US Filing: Pembrolizumab approval for recurrent, locally advanced or metastatic squamous cell carcinoma of the esophagus after 1 prior lines of therapy (2019, oncology therapeutic area lead)
12. US, Canada, Australia Simultaneous Filing (Project Orbis): Pembrolizumab + lenvima approval in 2L endometrial cancer (2019, oncology therapeutic area lead, joint development committee chair with Eisai)

#### **Health Authority Experience (Selected)**

1. FDA EOP2 Meeting June 11, 2014
  - Pembrolizumab head/neck program
2. EMA SAWP meeting September 3, 2014
  - Phase III Randomized Trial of MK-3475 (Pembrolizumab) versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer
3. FDA SEALD Meeting February 4, 2015
  - ePRO for head/neck program
4. FDA Type B Meeting June 30, 2015
  - Pembrolizumab head/neck program
5. FDA pre-sBLA meeting Nov 23, 2015
  - Pembrolizumab in recurrent/metastatic HNSCC who have progressed on platinum
6. Health Canada preS/NDS meeting March 29, 2016
  - Pembrolizumab in recurrent/metastatic HNSCC who have progressed on platinum
7. FDA Labelling meeting August 4, 2016
  - Pembrolizumab in recurrent/metastatic HNSCC who have progressed on platinum
8. EMA/HTA Parallel Scientific Advice September 28, 2016
  - Randomized phase III trial of either chemoradiation plus pembrolizumab; or chemoradiation plus placebo in subjects with locally advanced HNSCC
9. FDA pre-sBLA meeting January 31, 2017
  - Pembrolizumab for 3L+ treatment of gastric cancer patients
10. FDA Type C Meeting February 7, 2017

- Phase III Randomized Clinical Trial of Pembrolizumab (MK-3475) plus Chemotherapy (XP or FP) versus Placebo plus Chemotherapy (XP or FP) as Neoadjuvant/Adjuvant Treatment for Subjects with Gastric Adenocarcinoma
11. EMA SAWP meeting March 8, 2017
    - Phase III Randomized Clinical Trial of Pembrolizumab (MK-3475) plus Chemotherapy (XP or FP) versus Placebo plus Chemotherapy (XP or FP) as Neoadjuvant/Adjuvant Treatment for Subjects with Gastric Adenocarcinoma
  12. FDA BreakThrough Designation March 20, 2017
    - Neoadjuvant treatment of head/neck cancer
  13. FDA EOP3 meeting April 24, 2017
    - A Randomized, Open-Label Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab with Epcadostat vs the EXTREME Regimen as First-line Treatment for Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma. (KN040)
  14. FDA application orientation meeting April 26, 2017
    - Pembrolizumab for 3L+ treatment of gastric cancer patients
  15. FDA EOP3 meeting December 5, 2017
    - A Study of Pembrolizumab (MK-3475) Versus Paclitaxel for Participants With Advanced Gastric/Gastroesophageal Junction Adenocarcinoma That Progressed After Therapy With Platinum and Fluoropyrimidine (KN061)
  16. FDA pre-sBLA meeting December 11, 2017
    - a. Pembrolizumab for 2L+ treatment of cervical cancer patients
  17. FDA application orientation meeting March 5, 2018
    - a. Pembrolizumab for 2L+ treatment of cervical cancer patients
  18. EMA oral explanation lead presenter July 25, 2018
    - a. Pembrolizumab for 2L+ treatment of head/neck cancer patients
  19. EMA SAG-O January 10, 2019
    - a. Clinical Lead and presenter
    - b. Pembrolizumab early crossing of survival curve
  20. FDA pre-sBLA meeting January 25, 2019
    - a. Pembrolizumab for 2L+ treatment of esophageal cancer patients

### **Biomarker and Companion Diagnostic Development**

1. MK-1775 (Wee-1 inhibitor)
  - pCDC2 IHC for PD target engagement to determine target dose of MK-1775 (2010)
  - p53 Amplichip (CLIA certified, CoDx development) for patient enrichment in platinum sensitive ovarian cancer (2011)
2. MKMK Combination program
  - Ras signature for prospective enrichment of MK-8669 combinations in ER+ breast cancer and ovarian cancer (2012)

- IGF1 mRNA for prospective enrichment of MK-0646 combinations in ovarian and colorectal cancer (2012)
- 3. Pembrolizumab in gastric cancer
  - Companion Diagnostic in 3L+ gastric cancer (2017)
- 4. Pembrolizumab in head/neck cancer
  - Development of PD-L1 IHC as a companion diagnostic for phase III registration trials in head/neck cancer (2018)

### **Leadership Experience**

1. Biomarker lead for MK-1775 (2010-2011), MKMK combination program (2010-2012), and pembrolizumab in head/neck cancer (2013-current)
2. Early Development Team lead for MKMK (2010-2012)
3. ADAPT Workstream for adaptive design in clinical trials (2010)
4. Clinical lead for Signaling 1 Early Development Team (2012-2013)
5. Clinical lead for Vintafolide lung late stage development program (2013)
6. CTEP Application for Vintafolide (2013)
7. Safety Strategy for Clinical Development (2014)
8. Late Development Team lead pembrolizumab head/neck team (2014-2016)
  - sBLA of pembrolizumab in recurrent/metastatic HNSCC (2015)
9. Section Head of Head/neck, GI malignancies, and New Indications (2016-2018)
  - sBLA of pembrolizumab in locally advanced gastric cancer (2016)
10. Late Stage Oncology Therapeutic Area Lead (2018-current)
  - sBLA of pembrolizumab in recurrent or metastatic cervical cancer (2018)
  - sBLA of pembrolizumab in 1L as monotherapy and in combination with chemotherapy for squamous and non-squamous NSCLC (2018)
    - Real Time Oncology Review (RTOR) 1<sup>st</sup> Pilot
  - sBLA of pembrolizumab in 1L recurrent/metastatic HNSCC (2018)
  - sBLA of pembrolizumab in 2L esophageal cancer (2018)
    - RTOR, Assessment Aid
  - sBLA of pembrolizumab + lenvatinib in 2L endometrial cancer (2019)
    - Project Orbis 1<sup>st</sup> Pilot, RTOR, Assessment Aid

### **AWARDS:**

1988	Marquette University Summa Cum Laude in Computer Science
1988	Minnesota Medical Foundation Achievement Award
1992	MAP-RDIF International Fellowship Award
1998	Merit Award, ASCO
1999	RPR Oncology Annual Fellowship Award

2005	Eastern Cooperative Oncology Group Young Investigator Symposium Clinical Research Award
2007	“Guide to America’s Top Oncologists” by Consumers’ Research Council of America
2011	Special Achievement Award for Leadership
2011	Annual Performance Top 5-10%
2012	Annual Performance Top 10-20%
2013	Annual Performance Top 5-10%
2014	Special Achievement Award for ASCO
2018	Robert Krigel Memorial Fellows Award for Excellence in Teaching

### **MEMBERSHIPS:**

1997-	Member, American Society of Clinical Oncology
1998-	Member, American Association for Cancer Research
1999-2009	Member, Eastern Cooperative Oncology Group
1999-2000	Member, Head and Neck Cancer Steering Committee
2009	Member, Lab Science and Pathology Advisory Committee
1999-2009	Member, Radiation Therapy Oncology Group

### **PROFESSIONAL SERVICES**

#### Roswell Park Cancer Institute

1997-1998	Member: Medical Oncology Curricula Fellow Representative
1996-1998	Instructor: Clinical Practice of Medicine I
1997-1998	Preceptor: Clinical Practice of Medicine II
1998	Member: Quality Improvement Committee

#### Fox Chase Cancer Center

1999-2000	Preceptor: Temple University Medical School Fundamentals of Clinical Care 202
1999-2004	Moderator: Medical Oncology Head/Neck Noon Conference
1999-2009	Member: Research Review Committee
2007-2009	Substitute Chairman: Research Review Committee
2003-2009	Member: Response Verification Committee
2004-2009	Member: Developmental Therapeutics Program
2005-2008	Member: Howard Hughes Medical Institute Partnership for Cancer Education Advisory Board
2008-2009	Member: Student Scientist Advisory Committee
2005-2006	Member: Shared Resource Facility Task Force
2006-2009	Member: Research Information Technology Advisory Committee
2008-2009	Member: Advanced Practice Clinicians Advisory Committee
2009-2009	Member: Post-doctoral Day Selection Committee



Temple University School of Medicine

2004-2005 Member: Internal Medicine Residency Admissions Committee

**LECTURES AT LOCAL INSTITUTIONS**

“Monoclonal antibodies in solid tumors.” Fellows Research Conference. Roswell Park Cancer Institute, Buffalo, NY. November 21, 1996

“Neoadjuvant treatment of rectal cancer.” Combined City-wide Oncology Conference. Veterans Administration Medical Center, Buffalo, NY. January 22, 1997.

“Recent advances in Interleukin-2.” Fellows Research Conference. Roswell Park Cancer Institute, Buffalo, NY. March 27, 1997.

“CEA surveillance is appropriate following potentially curative resection of colorectal carcinoma.” Medical-Surgical Debate. Roswell Park Cancer Institute, Buffalo, NY. January 27, 1998

“CEA surveillance is appropriate following potentially curative resection of colorectal carcinoma.” Medical-Surgical Debate. Fox Chase Cancer Center, Philadelphia, PA. October 29, 1998

“Esophageal cancer: Epidemiology, demographics, and treatment.” Fox Chase Network Physician Education Symposium and Scientific Meeting. Fox Chase Cancer Center, Philadelphia, PA. February 8, 2000

“Esophageal and gastric cancers.” GI Core Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. October 20, 2000

“Head and neck clinical research overview.” Medical Oncology Research Reviews. Fox Chase Cancer Center, Philadelphia, PA. April 10, 2001.

“Tumor stromal fibroblasts.” Medical Oncology Research Reviews. Fox Chase Cancer Center, Philadelphia, PA. July 17, 2001.

“Esophageal and gastric cancers.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 28, 2001.

“Clinical radioimmunotherapy: Recent results and future direction.” Department of Radiation Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. March 18, 2002.

“Tumor stromal fibroblast: Friend or foe.” Medical Oncology Research Reviews. Fox Chase Cancer Center, Philadelphia, PA. June 25, 2002.

“Esophageal and gastric cancers.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 2, 2002.

“Hitting the target.” Fox Chase Cancer Center Scientific Retreat. Princeton, NJ. October 20, 2001.

“Desmoplasia, microenvironment, and metastases.” Fox Chase Cancer Center Scientific Retreat. Princeton, NJ. October 4, 2002.

“Localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. January 24, 2003.

“Cancer 101.” Medical Library Association. Thomas Jefferson University, Philadelphia, PA. March 28, 2003.

“Tilling the Microenvironment Soil.” Leapfrog Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. March 25, 2003

“Tumor Stromal Fibroblasts as Therapeutic Targets.” Centocor Inc. Malvern, PA. June 5, 2003.

“Tumor Stromal Fibroblasts as Therapeutic Targets.” 3-Dimensional Pharmaceuticals. Exton, PA. August 13, 2003

“Esophageal and gastric cancers.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 14, 2003.

“Localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. May 7, 2004.

“Esophageal and gastric cancers.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 2, 2004.

“Head and Neck Cancers.” Recent Advances in Oncology for the Primary Care Health Professional. Philadelphia College of Osteopathic Medicine. Philadelphia, PA. January 15, 2005.

“Overview of Esophageal Cancer.” Gastrointestinal Malignancy Nursing Conference. Philadelphia, PA. June 7, 2005.

“Esophageal and gastric cancers.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 30, 2005.

“Localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. December 16, 2005.

“Introduction to Chemotherapy” Chemotherapy Administration Course for Nurses. Fox Chase Cancer Center, Philadelphia, PA. February 28, 2006

“Esophageal and gastric cancers update.” Introduction to Clinical Oncology Lecture Series. Fox Chase Cancer Center, Philadelphia, PA. August 15, 2006.

“How to approach research in oncology” Temple Research Day. Temple University, Philadelphia, PA. October 24, 2006.

“Localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. December 8, 2006.

“Research opportunities in oncology” Temple Research Day. Temple University, Philadelphia, PA. October 26, 2007.

“New research in localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. November 16, 2007.

“Research opportunities in oncology” Temple Research Day. Temple University, Philadelphia, PA. October 2, 2008.

“Recent Advances in Localized esophageal cancer.” Thoracic Surgery Conference. Fox Chase Cancer Center, Philadelphia, PA. March 26, 2009.

### **INVITED LECTURES AND SYMPOSIA PARTICIPATION**

“A phase I study of monoclonal antibody 3622W94 in combination with low-dose interleukin-2 and granulocyte-macrophage colony stimulating factor.” ASCO/AACR Methods in Clinical Cancer Research Workshop. Vail, CO. July 27-31, 1997

“Impact of health stock on treatment valuations by patients considering early phase clinical trials.” Podium presentation. National Medical Oncology Fellows’ Forum. Tuscon, AZ. March 6, 1998.

“Tumor Stromal Fibroblast as Therapeutic Targets” Invited Speaker, Research Seminar. Centocor. Horsham, PA. April 15, 2003.

“Tumor Stromal Fibroblast as Therapeutic Targets” Invited Speaker, Research Seminar. Genentech. South San Francisco, CA. May 8, 2003.

“Tumor Stromal Fibroblast as Therapeutic Targets” Invited Speaker, Research Seminar. 3 Dimensional Pharmaceuticals. Yardley, PA. August 13, 2003.

“FAP: The Search for an Inhibitor” Invited Speaker, FAP Seminar. Ludwig Institute. New York City, NY. November 19, 2003.

“Fibroblast Activation Protein as a Therapeutic Target” Invited Speaker, Research Seminar. Point Therapeutics Inc. Boston, MA. June 9, 2005.

“Protease Beacons Utilizing Serine Proteases” Invited Speaker, Research Seminar. University of Pennsylvania. Philadelphia, PA. July 1, 2005.

“Fibroblast Activation Protein as a Therapeutic Target” Invited Speaker, Research Seminar. Tufts University. Boston, MA. July 21, 2005.

“Fibroblast Activation Protein as a Therapeutic Target” Invited Speaker, Research Seminar. Case Western University Cancer Center. Cleveland, OH. August 25, 2005.

“Tumor Stromal Fibroblasts as Therapeutic Targets” Invited Speaker, Research Seminar. University of Minnesota. Minneapolis, MN. October 17, 2005.

“Tumor Stromal Fibroblasts as Therapeutic Targets” Invited Speaker, Eastern Cooperative Group Young Investigator Symposium. Tampa, FL. November 19, 2005.

“Therapeutic Inhibition of FAP in Animal Models” Invited Speaker, Research Seminar. Point Therapeutics Inc. Boston, MA. February 24, 2006.

“Gastrointestinal Malignancies” Invited Speaker, Grand Rounds. Hualien Mennonite Hospital. Hualien, Taiwan. July 28, 2006.

“Exploiting Tumor Stromal Fibroblast as Therapeutic Targets” Invited Speaker, Research Seminar. Bristol-Myers Squibb. Princeton, NJ. September 5, 2006.

“Clinical Development of Novel Therapeutics” Invited Speaker, Research Seminar. Arisaph Pharmaceuticals Inc. Boston, MA. January 23, 2007

“Fibroblast Activation Protein as a Clinical Target” Invited Speaker, Expert Panel of Serine Proteases. Sponsored by Ferring Pharmaceuticals. London, England. February 8, 2007.

“Serine Proteases as a Therapeutic Target” Invited Speaker, Research Seminar. Arisaph Pharmaceuticals Inc. Boston, MA. July 26, 2007

“Fibroblast Activation Protein as a Therapeutic Target” Invited Speaker, Fox Chase Cancer Center Faculty Research Forum. Academy of Natural Sciences. Philadelphia, PA. October 2, 2007.

“Stromal Therapeutics” Invited Speaker, Research Seminar. Tufts University. Boston, MA. November 28, 2007.

“Pharmacologic Treatment of Carcinoid Syndrome” Invited Speaker, Indevus Research Forum. Boston, MA. November 29, 2007.

“CRC2 Colorectal cancer workshop” Discussion Leader, Biocontinuum Group. Philadelphia, PA. December 6, 2007.

“FAP and dipeptidyl peptidases as drug targets in oncology.” Invited Speaker. 3<sup>rd</sup> International Conference on Dipeptidyl peptidase and Related Proteins. Antwerp, Belgium. April 25, 2008.

“Tumor stromal fibroblasts as therapeutic targets”. Invited Speaker, Research Seminar. Lombardi Cancer Center, Georgetown University. Washington, D.C. June 10, 2008.

“Tumor stromal fibroblasts as therapeutic targets”. Invited Speaker, Research Seminar. Fels Institute for Cancer Research. Temple University. Philadelphia, PA. June 24, 2008.

"Pharmacodynamic evaluation of pCDC2 and Wee1 signature as biomarkers of target engagement for the Wee1 tyrosine kinase inhibitor MK-1775". Podium Presentation. Berlin, Germany. EORTC-NCI-AACR International Symposium Molecular Targets and Cancer Therapeutics. November 19, 2010.

"Therapeutically targeting tumor stromal biology". Invited Speaker, Winthrop P. Rockefeller Cancer Institute Forum presentation. Little Rock, AK. April 30, 2012.

“Vintafolide in lung cancer”. Invited Speaker, International Association for the Study of Lung Cancer. Santa Monica, CA. February 2, 2013.

“Best challenges and issues in the clinical execution of a biomarker driven clinical trial”. Invited Speaker, Advancements in Clinical Research Operations for Oncology Products. Alexandria, VA. June 20, 2013.

“Clinical Development of Anti-PD1 Antibody Pembrolizumab (MK-3475)” Invited Speaker, Antibody Engineering & Therapeutics. Huntington Beach, CA. November 10, 2014.

“Harnessing the Immune System to Fight Cancer” Invited Speaker, Cancer Therapeutics Training Program Lecture Series. San Diego, CA. May 3, 2016

“Approach to Clinical Development of Combination Therapies” Invited Speaker, PMWC 2017 Clinical Trials in Immunotherapies. Mountain View, CA January 25, 2017

“Merck experience with Real Time Oncology Review” Invited Panel Member, Friends of Cancer Research Annual Meeting. Washington, DC. November 13, 2018.

“Harnessing the Power of the Immune System: Lessons Learned from the Pembrolizumab Story” Invited Speaker, Antibody Engineering & Therapeutics meeting. San Diego, CA. December 13, 2018.

“Industry’s View on Global Drug Development” Invited Panel Member, FDA-Duke Global Regulatory Pre-Workshop, Rockville, MD. May 7, 2019

“Harnessing the Power of the Immune System: Lessons Learned from the Pembrolizumab Story” Invited Speaker, World Pharma Week: Immuno-Oncology Clinical Trials Strategy and Execution. Boston, MA. June 18, 2019.

### **EDITORIAL AND REVIEW ACTIVITIES**

Web alert editor for PIERS module of Gastric Cancer 2007-2009

### **JOURNAL REVIEWER**

Cancer	1999-present
Journal of Clinical Oncology	2000-present
EOBT	2001-present
International Journal of Cancer	2001-present
Cancer Research	2002-present
Clinical Cancer Research	2004-present
Molecular Cancer Therapeutics	2005-present
Molecular Carcinogenesis	2006-present
BBA - Proteins and Proteomics	2007-present
Journal of National Cancer Institute	2011-present
Current Molecular Medicine	2011-present
Lung Cancer	2012-present

### **GRANT REVIEWER:**

Division of Research Grants, National Cancer Institute  
Special Review Committee: Predictive Multiscale Models of the

Physiome in Health and Disease, 2008

Swiss National Science Foundation  
Division Biology and Medicine, 2008

Eastern Cooperative Oncology Group  
Advisory Committee Reviewer  
Lab Science and Pathology Committee, 2009

**CLINICAL TRIALS — Principal Investigator/Author**

A Phase I Study of Monoclonal Antibody 3622W94 in Combination with Low-Dose Interleukin-2 and Granulocyte-Macrophage Colony Stimulating Factor (Principal Investigator, Author, 1998, Chiron)

Phase II Evaluation of Paclitaxel, Cisplatin and 5-Fluorouracil Given in Combination with Radiation Therapy Prior to Surgery in Patients with Resectable Esophageal Cancer (Principal Investigator, Author, 1999)

A Phase II Study of SU6668 in Patients with Head and Neck Cancers (Principal Investigator, Author, 2001, Sugen)

Phase II Trial of Single Agent Talabostat in Metastatic or Recurrent Colorectal Cancer (Principal Investigator, Author, 2004, Point Therapeutics) (IND 71,302)

Pharmacodynamic Study of Talabostat + FOLFOX in Patients with Metastatic Esophageal/Gastric Cancer (Principal Investigator, Author, 2006, Point Therapeutics) (IND 71,302)

Induction Therapy for Locally Advanced Resectable Cancer of the Esophagus, GE Junction, and Gastric Cardia: A Phase I Trial of ZD6474 (Zactima), Paclitaxel, Carboplatin, 5-Fluorouracil, and XRT followed by Surgery (Principal Investigator, Co-Author, 2007)

Comparative Pharmacodynamic Study of Talabostat in Patients with Localized Pancreas Cancer Prior to Surgical Resection (Principal Investigator, Author, 2007, R21 CA122301) (IND 71,302)

A Phase II Study of the Combination of Talabostat, Gemcitabine, and Radiation Therapy in Patients with Locally Advanced Pancreatic Cancer (Principal Investigator, Author, 2007, R21 CA122301) (IND 71,302)

Induction Therapy for Locally Advanced, Resectable Cancer of the Esophagus, GE Junction, and Gastric Cardia: A Phase I Trial of ZD6474 (Zactima), Paclitaxel,

Carboplatin, 5-Fluorouracil, and XRT Followed by Surgery (Principal Investigator, Author, 2008) (IND 76,590)

E2208, Randomized Phase II Study of Paclitaxel with or without the Anti-IGF-IR mAb IMCA12 as Second Line Treatment of Patients with Metastatic Esophageal or GE Junction Cancer (Principal Investigator, Author, 2009)

### **CLINICAL TRIALS — Local Principal Investigator**

ECOG 5397 Randomized, Double Blind, Placebo Controlled Phase III Evaluation of Cisplatin + Placebo Versus Cisplatin + C225 a Mouse/Human Monoclonal Antibody to the Epidermal Growth Factor Receptor, in Patients with Metastatic And/or Recurrent Squamous Cell Cancer of the Head and Neck (Local Principal Investigator, 2000)

A Phase II Study of Recombinant Human Keratinocyte Growth Factor (rHuKGF) in Head and Neck Cancer Patients Receiving Concurrent Chemotherapy with Standard or Hyperfractionated Radiation Therapy (Local Principal Investigator, 2000)

Phase I Single Dose Escalation Study of <sup>131</sup>I Sibrotuzumab in Patients with Advanced or Metastatic Colorectal Cancer (Local Principal Investigator, 2001, Boehringer Ingelheim)

ECOG2399: A Phase II Trial of Chemoradiation for Organ Preservation in Resectable Stage III or IV Squamous Cell Carcinomas of the Larynx or Oropharynx (Local Principal Investigator, 2001)

A Phase II Study of Tezacitabine with or without 5-Fluorouracil (5-FU) as Second Line Therapy of Advanced Esophageal or Gastric Adenocarcinoma. (Local Principal Investigator, 2002)

NCI #5917: An evaluation of preoperative chemotherapy with irinotecan and cisplatin for advanced, but respectable gastric cancer: A coordinated multidisciplinary, multicenter study linking functional imaging, genomic expression profiles and histopathology. (Local Principal Investigator, 2003)

NCI 5941-Phase II Study of PS341 Alone or in Combination with Irinotecan in Patients with Adenocarcinoma of the Gastroesophageal Junction (GEJ) or Stomach (Local Principal Investigator, 2004)

CTSU/CALGB 80101: Phase III Intergroup Trial of Adjuvant Chemoradiation after Resection of Gastric or Gastroesophageal Adenocarcinoma (Local Principal Investigator, 2005)

### **PEER REVIEWED RESEARCH SUPPORT**



National Cancer Institute      K12 CA 01728-07      7/98-6/00  
Clinical Investigation Training Program  
Direct Costs: \$200,000

American Cancer Society      IRG-92-027-06      7/00-6/01  
“Therapeutic Inhibition of FAP”  
Principal Investigator  
Direct Costs: \$20,000

National Institute of Health      K08 CA090468      8/03-7/09  
“Therapeutic Inhibition of FAP”  
Principal Investigator  
Direct Costs: \$580,000

Commonwealth Universal Research Enhancement      5/04-4/05  
“Inhibition of FAP by Boronic Acid Compounds”  
Principal Investigator  
Direct Costs: \$100,000

National Cancer institute      R21 CA103991      6/04-5/07  
“Therapeutic Inhibition of FAP in Colorectal Cancer”  
Principal Investigator  
Direct Costs: \$200,000

Department of Defense      BC032784      8/04-7/05  
“Radioimmunotherapeutic Targeting of Breast Cancer Stroma”  
Principal Investigator  
Direct Costs: \$75,000

National Cancer institute      R21 CA122301      4/07-3/09  
“Clinical Inhibition of the Stromal Target Fibroblast Activation Protein”  
Principal Investigator  
Direct Costs: \$220,000

Ewing Foundation      6/07-5/08  
“Optimizing Therapeutics for Clinical Inhibition of FAP”  
Principal Investigator  
Direct Costs: \$60,000

Hirshberg Foundation for Pancreatic Cancer Research      11/08-11/09  
“Tumor Stromal Fibroblasts as a Therapeutic Target”  
Principal Investigator  
Direct Costs: \$40,000

**OTHER RESEARCH SUPPORT**

Telik Corporation                    10/02-3/08  
 “Small molecule inhibitor of FAP”  
 Principal Investigator  
 Direct Costs: \$120,000

RFAC Foundation                    6/03-6/09  
 “Developing novel head/neck cancer treatments”  
 Principal Investigator  
 Direct Costs: \$150,000

Herbert Donsky Fund                10/03-10/08  
 “Novel stromal treatments”  
 Principal Investigator  
 Direct Costs: \$18,000

Domantis Ltd                        1/05-7/08  
 “Inhibitory domain antibodies targeting FAP”  
 Principal Investigator  
 Direct Costs: \$132,000

Point Therapeutics Inc              4/05-3/08  
 “Biologic Effects of PT100 and PT630”  
 Principal Investigator  
 Direct Costs: \$243,000

Arisaph Pharmaceuticals, Inc 5/06-12/09  
 “Preclinical development of prodrugs in solid tumors”  
 Principal Investigator  
 Direct Costs: \$343,000

Ferring Pharmaceuticals            9/06-8/07  
 “Preclinical investigation of FAP Inhibition”  
 Principal Investigator  
 Direct Costs: \$32,000

**TRAINEES**

Behrang Emami	Medical Student	2001
Melissa Catlin	Pre-med Student	2002-2003
Patricia Jann	Medical Student	2003-2004

Michael Seidman	Medicine Resident	2004
Leonard Henry	Surgical Fellow	2004-2005
Kalyani Narra	Medical Resident	2004-2007
Hillary Maitland	Medical Student	2005-2005
Eliezer Oberstein	Medical Student	2005-2005
Oluwamayowa Azeez	High School Student	2005-2006
Kelly Perlewitz	Medicine Resident	2005-2006
David Heimann	Surgical Fellow	2006-2007
Marson Davidson	Surgical Fellow	2006-2007
Hyung-Ok Lee	Postdoctoral Fellow	2004-2009
Stefanie R. Mullins	Postdoctoral Fellow	2006-2009
Jiping Zhang	Postdoctoral Fellow	2006-2009
Susanna Concilio	High School Student	2007-2009
Stephen Weitzner	High School Student	2008-2009

### **MANUSCRIPTS — Original Research**

1. Cheng JD, Werness B, Babb JS, and Meropol NJ. Paradoxical correlations of cyclin-dependent kinase inhibitors p21<sup>waf1/cip1</sup> and p27<sup>kip1</sup> in metastatic colorectal carcinomas. *Clin Cancer Res.* 1999;5:1057-1062.
2. Cheng JD, Hitt J, Koczwara B, Schulman KA, Burnett C, Gaskin D, Rowland J, and Meropol NJ. Impact of quality of life on patient expectations regarding phase I clinical trials. *J Clin Oncol.* 2000;18:421-428.
3. Cheng JD, Dunbrack RL, Vilianou M, Rogatko A, Alpaugh RK, and Weiner LM. Promotion of tumor Growth by murine fibroblast activation protein (FAP), a serine protease, in an Animal Model. *Cancer Res* 62:4767-4772, 2002
4. Cheng JD, Langer C, Aamdal S, Robert F, Engelhardt LR, Fernberg O, Schiller J, Forsberg G, Alpaugh RK, Weiner LM, Babb JS, and André Rogatko A.

- Individualized patient dosing in phase I clinical trials: The role of EWOC in PNU-214936. *J Clin Oncol.* 22:602-609, 2004.
5. Schnoll RA, Rothman RL, Lerman C, Miller SM, Newman H, Movsas B, Sherman E, Ridge JA, Unger M, Langer C, Goldberg M, Scott W, and Cheng J. Comparing cancer patients who enroll in a smoking cessation program at a comprehensive cancer Center with those who decline enrollment. *Head Neck* 26:278-286, 2004.
  6. Schnoll RA, Rothman RL, Newman H, Lerman C, Miller SM, Movsas B, Sherman E, Ridge JA, Unger M, Langer C, Goldberg M, Scott W, and Cheng J. Characteristics of cancer patients entering a smoking cessation program and correlates of quit motivation. *Psychooncology* 13:346-358, 2004.
  7. Cheng JD, Valianou M, Canutescu AA, Jaffe EK, Lee H, Wang H, Lai JH, Bachovchin WW, and Weiner LM. Abrogation of Fibroblast Activation Protein Enzymatic Activity Attenuates Tumor Growth. *Mol Cancer Ther* 4:351-360, 2005
  8. Kramer NM, Horwitz EM, Cheng J, Ridge JA, Feigenberg SJ, Cohen RB, Nicolaou N, Sherman EJ, Babb JS, Damsker JA, and Langer CJ. Toxicity and outcome analysis of patients with recurrent head and neck cancer treated with hyperfractionated split-course reirradiation and concurrent cisplatin and paclitaxel chemotherapy from two prospective phase I and II studies. *Head Neck* 27:406-414, 2005.
  9. Ang KK, Harris J, Garden AS, Trotti A, Jones CU, Carrascosa L, Cheng JD, Spencer SS, Forastiere A, and Weber RS. Concomitant Boost Radiation plus Concurrent Cisplatin for Advanced Head and Neck Carcinomas: A Phase II Trial of the Radiation Therapy Oncology Group (RTOG 99-14). *J Clin Oncol* 23:3008-3015, 2005.
  10. Berger AC, Farma J, Scott WJ, Freedman G, Weiner L, Cheng JD, Wang H, and Goldberg M. Complete Response to Neoadjuvant Chemoradiotherapy in Esophageal Carcinoma Is Associated With Significantly Improved Survival. *J Clin Oncol* 23:4330-4337, 2005.
  11. Pedri H, Wang H, Babb J, Miller SM, Movsas B, Sherman E, Ridge JA, Unger M, Langer C, Goldberg M, Scott W, and Cheng J. A Randomized Pilot Study of Cognitive-Behavioral Therapy Versus Basic Health Education for Smoking Cessation Among Cancer Patients. *Ann Behav Med* 30:1-11, 2005.
  12. Kanski A, Hoffman J, Sigurdson E, Haluszka O, Engstrom P, Cheng JD, Cohen SJ, Watson JC, Eisenberg D, McGarrity E, Freedman G, and Meropol NJ. Can

- Molecular Imaging Predict Response to Pre-operative Chemoradiation in Patients with Rectal Cancer? A Fox Chase Cancer Center Prospective Experience. *Semin Oncol* 32:S63-67, 2005
13. Berger AC, Scott WJ, Freedman G, Konski A, Weiner L, Cheng JD, and Goldberg M. Morbidity and mortality are not increased after induction chemoradiotherapy followed by esophagectomy in patients with esophageal cancer. *Semin Oncol*. 32:S16-20, 2005
  14. Henry LH, Goldberg M, Scott W, Konski A, Meropol NJ, Freedman G, Weiner L, Watts P, Beard M, McLaughlin S, and Cheng JD. Induction cisplatin and paclitaxel followed by combination chemoradiotherapy with 5-fluorouracil, cisplatin, and paclitaxel before resection in localized esophageal cancer- a phase II report. *Ann Surg Oncol* 13:214-220, 2006.
  15. Chen H, Cheng JD, Wang SJ, Zhuang M, and Wang WR. Expression and significance of FAP in gastric carcinoma. *Chin J Gen Surg* 21:452-453, 2006.
  16. Cohen SJ, Alpaugh RK, Gross S, O'Hara SM, Smirnov DA, Terstappen LW, Allard WJ, Bilbee M, Cheng JD, Hoffman JP, Lewis NL, Pellegrino A, Rogatko A, Sigurdson E, Wang H, Watson JC, Weiner LM, and Meropol NJ. Isolation and Characterization of Circulating Tumor Cells in Patients with Metastatic Colorectal Cancer. *Clin Colorectal Cancer* 6:125-132, 2006.
  17. Henry LR, Sigurdson E, Ross EA, Lee JS, Watson JC, Cheng JD, Freedman GM, Konski A, and Hoffman JP. Resection of isolated pelvic recurrences after colorectal surgery: Long-term results and predictors of improved clinical outcome. *Ann Surg Oncol* 14:1081-1091, 2007.
  18. Henry LR, Lee HO, Lee JS, Klein-Szanto A, Watts P, Ross EA, Chen WT, and Cheng JD. Clinical implications of fibroblast activation protein (FAP) in patients with colon cancer. *Clin Cancer Res* 2007 13: 1736-1741, 2007.
  19. Freedman GM, Meropol NJ, Sigurdson ER, Hoffman J, Callahan E, Price R, Cheng J, Cohen S, Lewis N, Watkins-Bruner D, Rogatko A, and Konski A. Phase I trial of preoperative hypofractionated intensity modulated radiation therapy (IMRT) with incorporated boost and oral capecitabine in locally advanced rectal cancer. *Int J Radiat Oncol Biol Phys* 67:1389-1393, 2007.
  20. Maes MB, Dubois V, Brandt I, Lambeir AM, VanderVeken P, Augustyns K, Cheng JD, Chen X, Scharpe S, and DeMeester I. Dipeptidyl peptidase 8/9 like activity in human leukocytes. *J Leuk Biol* 81:1252-1257, 2007.

21. Lai KS, Ho NH, Cheng JD, and Tung CH. Selective fluorescence probes for dipeptidyl peptidase activity – fibroblast activation protein and dipeptidyl peptidase IV. *Bioconjug Chem* 18:1246-1250, 2007.
22. Konski AA, Cheng JD, Goldberg M, Li T, Maurer A, Yu JQ, Haluszka O, Scott W, Meropol NJ, Cohen SJ, Freedman G, and Weiner LM. Correlation of molecular response as measured by 18-FDG-PET with outcome after chemoradiation in patients with esophageal carcinoma. *Int J Radiat Oncol Biol Phys* 69:358-363, 2007.
23. Narra K, Mullins SR, Lee HO, Strzemkowski-Brun B, Magalong K, Christiansen VJ, McKee PA, Egleston B, Cohen SJ, Weiner LM, Meropol NJ, and Cheng JD. Phase II Trial of Single Agent Val-boroPro (Talabostat) Inhibiting Fibroblast Activation Protein in Patients with Metastatic Colorectal Cancer. *Cancer Biol Ther* 6:1-9, 2007.
24. Cohen SJ, Alpaugh RK, Palazzo I, Meropol NJ, Rogatko A, Xu Z, Hoffman JP, Weiner LM, and Cheng JD. Fibroblast activation protein and its relationship to clinical outcome in pancreatic adenocarcinoma. *Pancreas* 37:154-158, 2008.
25. von Mehren M, Schilder RJ, Cheng JD, Temmer E, Cardoso TM, Renshaw FG, Bayever E, Zannikos P, Yuan Z, and Cohen RB. A phase I study of the safety and pharmacokinetics of trabectedin in combination with pegylated liposomal doxorubicin in patients with advanced malignancies. *Ann Oncol* 19:1802-1809, 2008.
26. Lo PC, Chen J, Stefflova K, Warren M, Navab R, Bandarchi B, Mullins S, Tsao MS, Cheng JD, and Zheng G. Photodynamic molecular beacon triggered by fibroblast activation protein on cancer-associated fibroblasts for diagnosis and treatment of epithelial cancers. *J Med Chem* 52:358-368, 2009.
27. Haley M, Kanski A, Li T, Cheng JD, Maurer A, Haluszka O, Scott W, Meropol NJ, Cohen SJ, and Freedman G. The influence of diabetes on interpretation of PET scans in patients with esophageal cancer. *Gastrointest Cancer Res* 3:149-152, 2009.
28. Cohen RB, Jones SJ, Aggarwal C, von Mehren M, Cheng J, Spigel DR, Greco FA, Mariani M, Rocchetti M, Ceruti R, Comis S, Laffranchi B, Moll J, Burris HA. Phase I Dose-Escalation Study of Danusertib PHA-739358 Administered as 24-hour Infusion With & Without GCSF in a 14-day Cycle in Patients with Advanced Solid Tumors. *Clin Cancer Res* 15:6694-6701, 2009.
29. Zhang J, Valianou M, and Cheng JD. Identification and characterization of the promoter of fibroblast activation protein. *Front Biosci* 2:1154-1163, 2010.

30. Sipes NS, Feng YX, Guo FK, Lee HO, Chou FS, Cheng J, Mulloy J, Zheng Y. Cdc42 Regulates Extracellular Matrix Remodeling in Three Dimensions. *Journal of Biological Chemistry*. 286:36469-77, 2011.
31. Astsaturon IA, Meropol NJ, Alpaugh RK, Burtneess BA, Cheng JD, McLaughlin S, Rogatko A, Xu Z, Watson JC, Weiner LM, Cohen SJ. Phase II and coagulation cascade biomarker study of bevacizumab with or without docetaxel in patients with previously treated metastatic pancreatic adenocarcinoma. *Am J Clin Oncol*. 34:70-75, 2011
32. Lee HO, Mullins SR, Franco-Barraza J, Valianou M, Cukierman E, and Cheng JD. FAP-overexpressing fibroblasts produce an extracellular matrix that enhances invasive velocity and directional of pancreatic cancer cells. *BMC Cancer* 11:245-257, 2011
33. Astsaturon IA, Meropol NJ, Alpaugh RK, Burtneess BA, Cheng JD, McLaughlin S, Rogatko A, Xu Z, Watson JC, Weiner LM, Cohen SJ. Phase II and coagulation cascade biomarker study of bevacizumab with or without docetaxel in patients with previously treated metastatic pancreatic adenocarcinoma. *Am J Clin Oncol* 34:70-75, 2011.
34. Lee HO, Silva AS, Concilio S, Li YS, Slifker M, Gatenby R, and Cheng JD. Mathematical modeling of the adaptive tumor microenvironment landscape. *Cancer Res* 71:6327-37, 2011.
35. Sharma NK, Silverman JS, Li T, Cheng J, Yu JQ, Haluszka O, Scott W, Meropol NJ, Cohen SJ, Freedman GM, Kanski AA. Decreased Posttreatment SUV on PET Scan Is Associated With Improved Local Control in Medically Inoperable Esophageal Cancer. *Gastrointest Cancer Res* 4:84-9, 2011.
36. Ryabtsova O, Jansen K, Van Goethem S, Joossens J, Cheng JD, Lambeir AM, De Meester I, Augustyns K, Van der Veken P. Acylated Gly-(2-cyano)pyrrolidines as inhibitors of fibroblast activation protein (FAP) and the issue of FAP/prolyl oligopeptidase (PREP)-selectivity. *Bioorg Med Chem Lett* 22:3412-3417, 2012.
37. Li J, Chen K, Liu H, Cheng K, Yang M, Zhang J, Cheng JD, Zhang Y, Cheng Z. Activatable near-infrared fluorescent probe for in vivo imaging of fibroblast activation protein- $\alpha$ . *Bioconjug Chem* 23:1704-1711, 2012
38. Kanski A, Li T, Christensen M, Cheng J, Yu JQ, Crawford K, Haluszka O, Tokar J, Scott W, Meropol NJ, Cohen SJ, Maurer A, and Freedman GM. Symptomatic cardiac toxicity is predicted by dosimetric and patient factors rather than changes

- in 18F-FDG PET determination of myocardial activity after chemoradiotherapy for esophageal cancer. *Radiother Oncol* 104:72-77, 2012.
39. Klayton T, Li T, Yu JQ, Cheng J, Cohen SJ, Meropol N, Scott W, Welliver MX, and Konski A. The role of qualitative and quantitative analysis of F18-FDG positron emission tomography in predicting pathologic response following chemoradiotherapy in patients with esophageal carcinoma. *J Gastrointest Canc* 43:612-618, 2012.
  40. Zhang J, Valianou M, Simmons H, Robinson MK, Lee HO, Marasco WA, Adams GP, Weiner LM, and Cheng JD. Identification of fibroblast activation protein inhibitory antibodies utilizing phage display functional screens. *FASEB J* 27:581-589, 2012.
  41. Zhang W, Haines BB, Efferson C, Zhu J, Ware C, Kunii K, Tammam J, Angagaw M, Hinton MC, Keilhack H, Paweletz CP, Zhang T, Winter C, Sathyanarayanan S, Cheng J, Zawel L, Fawell S, Gilliland G and Majumder PK. Evidence of mTOR activation by an AKT-independent mechanism provides support for the combined treatment of PTEN-deficient prostate tumors with mTOR and AKT inhibitors. *Transl Oncol* 5:422-429, 2012.
  42. Van der Veken P, Fülöp V, Rea D, Gerard M, Van Elzen R, Joossens J, Cheng JD, Baekelandt V, De Meester I, Lambeir AM, and Augustyns K. P2-substituted N-acylprolylpyrrolidine inhibitors of prolyl oligopeptidase: biochemical evaluation, binding mode determination, and assessment in a cellular model of synucleinopathy. *J Med Chem.* 55:9856-9867, 2012.
  43. Ryabtsova O, Jansen K, Van Goethem S, Joossens J, Cheng JD, Lambeir AM, De Meester I, Augustyns K, and Van der Veken P. Acylated Gly-(2-cyano)pyrrolidines as inhibitors of fibroblast activation protein (FAP) and the issue of FAP/prolyl oligopeptidase (PREP)-selectivity. *Bioorg Med Chem Lett.* 22:3412-3417, 2012.
  44. Jansen K, Heirbaut L, Cheng JD, Joossens J, Ryabtsova O, Cos P, Maes L, Lambeir AM, De Meester I, Augustyns K, Van der Veken P. Selective Inhibitors of Fibroblast Activation Protein (FAP) with a (4-Quinolinoyl)-glycyl-2-cyanopyrrolidine Scaffold. *Acs Medicinal Chemistry Letters.* 4:491-496, 2013.
  45. Tait LM, Meyer JE, McSpadden E, Cheng JD, Baciewicz FA, Meropol NJ, Cohen SJ, Wozniak AJ, Choi M, Konski AA. Women at increased risk for cardiac toxicity following chemoradiation therapy for esophageal carcinoma. *Pract Radiat Oncol.* 2013 3:149-55, 2013.
  46. Denlinger CS, Meropol NJ, Li T, Lewis NL, Engstrom PF, Weiner LM, Cheng JD, Alpaugh RK, Cooper H, Wright JJ, Cohen SJ. A Phase II Trial of the



- Proteasome Inhibitor Bortezomib in Patients With Advanced Biliary Tract Cancers. *Clin Colorectal Cancer*. 13:81-86, 2014.
47. Jansen K, Heirbaut L, Verkerk R, Cheng JD, Joossens J, Cos P, Maes L, Lambeir AM, De Meester I, Augustyns K, Van der Veken P. Extended Structure-Activity Relationship and Pharmacokinetic Investigation of (4-Quinolinoyl)glycyl-2-cyanopyrrolidine Inhibitors of Fibroblast Activation Protein (FAP). *J Med Chem*. 57:3053-3074, 2014
  48. Brana I, Berger R, Golan T, Haluska P, Edenfield J, Fiorica J, Stephenson J, Martin LP, Westin S, Hanjani P, Jones MB, Almhanna K, Wenham RM, Sullivan DM, Dalton WS, Gunchenko A, Cheng JD, Siu LL, J E Gray JE. A parallel-arm phase I trial of the humanized anti-IGF-1R antibody dalotuzumab in combination with the AKT inhibitor MK-2206, the mTOR inhibitor ridaforolimus, or the NOTCH inhibitor MK-0752, in patients with advanced solid tumours. *Br J Cancer*. 111: 1932-1944, 2014.
  49. Marton MJ, McNamara AR, Nikoloff DM, Nakao A, Cheng J. Analytical Validation of AmpliChip p53 Research Test for Archival Human Ovarian FFPE Sections. *PLoS One*. 10(6), 2015.
  50. Oza AM, Pignata S, Poveda A, McCormack M, Clamp A, Schwartz B, Cheng J, Li X, Campbell K, Dodion P, Haluska FG. Randomized phase II trial of ridaforolimus in advanced endometrial carcinoma. *J Clin Oncol*. 33:3576-3582, 2015.
  51. Gupta S, Argiles G, Munster PN, Hollebecque A, Dajani O, Cheng J, Wang R, Swift A, Tosolini A, Piha-Paul SA. A Phase I Trial of Combined Ridaforolimus and MK-2206 in Patients with Advanced Malignancies. *Clin Cancer Res* 21:5235-5244, 2015.
  52. Piha-Paul SA, Munster PN, Hollebecque A, Argilés G, Dajani O, Cheng JD, Wang R, Swift A, Tosolini A, Gupta S. Results of a phase I trial combining ridaforolimus and MK-0752 in patients with advanced solid tumours. *Eur J Cancer* 51:1865-73, 2015.
  53. Heirbaut L, van Goethem S, Jansen K, de Winter H, Lamoen N, Joossens J, Cheng J, Chen X, Lambeir AM, de Meester I, Augustyns K and van der Veken P. Probing for improved selectivity with dipeptide derived inhibitors of dipeptidyl peptidases 8 and 9: the impact of P1-variation. *Med. Chem. Commun* 7:433-438, 2016.
  54. Nanda R, Chow LQM, Claire Dees E, Berger R, Gupta S, Geva R, Pusztai L, Pathiraja K, Aktan G, Cheng JD, Karantza V, and Buisseret L. Pembrolizumab in Patients With Advanced Triple-Negative Breast Cancer: Phase Ib KEYNOTE-012 Study. *J Clin Oncol*. 34:2460-2467, 2016.

55. Seiwert TY, Burtneß B, Mehra R, Weiss J, Berger R, Eder JP, Heath K, McClanahan T, Lunceford J, Gause C, Cheng JD, Chow LQ. Safety and clinical activity of pembrolizumab for treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-012): an open-label, multicentre, phase 1b trial. *Lancet Oncol.* 17:956-965, 2016.
56. Mehnert JM, Panda A, Zhong H, Hirshfield K, Damare S, Lane K, Sokol L, Stein MN, Rodriguez-Rodriguez L, Kaufman HL, Ali S, Ross JS, Pavlick DC, Bhanot G, White EP, DiPaola RS, Lovell A, Cheng J, Ganesan S. Immune activation and response to pembrolizumab in POLE-mutant endometrial cancer. *J Clin Invest.* 126:2334-2340, 2016
57. Chow LQ, Haddad R, Gupta S, Mahipal A, Mehra R, Tahara M, Berger R, Eder JP, Burtneß B, Lee SH, Keam B, Kang H, Muro K, Weiss J, Geva R, Lin CC, Chung HC, Meister A, Dolled-Filhart M, Pathiraja K, Cheng JD, Seiwert TY. Antitumor Activity of Pembrolizumab in Biomarker-Unselected Patients With Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma: Results From the Phase Ib KEYNOTE-012 Expansion Cohort. *J Clin Oncol.* 34:3838-3845, 2016
58. Boland PM, Meyer JE, Berger AC, Cohen SJ, Neuman T, Cooper HS, Olszanski AJ, Davey M, Cheng JD, Lebenthal A, Burtneß BA, Scott WJ, Astsaturov IA. Induction Therapy for Locally Advanced, Resectable Esophagogastric Cancer: A Phase I Trial of Vandetanib (ZD6474), Paclitaxel, Carboplatin, 5-Fluorouracil, and Radiotherapy Followed by Resection. *Am J Clin Oncol.* 40:393-398, 2017.
59. Bauml J, Seiwert TY, Pfister DG, Worden F, Liu SV, Gilbert J, Saba NF, Weiss J, Wirth L, Sukari A, Kang H, Gibson MK, Massarelli E, Powell S, Meister A, Shu X, Cheng JD, and Haddad R. Pembrolizumab for Platinum- and Cetuximab-Refractory Head and Neck Cancer: Results From a Single-Arm, Phase II Study. *J Clin Oncol* 35:1542-1549, 2017.
60. Ayers M, Lunceford J, Nebozhyn M1, Murphy E, Loboda A, Kaufman DR, Albright A, Cheng JD, Kang SP, Shankaran V, Piha-Paul SA, Yearley J, Seiwert TY, Ribas A, McClanahan TK. IFN- $\gamma$ -related mRNA profile predicts clinical response to PD-1 blockade. *J Clin Invest.* 127:2930-2940, 2017.
61. Yearley JH, Gibson C, Yu N, Moon C, Murphy E, Juco J, Lunceford J, Cheng J, Chou LQM, Seiwert TY, Handa M, Tomassini JE, McClanahan T. PD-L2 expression in human tumors: relevance to anti-PD-1 therapy in cancer. *Clin. Cancer Res* 23:3158-3167, 2017.

62. Hsu C, Lee SH, Ejadi S, Even C, Cohen RB, Le Tourneau C, Mehnert JM, Algazi A, van Brummelen EMJ, Saraf S, Thanigaimani P, Cheng JD, Hansen AR. Safety and Antitumor Activity of Pembrolizumab in Patients With Programmed Death-Ligand 1–Positive Nasopharyngeal Carcinoma: Results of the KEYNOTE-028 Study. *J Clin Oncol* 35:4050-4056, 2017
63. Tahara M, Muro K, Hasegawa Y, Chung HC, Lin CC, Bhumsuk Keam, Takahashi K, Cheng JD, Bang YJ. Pembrolizumab in Asia-Pacific patients with advanced head and neck squamous cell carcinoma: analyses from KEYNOTE-012. *Cancer Sci* 109:771-776, 2018
64. Cohen RB, Delord JP, Doi T, Piha-Paul SA, Liu SV, Gilbert J, Algazi AP, Damian S, Hong RL, Le Tourneau C, Day D, Varga A, Elez E, Wallmark J, Saraf S, Thanigaimani P, Cheng J, Keam B. Pembrolizumab for the Treatment of Advanced Salivary Gland Carcinoma: Findings of the Phase 1b KEYNOTE-028 Study. *Am J Clin Oncol*. 2018 Feb 16 [Epub ahead of print]
65. Mehra R, Stewart T, Gupta S, Weiss J, Gluck I, Eder J, Burtness B, Tahara M, Keam B, Kang H, Muro K, Geva G, Chung HC, Lin CC, Aurora-Garg D, Ray A, Pathiraja K, Cheng J, Chow LQM, and Haddad RI. Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma: pooled analyses after long-term follow-up in KEYNOTE-012. *Br J Cancer* 119:153-159, 2018
66. Lala M, Chirovsky D, Cheng JD, Mayawala K. Clinical outcomes with therapies for previously treated recurrent/metastatic head-and-neck squamous cell carcinoma (R/M HNSCC): A systematic literature review. *Oral Oncology* 84: 108-120, 2018
67. Kim ST, Cristescu R, Bass AJ, Kim KM, Odegaard JI, Kim K, Liu XQ, Sher X, Jung H, Lee M, Lee S, Park SH, Park JO, Park YS, Lim HY, Lee H, Choi M, Talasaz A, Kang PS, Cheng J, Loboda A, Lee J, Kang WK. Comprehensive molecular characterization of clinical responses to PD-1 inhibition in metastatic gastric cancer. *Nat Med* 24:1449-1458, 2018
68. Cristescu R, Mogg R, Ayers M, Albright A, Murphy E, Yearley J, Sher X, Liu XQ, Lu H, Nebozhyn M, Zhang C, Lunceford JK, Joe A, Cheng J, Webber AL, Ibrahim N, Plimack ER, Ott PA, Seiwert TY, Ribas A, McClanahan TK, Tomassini JE, Loboda A, Kaufman D. Pan-tumor genomic biomarkers for PD-1 checkpoint blockade-based immunotherapy. *Science* 362:6411, 2018
69. Mehnert JM, Varga A, Brose MS, Aggarwal RR, Lin CC, Prawira A, de Braud F, Tamura K, Doi T, Piha-Paul SA, Gilbert J, Saraf S, Thanigaimani P, Cheng JD, Keam B. Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab

- in patients with advanced, PD-L1-positive papillary or follicular thyroid cancer. *BMC Cancer* 19:196, 2019.
70. Ayers M, Nebozhyn M, Cristescu R, McClanahan TK, Perini R, Rubin E, Cheng JD, Kaufman DR, Loboda A. Molecular Profiling of Cohorts of Tumor Samples to Guide Clinical Development of Pembrolizumab as Monotherapy. *Clin Cancer Res* 25:1564-1573, 2019.
  71. Cohen EEW, Soulières D, Le Tourneau C, Dinis J, Licitra L, Ahn MJ, Soria A, Machiels JP, Mach N, Mehra R, Burtness B, Zhang P, Cheng J, Swaby RF, Harrington KJ Pembrolizumab versus methotrexate, docetaxel, or cetuximab for recurrent or metastatic head-and-neck squamous cell carcinoma (KEYNOTE-040): a randomised, open-label, phase 3 study. *Lancet* 393:156-167, 2019.
  72. Burtness B, Harrington KJ, Greil R, Soulières D, Tahara M, de Castro G Jr, Psyrri A, Basté N, Neupane P, Bratland Å, Fueeder T, Hughes BGM, Mesía R, Ngamphaiboon N, Rordorf T, Wan Ishak WZ, Hong RL, González Mendoza R, Roy A, Zhang Y, Gumuscu B, Cheng JD, Jin F, Rischin D. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *Lancet* 394:1915-1928, 2019

### **MANUSCRIPTS — Invited Editorials/Reviews**

1. Cheng JD. Rising CEA...What Does It Mean? *Prim Care Cancer*. 1999;19(9):31-33.
2. Cheng JD, Rieger PT, von Mehren M, Adams GP, and Weiner LM. Recent Advances in Immunotherapy and Monoclonal Antibody Treatment of Cancer. *Sem Oncol Nurs*. 2000;16(4):2-12.
3. Cheng JD and Weiner LM. Tumors and Their Microenvironments: Tilling the Soil. *Clin Cancer Res* 9:1639-1647, 2003.
4. Albert K and Cheng JD. New Journal Review: Journal of the National Comprehensive Cancer Network. *JAMA* 293:1144-1145, 2005
5. Tetzlaff ED, Cheng JD, and Ajani JA. Review of docetaxel in the treatment of gastric cancer. *Ther Clin Risk Manag* 5:999-1007, 2008.
6. Tetzlaff ED, Cheng JD, and Ajani JA. Thromboembolism in gastrointestinal cancers. *Gastrointest Cancer Res* 6:267-272, 2008.

### **BOOK CHAPTERS**

1. Cheng JD, Compton CC, and Meropol NJ. Uncommon cancers of the esophagus. In: Textbook of Uncommon Cancers, 2nd Ed. Raghavan D, Brecher ML, Johnson DH, Meropol NJ, Thigpen JT, eds. John Wiley and Sons, Sussex, England 1999:377-388.
2. Cheng JD, Compton CC, and Meropol NJ. Uncommon cancers of the stomach. In: Textbook of Uncommon Cancers, 2nd Ed. Raghavan D, Brecher ML, Johnson DH, Meropol NJ, Thigpen JT, eds. John Wiley and Sons, Sussex, England 1999:389-403.
3. Cheng JD. Gastrointestinal cancers. In: The Cancer Protocol Guide. Weiner LM ed. Lippincott Williams & Wilkins 2000:33-43.
4. Cheng JD, Adams GP, Robinson MK, and Weiner LM. Monoclonal antibodies. In: Cancer: Principles and Practice of Oncology, 7<sup>th</sup> Ed. DeVita VT, Hellman S, Rosenberg SA, eds. Lippincott Williams & Wilkins 2005: 445-456.

## **ABSTRACTS**

1. Cheng JD, Hitt J, Koczwara B, Schulman KA, Burnett C, Gaskin D, Rowland J, and Meropol NJ. Impact of health stock on treatment valuations by patients considering early phase clinical trials. Proc Am Soc Clin Oncol 1998;17:A191.
2. Alpaugh K, Schultz J, Cheng J, von Mehren M, Kopreski M, Weiner L, Goldstein L, and Langer C. Staphylococcal enterotoxin A-Fab fusion protein treatment-associated toxicities can be blunted by a mutation in the SEA MHC class II binding domain. Proc Am Assoc Cancer Res 1999;40:A1203.
3. Cheng JD, Knox SJ, Tempero M, Weiden PL, Horak ID, Gentner L, Bryan K, Gaffigan S, Shaller C, Adams GP, and Weiner LM. Phase II trial of NR-LU-10 pretargeted delivery of <sup>90</sup>yttrium in patients with metastatic colon cancer. Proc Am Soc Clin Oncol 1999;18:A1679.
4. VonMehren M, Davey M, Rivera V, Yeslow G, Gillon T, Alpaugh K, Cheng J, Meropol N, Rosvold E, Scher R, Cooper H, Schlom J, and Weiner LM. Phase I trial with ALVAC-CEA B7.1 immunization in advanced CEA-expressing adenocarcinomas. Proc Am Soc Clin Oncol 1999;18:A1686.
5. Khwaja R, Langer C, Padavic K, Keenan E, Obasaju C, Cheng J, Ridge J, and Ozols R. Phase II evaluation of weekly cisplatin and gemcitabine in the treatment of incurable squamous cell carcinoma of the head and neck. Proc Am Soc Clin Oncol 2000;19:A1690.

6. Szarka CE, Babb J, Cheng JD, Meropol NJ, Weiner LM, Engstrom PF, Rogatko A, Lewis NL, Adams A, Gallo JM, Lenaz L, and Sun S-L. Phase I study of rubitecan and gemcitabine in patients with unresectable pancreas cancer. Proc Am Soc Clin Oncol 2001;20:A2289.
7. Cheng JD, Simmons H, Horak E, Dunbrack R, Valianou M, Alpaugh RK, and Weiner LM. Generation of antibodies targeting murine fibroblast activation protein (FAP), a tumor stromal fibroblast protease. Proc Am Assoc Cancer Res 2001;42:A5094.
8. Cheng JD, Valianou M, Nakajima P, Renner K, Rogatko A, Alpaugh RK, and Weiner LM. Promotion of Tumor Growth by Murine Fibroblast Activation Protein (FAP), a Serine Protease. Proc Am Assoc Cancer Res 2002;43:A5624
9. Ang KK, Harris J, Garden A, Jones C, Trotti A, Cheng J, Spencer S, and Weber R: Concomitant Boost Radiation and Concurrent Cisplatin for Advanced Head and Neck Carcinomas: Preliminary Results of a Phase II Trial of the RTOG (99-14). Proc Am Soc Thera Rad Oncol (ASTRO), Int J Radiat Oncol Biol Phys, 54(2):71, 2002.
10. Cheng JD, Valianou M, Simmons S, Jann P, Yuan QA, Russeva MG, Marasco W, Cukierman E, Adams GP, and Weiner LM. Abrogation of Fibroblast Activation Protein Enzymatic Activity Attenuates Tumor Growth Proc Am Assoc Cancer Res 45:A377, 2004.
11. Schnoll RA, Rothman RL, Miller SM, Lerman C, Ridge JR, Movsas B, Sherman EJ, Unger M, Langer C, Goldberg M, Scott W, and Cheng J. Characteristics of cancer patients entering a smoking cessation program and correlates of quit motivation. Poster presented at the annual meeting of the Society for Research on Nicotine and Tobacco, New Orleans, LA, February 2003.
12. Schnoll RA, Rothman RL, Lerman C, Miller SM, Ridge JR, Movsas B, Sherman EJ, Unger M, Langer C, Goldberg M, Scott W, and Cheng J. A smoking cessation program for cancer patients: Comparing enrollees to decliners. Poster presented at the annual meeting of the Society for Research on Nicotine and Tobacco, New Orleans, LA, February 2003.
13. Kramer NM, Horwitz EM, Cheng J, Babb JS, Ridge JA, Nicolaou N, Damsker JA, and Langer CJ. Toxicity and outcome analysis of patients with recurrent head and neck cancer treated with hyperfractionated split-course re-irradiation and concurrent cisplatin and paclitaxel chemotherapy from two prospective phase I and II studies. Oral presentation 89th Scientific Assembly and Annual Meeting of the Radiological Society of North America Chicago, IL, 12/1/03.

14. von Mehren M, Schilder RJ, Cheng J, Lee JW, Cardoso T, Trifan OC, Wei X, Sternas LA, and Cohen RB. Trabectedin in Combination with Pegylated Liposomal Doxorubicin (PLD) is a well-tolerated regimen with good dose intensity in patients with advanced malignancies. Proc ESMO 2004.
15. Cohen SJ, Alpaugh RK, Allard J, Cheng JD, Gross ST, Lewis NL, Rogatko A, Sigurdson E, Weiner LM, and Meropol NJ. Isolation and characterization of circulating tumor cells in patients with colorectal cancer. Proc Am Soc Clin Oncol 22:A1186, 2003
16. Cohen SJ, Palazzo I, Meropol NJ, Rogatko A, Weiner LM, Golemis EA, Cheng JD, and Alpaugh RK Fibroblast activation protein and focal adhesion kinase: Novel stromal therapeutic targets in pancreatic adenocarcinoma. Proc Am Soc Clin Oncol 23:A4094, 2004
17. Cheng JD, Jann P, Seidman M, Valianou M, Lee HO., Amatangelo MD, Bachovchin WW, Weiner LM, and Cukierman E. Fibroblast Activation Protein Overexpression Confers an Enhanced Adherence and Motility Phenotype. Proc Am Assoc Cancer Res 46:A5636, 2005.
18. Cohen RB, Schilder RJ, Cheng J, Lee JW, Cardoso T, Trifan O, Ding L, and von Mehren M. Final results of a combination study between trabectedin and pegylated liposomal doxorubicin (PLD) in patients with advanced malignancies. Proc Am Soc Clin Oncol 24:A3074, 2005.
19. Henry LR, Lee JS, Kein-Szanto A, Chen WT, Renner C, Watts P, Ross E, and Cheng JD The expression of Fibroblast Activation Protein in human colon carcinoma. Proc Am Soc Clin Oncol 24:A9668, 2005
20. Garden AS, Harris J, Jones CU, Trotti A, Carrascoca L, Cheng J, Spencer SA, Weber RS, and Ang KK. Concomitant Boost Radiation and Concurrent Cisplatin for Advanced Head and Neck Carcinomas: Update of a Phase II Trial of the RTOG (99-14). Proc Am Soc Thera Rad Oncol (ASTRO), Int J Radiat Oncol Biol Phys, 63(Suppl1), S71-72, 2005.
21. Konski A, Sigurdson E, Maurere A, Hoffman J, Haluszka O, Cheng J, Cohen SJ, Engstrom P, Watson J, Tokar J, Freedman G, and Meropol NJ. Negative Post-treatment 18-FDG PET scans may not predict pathologic complete response in patients with rectal cancer undergoing neoadjuvant chemoradiation. Radiother Oncol. 78(Suppl1); S37, 2006.
22. Narra K, Lee HO, Lerro A, Valvardi J, Azeez O, Jesson M, Aziz N, Jones B, and Cheng JD. Inhibitors of the Stromal Protease Fibroblast Activation Protein Attenuate Tumor Growth in vivo Proc Am Assoc Cancer Res 47:A4382, 2006.

23. Lee HO, Narra K, Maitland H, Valianou M, Amatangelo M, Cukierman E, and Cheng JD. Overexpression of Fibroblast Activation Protein in Fibroblasts Confers an Enhanced Directional Motility in the 3D Matrix System Proc Am Assoc Cancer Res 47:A3294, 2006.
24. Cheng JD, Cohen SJ, Stzempkowski-Brun B, Magalong K, Christiansen VJ, McKee PA, Alpaugh RK, Lee H, Weiner LM, and Meropol NJ. Phase II pharmacodynamic study of the fibroblast activation protein inhibitor Val-boro-Pro in patients with metastatic colorectal cancer. Proc Am Soc Clin Oncol 24:A3594, 2006.
25. Astsaturov IA, Meropol NJ, Alpaugh RK, Cheng JD, Lewis NL, Beard M, Rogatko A, Xu Z, Weiner LM, and Cohen SJ. A randomized phase II and coagulation study of bevacizumab alone or with docetaxel in patients with previously treated metastatic pancreatic adenocarcinoma. Proc Am Soc Clin Oncol 25:A4556, 2007.
26. Cheng JD. FAP and dipeptidyl peptidases as drug targets in oncology. Clin Chem Lab Med 46:A15, 2008.
27. Cohen RB, Jones SF, von Mehren M, Cheng J, Spiegel DM, Laffranchi B, Mariani M, Spinelli R, Magazzu D, and Burris HA III. Phase I study of the pan aurora kinases inhibitor PHA-739358 administered as a 24 hour infusion with or without G-CSF in a 14-day cycle in patients with advanced solid tumors. Proc Am Soc Clin Oncol 26:A2520, 2008.
28. Kanski AK, Yu JQ, Cheng J, Scott W, Cohen SJ, Lewis N, and Burtness B, Meropol NJ. Post-treatment 18-FDG PET scans in esophageal cancer patients receiving combination chemoradiation: Too much information? Proc Gastrointestinal Cancers Symposium A4, 2008.
29. Cheng JD, Lee H, Mullins S, Zhang J, Cukierman E, Cohen S, Egleston B, Liu Y, Lai J, and Bachovchin W. Fibroblast activation protein promotes pancreas cancer tumor growth by remodeling the extracellular matrix leading to enhanced motility. Proc Gastrointestinal Cancers Symposium A178, 2008.
30. Lee HO, Concilio S, Slifker M, Li YS, Gatenby R, and Cheng J. Mathematical modeling of the adaptive tumor landscape. Proc Am Assoc Cancer Res 50:A316, 2009.
31. Davidson M, Heimann D, Lee HO, Zhang J, Mullins S, and Cheng JD. The importance of the in vivo tumor microenvironment in determining pancreatic cancer growth. Proc Am Assoc Cancer Res 50:A342, 2009.



32. Leijen S, Schellens JH, Shapiro G, Pavlick AC, Tibes R, Demuth T, Viscusi J, Cheng JD, Xu Y, Oza AM. A phase I pharmacological and pharmacodynamic study of MK-1775, a Wee1 tyrosine kinase inhibitor, in monotherapy and combination with gemcitabine, cisplatin, or carboplatin in patients with advanced solid tumors. *J Clin Oncol* 28:15s, 2010 (suppl; abstr 3067)
33. Cheng JD, Schellens JH, Shapiro GI, Pavlick AC, Tibes R, Oza AM, Xu Y, Song Y, Lam RLH, Demuth T. Pharmacodynamic evaluation of pCDC2 and Wee1 signature as biomarkers of target engagement for the Wee1 tyrosine kinase inhibitor MK-1775. *Proc EORTC-NCI-AACR International Symposium Molecular Targets and Cancer Therapeutics A651*, 2010.
34. Schellens JHM, Shapiro G, Pavlick AC, Tibes R, Leijen S, Tolaney SM, Diaz-Padilla I, Ramanathan RK, Demuth T, Viscusi J, Cheng JD, Lam R, Xu Y, Oza AM. Update on a phase I pharmacologic and pharmacodynamic study of MK-1775, a Wee1 tyrosine kinase inhibitor, in monotherapy and combination with gemcitabine, cisplatin, or carboplatin in patients with advanced solid tumors. *J Clin Oncol* 29: 3068, 2011
35. Oza AM, Poveda A, Clamp AR, Pignata S, Scambia G, Del Campo JM, McCormack M, Sevcik L, Schwartz BM, Guan S, Lee R, Cheng JD, Haluska FG. A randomized phase II (RP2) trial of ridaforolimus (R) compared with progestin (P) or chemotherapy (C) in female adult patients with advanced endometrial carcinoma. *J Clin Oncol* 29: 5009s, 2011
36. Haines BB, Wick MJ, Papadopoulos KP, Tolcher AW, Tammam JG, Chaney MF, Nebozhyn M, Zhang T, Ebbinghaus SW, Cheng JD, Zawel L, Sathyanarayanan S. Response biomarkers to IGF1R and mTOR inhibitor combination therapy in ovarian carcinoma. *Proc Am Assoc Cancer Res* 53:A1868, 2012.
37. Brana I, Gray JE, Haluska P, Berger R, Golan T, Jones ME, Gunchenko A, Cheng JD, Siu LL. Rational molecularly targeted combinations: A parallel-arm phase I trial of the humanized anti-IGF-1R antibody dalotuzumab (D) in combination with the allosteric AKT inhibitor MK-2206 or the gamma secretase inhibitor MK-0752, in patients with advanced solid tumors. *J Clin Oncol* 30, 2012 (suppl; abstr 3027).
38. Astsaturov IA, Meyer JE, Cheng JD, Olszanski AJ, Dushkin H, Berger AC, Davey M, Cohen SJ, Burtness B, Scott WJ. A phase I evaluation of vandetanib plus paclitaxel, carboplatin, 5-fluorouracil, and XRT induction therapy followed by surgery for previously untreated locally advanced cancer of the esophagus and GE junction. *J Clin Oncol* 30, 2012 (suppl 4; abstr 74).

39. Rose S, Cheng JD, Viscusi J, Iannone R, Schellens JHM, Leijen S, Shapiro G, Pavlick AC, Oza AM, Rosen LS, Tosolini A, Lam R, Demuth T. Pharmacodynamic evaluation of pCDC2 as the target engagement biomarker to assess activity of MK-1775 a Wee1 tyrosine kinase inhibitor. *J Clin Oncol* 30, 2012 (suppl; abstr e13598).
40. Seiwert TY, Burtneß B, Weiss J, Gluck I, Eder JP, Pai SI, Dolled-Filhart M, Emancipator K, Pathiraja K, Gause C, Iannone R, Brown B, Houp J, Cheng JD, Chow LQM. A phase Ib study of MK-3475 in patients with human papillomavirus (HPV)-associated and non-HPV-associated head and neck (H/N) cancer. *J Clin Oncol* 32:5s, 2014 (suppl; abstr 6011).
41. Piha-Paul SA, Munster PN, Hollebecque A, Argiles G, Dajani P, Cheng JD, Wang R, Swift AM, Tosolini A, Gupta S. Results of a phase I trial combining ridaforolimus (mTOR inhibitor) and MK-0752 (Notch inhibitor) in patients with advanced solid tumors. *J Clin Oncol* 32:5s, 2014 (suppl; abstr 2601).
42. Gupta S, Munster PN, Hollebecque A, Argiles G, Dajani O, Cheng JD, Swift AM, Tosolini A, Piha-Paul SA. Safety/efficacy of MK-8669 (ridaforolimus) plus MK-2206 (AKT inhibitor) in patients with advanced breast cancer with low RAS signature and PTEN deficient prostate cancer. *J Clin Oncol* 32:5s, 2014 (suppl; abstr 2509).
43. Muro K, Bang Y, Shankaran V, Geva R, Catenacci DVT, Gupta S, Eder JP, Berger R, Gonzalez EJ, Pulini J, Ray AB, Dolled-Filhart M, Emancipator K, Pathiraja K, Shu X, Koshiji MR, Cheng J, Chung HC. A phase Ib study of pembrolizumab (MK-3475) in patients with advanced gastric cancer. *Annals of Oncology* 25 (Supplement 5): v1-v41, LBA15, 2014.
44. Plimack ER, Gupta S, Bellmunt J, Berger R, Montgomery B, Gonzalez EJ, Pulini J, Dolled-Filhart M, Emancipator K, Pathiraja K, Gause C, Perini R, Cheng J, O'Donnell PH. A phase Ib study of pembrolizumab (MK-3475) in patients with advanced urothelial tract cancer. *Annals of Oncology* 25 (Supplement 5): v1-v41, LBA 23, 2014.
45. Chow LQ, Burtneß B, Weiss J, Berger R, Eder JP, Gonzalez EJ, Pulini J, Johnson J, Dolled-Filhart M, Emancipator K, Lunceford JK, Pathiraja K, Gause C, Cheng JD, Seiwert T. A phase Ib study of pembrolizumab (MK-3475) in patients with human papilloma virus (HPV) positive and negative head and neck cancer. *Annals of Oncology* 25 (Supplement 5): v1-v41, LBA31 2014.
46. Alley EW, Molife LR, Santoro A, Beckey K, Yuan S, Cheng JD, Piperdi B, Schellens JHM. Clinical safety and efficacy of pembrolizumab (MK-3475) in

- patients with malignant pleural mesothelioma: Preliminary results from KEYNOTE-028. Proc AACR Annual Meeting CT103, 2015.
47. Ayers MD, Nebozhyn M, Cristescu R, McClanahan TK, Hirsch HA, Cheng JD, Loboda A. Identification of additional cancers likely to respond to anti-PD-1 therapy (pembrolizumab): Evaluation of PD-L1 expression in a large molecular tumor profiling gene expression database. Proc AACR Annual Meeting A256, 2015.
  48. Bang YJ, Chung HC, Shankaran V, Geva R, Catenacci DVT, Gupta S, Eder JP, Berger R, Gonzalez EJ, Ray A, Dolled-Filhart M, Emancipator K, Pathiraja K, Lunceford JK, Cheng JD, Koshiji M, Muro K. Relationship between PD-L1 expression and clinical outcomes in patients with advanced gastric cancer treated with the anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) in KEYNOTE-012. J Clin Oncol 33, 2015 (suppl; abstr 4001).
  49. Shankaran V, Muro K, Bang YJ, Geva R, Catenacci DVT, Gupta S, Eder JP, Berger R, Loboda A, Albright A, Cristescu R, Murphy E, McClanahan T, Ayers M, Nebozhyn M, Lunceford JK, Koshiji M, Heath K, Cheng JD, Chung HC. Correlation of gene expression signatures and clinical outcomes in patients with advanced gastric cancer treated with pembrolizumab (MK-3475). J Clin Oncol 33, 2015 (suppl; abstr 3026).
  50. Ott PA, Fernandez MEE, Hiret S, Kim DW, Moss RA, Winser T, Yuan S, Cheng JD, Piperdi B, Mehnert JM. Pembrolizumab (MK-3475) in patients with extensive-stage small cell lung cancer: Preliminary safety and efficacy results from KEYNOTE-028. J Clin Oncol 33, 2015 (suppl; abstr 7502).
  51. O'Donnell PH, Plimack ER, Bellmunt J, Berger R, Montgomery RB, Heath K, Dolled-Filhart M, Pathiraja K, Gause CK, Cheng JD, Perini RF, Gupta S. Pembrolizumab (MK-3475) for advanced urothelial cancer: Results of a phase IB study. J Clin Oncol 33, 2015 (suppl 7; abstr 296).
  52. Seiwert TY, Burtress B, Weiss J, Eder JP, Yearley J, Murphy E, Nebozhyn M, McClanahan T, Ayers M, Lunceford JK, Mehra R, Heath K, Cheng JD, Chow LQ. Inflamed-phenotype gene expression signatures to predict benefit from the anti-PD-1 antibody pembrolizumab in PD-L1+ head and neck cancer patients. J Clin Oncol 33, 2015 (suppl; abstr 6017).
  53. Seiwert TY, Haddad RI, Gupta S, Mehra R, Tahara M, Berger R, Lee SH, Burtress B, Le DT, Heath K, Blum A, Dolled-Filhart M, Emancipator K, Pathiraja K, Cheng JD, Chow LQ. Antitumor activity and safety of pembrolizumab in patients with advanced squamous cell carcinoma of the head and neck: Preliminary results from KEYNOTE-012 expansion cohort. J Clin Oncol 33, 2015 (suppl; abstr LBA6008).

54. Varga A, Piha-Paul SA, Ott PA, Mehnert JM, Berton-Rigaud D, Johnson EA, Cheng JD, Yuan S, Rubin EH, Matei DE. Antitumor activity and safety of pembrolizumab in patients with PD-L1 positive advanced ovarian cancer: Interim results from a phase Ib study. *J Clin Oncol* 33, 2015 (suppl; abstr 5510).
55. Das L, Haraf D, Brisson R, McHugh M, Cheng J, Heath K, Villaflor V, Vokes EE, Weichselbaum RR, Seiwert TY. PD-1 inhibition with pembrolizumab and hypofractionated radiation therapy to progressing lesions in patients with head and neck cancer – assessment of local and systemic effects. *European J Cancer*. 51(S3):S105, 2015
56. Ayers M, Lunceford J, Nebozhyn M, Murphy E, Loboda A, Albright A, Cheng J, Kang SP, Ebbinghaus S, Yearley J, Shankaran V, Seiwert T, Ribas A, McClanahan T. Relationship between immune gene signatures and clinical response to PD-1 blockade with pembrolizumab (MK-3475) in patients with advanced solid tumors. *J ImmunoTherapy Cancer*.3(Suppl 2):P80, 2015
57. Mehnert JM, Panda A, Zhong H, Hirshfield K, Massar-Bourscheid E, Stiles K, Moss RA, Stein MN, Rodriguez L, Kaufman HL, Ali S, Bhanot G, White E, DiPaola RS, Lovell A, Cheng J, Ganesan S. Exceptional Response to PD-1 antibody treatment in a POLE-mutant endometrial cancer. *Mol Cancer Ther*. 14(12):PR05, 2015
58. Gupta S, O'Donnell PH, Plimack ER, Berger R, Montgomery B, Heath K, Dolled-Filhart M, Pathiraja K, Gause C, Cheng J, Perini R, Bellmunt J. A Phase 1b Study of Pembrolizumab (Pembro; MK-3475) for Advanced Urothelial Cancer. *Journal of Urology*. 04-01(193-4):e861-e862, 2015
59. Hsu C, Lee SH, Ejadi S, Even C, Cohen R, Le Tourneau C, Mehnert J, Algazi A, van Brummelen E, Yuan S, Thanigaimani P, Cheng J, Hansen A. Antitumor activity and safety of pembrolizumab in patients with PD-L1–positive nasopharyngeal carcinoma: interim results from a phase 1b study. *European J Cancer*. 51(Suppl 3):S558, 2015
60. Bang YJ, Chung CH, Shankaran V, Geva R, Catenacci D, Gupta S, Eder JP, Berger R, Pathiraja, Cheng J, Koshiji M, Chung HC, Muro K. Clinical outcomes and their correlation with gene expression in patients with advanced gastric cancer treated with pembrolizumab (MK-3475): KEYNOTE-012. *Ann Oncol* 26(Suppl 4):LBA-04, 2015
61. Kao HF, Hsu C, Huang HC, Wang C-W, Cheng J, Hong RL. Correlation between serum EBV DNA and clinical response to pembrolizumab in patients with

- advanced or metastatic nasopharyngeal carcinoma. *Ann Oncol* 26(Suppl 8):viii 6 Abs 17P, 2015
62. Kao HF, Hsu C, Huang HC, Cheng JD, Hong RL. Low neutrophil-to-lymphocyte ratio (NLR) may predict efficacy of pembrolizumab in patients with recurrent or metastatic nasopharyngeal carcinoma (NPC). *Ann Oncol* 26(Suppl 8):viii8 Abs 22P, 2015
  63. Mehra R, Seiwert TY, Mahipal A, Weiss J, Berger R, Eder JP, Burtness B, Tahara M, Keam B, Le DT, Muro K, Geva R, Chung HC, Lin CC, Meister A, Hille D, Cheng JD, Chow LQM, Haddad RI. Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC): Pooled analyses after long-term follow-up in KEYNOTE-012. *J Clin Oncol* 34, 2016 (suppl; abstr 6012)
  64. Chow LQM, Mehra R, Haddad RI, Mahipal A, Weiss J, Berger R, Eder JP, Burtness B, Tahara M, Keam B, Le DT, Muro K, Geva R, Chung HC, Lin CC, Ayers M, Aurora-Garg D, Lunceford JK, Cheng JD, Seiwert TY. Biomarkers and response to pembrolizumab (pembro) in recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC). *J Clin Oncol* 34, 2016 (suppl; abstr 6010)
  65. Bauml J, Seiwert TY, Pfister DG, Worden FP, Liu SV, Gilbert J, Saba NF, Weiss J, Wirth LJ, Sukari A, Kang H, Gibson MK, Massarelli E, Powell SF, Meister A, Shu X, Cheng JD, Haddad RI. Preliminary results from KEYNOTE-055: Pembrolizumab after platinum and cetuximab failure in head and neck squamous cell carcinoma (HNSCC). *J Clin Oncol* 34, 2016 (suppl; abstr 6011)
  66. Cohen RB, Delord JP, Doi T, Piha-Paul SA, Liu SV, Gilbert J, Algazi AP, Cresta S, Hong RL, Le Tourneau C, Day D, Varga A, Elez E, Wallmark JM, Saraf S, Morosky A, Cheng JD, Keam B. Preliminary results for the advanced salivary gland carcinoma cohort of the phase 1b KEYNOTE-028 study of pembrolizumab. *J Clin Oncol* 34, 2016 (suppl; abstr 6017).
  67. Mehnert JM, Varga A, Brose M, Aggarwal RR, Lin CC, Prawira A, de Braud F, Tamura K, Doi T, Piha-Paul SA, Gilbert J, Saraf S, Thanigaimani P, Cheng JD, Keam B. Pembrolizumab for advanced papillary or follicular thyroid cancer: preliminary results from the phase 1b KEYNOTE-028 study. *J Clin Oncol* 34, 2016 (suppl; abstr 6091)
  68. Haddad R, Seiwert T, Pfister DG, Worden F, Liu S, Gilbert J, Saba NF, Weiss J, Wirth L, Sukari A, Kang H, Gibson MK, Massarelli E, Powell S, Meister A, Shu X, Cheng J, Bauml J. Pembrolizumab after progression on platinum and

- cetuximab in head and neck squamous cell carcinoma (HNSCC): Results from KEYNOTE-055. *Ann Oncol.* 2016;27(s6):vi331.
69. Seiwert TY, Cristescu R, Mogg R, Ayers M, Albright A, Sher X, Liu XQ, Nebozhyn M, Zhang C, Lunceford J, Joe AK, Cheng J, Webber AL, Ibrahim N, Plimack ER, Ott PA, Ribas A, McClanahan TK, Loboda A, Kaufman D. Genomic biomarkers stratify response to PD-1 checkpoint blockade. ASCO SITC 2017
  70. Haddad R, Seiwert TY, Chow LQ, Gupta S, Weiss J, Gluck I, Eder JP, Burtress B, Tahara M, Keam B, Kang H, Muro K, Albright A, Huang L, Ayers M, Mogg R, Cristescu R, Cheng J, Mehra R. Genomic Determinants of Response to Pembrolizumab in Head and Neck Squamous Cell Carcinoma. *Journal of Clinical Oncology.* 2017;35(15s):6009.
  71. Cristescu R, Mogg R, Ayers M, Albright A, Murphy E, Yearley J, Sher X, Liu XQ, Nebozhyn M, Lunceford J, Joe A, Cheng J, Plimack ER, Ott PA, Seiwert T, McClanahan TK, Loboda A, Kaufman D. Mutational load (ML) and T cell inflamed microenvironment as predictors of response to pembrolizumab . *J Clin Oncol.* 2017;35(7S):1.
  72. Harrington K, Kong A, Mach N, Rordorf T, Corral J, Espeli V, Treichel S, Cheng J, Kim JJ, Chesney J. Early safety from phase 1b/3, multicenter, open-label, randomized trial of talimogene laherparepvec (T-VEC) + pembrolizumab (pembro) for recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN): MASTERKEY-232. *Ann Oncol.* 2017;28(Suppl 5):444.