

## **CURRICULUM VITAE**

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

**NAME:** Jonathan Dean Cheng

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Philadelphia, PA 19111  
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**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:**

2020-current Senior Vice President  
Head of Oncology Development  
Global Drug Development  
Bristol Myers Squibb  
Princeton, NJ

2018-2020 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/Approval Experience (Select)**

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. Approval: Pembrolizumab accelerated approval for patients with ipilimumab refractory metastatic melanoma (2014)
  - Safety adjudicator for immune related adverse events
4. U.S. Approval: 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 Approval: 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. Approval: 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. Approval: Pembrolizumab accelerated approval for patients with advanced cervical cancer with progression after 1 prior lines of therapy (2018, clinical lead)

8. U.S. Approval: 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 Approval: Lenvima approval for 1L treatment of patients with unresectable hepatocellular carcinoma (2018, oncology therapeutic area lead)
10. Global Approval: 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, Japan Approval: 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 Approval (Project Orbis): Pembrolizumab + lenvima approval in 2L endometrial cancer (2019, oncology therapeutic area lead, joint development committee chair with Eisai)
13. US Approval (Project Orbis, RTOR, Summary Review): Pembrolizumab approval in 1L MSI-H colorectal cancer (2020, oncology therapeutic area lead, approval 29 days from submission)
14. US Approval (Project Orbis, RTOR): Pembrolizumab approval in 2L relapsed/refractory Hodgkin's lymphoma (2020, oncology therapeutic area lead)
15. US Approval: Pembrolizumab approval in 1L unresectable/metastatic triple negative breast cancer (2020, oncology therapeutic area lead)

**Health Authority Experience (Select)**

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
21. FDA ODAC December 17, 2019
  - a. Olaparib maintenance in gBRCA mutated metastatic pancreas cancer
22. EMA oral explanation May 25, 2020
  - a. Olaparib maintenance in gBRCA mutated metastatic pancreas cancer
23. FDA ODAC Industry Representative 2019-current
  - a. ODAC of NDA for tazemetostat, by Epizyme. December 18, 2019

- b. ODAC of NDA for padeliporfin di-potassium, by STEBA and sBLA for ramucirumab, by Eli Lilly. February 26, 2020
- c. Peds ODAC of (1) SP 2577, by Salarius Pharmaceuticals (2) Marizomib, by Celgene (3) CD30.CAR-T, by Tessa (4) SNDX-5613, by Syndax. June 17-18, 2020
- d. ODAC of NDA for belantamab mafodotin by GSK. July 14, 2020
- e. ODAC of NDA for Remestemcel-L by Mesoblast. August 13, 2020
- f. Peds ODAC for the development of Pediatric PRO-CTCAE May 11, 2021 and RWE and RWD for regulatory use and safety assessment in pediatrics May 12, 2021.
- g. ODAC of NDA for Sintilimab by Innovent Biologics and Eli Lilly. February 10, 2022

### **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. Merck Late Stage Oncology Therapeutic Area Lead for select FDA submissions and approvals (2018-2020)
  - 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
  - sBLA of pembrolizumab in 1L MSI-H colorectal cancer (2020)
    - Project Orbis, RTOR, Assessment Aid
  - sBLA of pembrolizumab in 2L Hodgkin's lymphoma (2020)
    - Project Orbis, Assessment Aid
- 11. BMS Therapeutic Area Head of Oncology Clinical Development for select global approvals (2020-current)
  - sBLA of nivolumab and cabozantinib in 1L renal cell carcinoma US, EU, Japan (2021)
  - sBLA of nivolumab in 1L gastric cancer US, EU, Japan, China (2021)
  - sBLA of nivolumab and ipilimumab in 1L mesothelioma EU, China, Japan (2021)
  - sBLA of nivolumab and ipilimumab in 2L MSI-H colorectal cancer EU (2021)
  - sBLA of nivolumab in adjuvant esophageal/GE junction US, EU, Japan (2021)
  - sBLA of nivolumab in adjuvant bladder US (2021)

**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
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**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.

“The Evolving Landscape of Immunotherapy Combinations” Invited Speaker, Society for Immunotherapy of Cancer (SITC) Annual Meeting, Washington, DC. November 10, 2021.

“The Checkpoint Debate Is About to Get Real” Invited Panel Member, Endpoint News Webinar. January 27, 2022.

“Moonshot: The Latest in Cancer Research”. Invited Panel Member, Asian Pacific American Institute for Congressional Studies (APAICS) 2022 Health Summit, Virtual Broadcast Summit. February 16, 2022.

### **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.
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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.
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  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. Konski 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.

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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.
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33. Astsaturon IA, Meropol NJ, Alpaugh RK, Burtness 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.

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