# MARIO JAVIER PINEDA, MD/PhD

#### **CURRICULUM VITAE**

# Ironwood Cancer & Research Centers a division of Ironwood Physicians, PC

#### **EDUCATION**

June 1997 University of San Francisco, College of Arts and Sciences

B.S. Summa Cum Laude, Major: Biology, Minor: Biochemistry

March 2006 University of Washington, Program in Molecular and Cellular

Biology, PhD

June 2007 University of Washington, School of Medicine

MD

## **POST-DOCTORAL TRAINING**

June 2008 Los Angeles County & University of Southern California Medical Center

Residency in Obstetrics and Gynecology

June 2011 Los Angeles County & University of Southern California Medical Center

Gynecological Oncology Residency Program

June 2014 Northwestern Feinberg School of Medicine

Gynecological Oncology Fellowship Program

#### **Board Certification and Licensure**

April 2017 State of Arizona License
October 2008 State of California License
March 2011 State of Illinois License

December 2016 Diplomate, American Board of Obstetrics & Gynecology

June 2014 American Board of Obstetrics & Gynecology,

Gynecologic Oncology Written Examination, Pass

# PROFESSIONAL APPOINTMENTS

August 2017 Gynecological Oncologist

Ironwood Physicians, PC

Chandler, AZ

August 2014 - Department of Obstetrics and Gynecology

June 2017 Northwestern Medical Group

Chicago, IL

# **Honors and Awards**

1993-1997	Citibank Employee Foundation Scholar
1993-1997	University Scholar Fellowship, USF
1995	San Francisco State University Minority Research Scholar
1996-1997	Achievement Rewards for College Scientists
1997	Dean's Medal/Purse for Excellence in Science, USF
1997-2001	Medical Scientist Training Program Fellowship
2000	Angela Paez Service Award, UW School of Medicine
2001-2004	Poncin Scholarship
2004	Acres of Diamonds Award, Minority Research Training Fellowship, NIH
2004-2005	STD/AIDS Training Grant Fellowship
2008-2011	Nursing Choice Award for Excellence in Patient Care
2009-2011	Patient Advocacy, Resident Selection Award
2010-2011	Chief Resident, Obstetrics and Gynecology LAC+USC Medical Center
2011	The Daniel R. Mishell Jr. Excellence in Medical Student Education Award
2014-2015	Resident & Student Top Teaching Recognition, Northwestern Memorial Hospital
2016	Excellence in Teaching, Feinberg School of Medicine, Northwestern University
2016	Hospital Nora Cooney Marra Compassionate Care Award, The Woman's Board
	of Northwestern Memorial
	of Northwestern Memorial

# **SOCIETY MEMBERSHIPS**

 $American\ College\ of\ Obstetrics\ and\ Gynecology,\ Fellow$ 

Society of Gynecologic Oncologists, Candidate

ASCO, Full Member

# RECENT RESEARCH EXPERIENCE

2011-2012	Fellowship Research, Northwestern University, Advisor: J. Julie Kim, PhD Characterization of stromal derived factors in progression of endometrioid endometrial carcinoma
2016-Current	Navigating end-of-life care: understanding barriers to palliative
care utilization	
	in women with gynecologic cancer. Mixed methods.
2017-Current	Enhanced Recovery after Surgery Protocol for patients undergoing
	laparotomy for suspected gynecologic malignancy
2012-Current	The Efficacy and Safety of Tivozanib in Recurrent, Platinum-
	resistant
	Ovarian, Fallopian Tube & Peritoneal Cancer

# TEACHING EXPERIENCE

2000	Teaching Assistant Antarctic Biology Program, USC/NSF Area: Photobiology and Molecular Biology
2001	Assistant Coordinator, Minority Medical Education Program, UW
2003	Curriculum Coordinator, Minority Medical Education Program,
	UW
2001-2004	Instructor, Summer Medical Education Program, UW
	Biology (Physics 2001)
2002-2003	Research Supervisor Undergraduate Research Fellow, FHCRC
2003-2004	MCAT Biology Instructor, The Princeton Review
2004	Research Mentor, STAR Program, UW/NIH
2004-2005	Research Supervisor, Undergraduate/Post-Bac Research Assistant,
	FHCRC
2010-2011	Clinical Instructor, LSC+USC Medical Center
2011-2014	Resident & Medical Student Clerkship Instructor, Dept. Ob/Gyn
	Feinberg School of Medicine, Northwestern University
2014-Current	Second Year Medical Student Lecturer, Reproduction/GU Module
	Feinberg School of Medicine, Northwestern University

#### **COMMITTEE APPOINTMENT**

2014-Current	Big 10 Cancer Research Consortium, Gynecologic Clinical Trial
	Working Group
2014-Current	National Clinical Trial Network, Northwestern University
2014-Current	Women's Cancer Disease Team-Co-Chair, Northwestern University
2014-2016	Clinical Competence Committee, OB/GYN Residency,
	Northwestern University
2015-2016	Scientific Review Committee, Robert H Lurie Comprehensive
	Cancer Center
2015-Current	National Comprehensive Cancer Network, Ovarian Cancer Panel
2016-Current	Clinical Competence Committee, Gyn-Onc Fellowship,
	Northwestern University
2016-Current	NRG Oncology, Corpus Committee

#### LANGUAGE SKILLS

Spanish: Fluent in Spoken & Written

## **PUBLICATIONS**

Brown CY, Mize GJ, **Pineda MJ**, George DL, Morris DR. Role of two upstream open reading frames in the translational control of oncogene *mdm*2. Oncogene. (1999) Oct 7;18(41):5631-7.

Forte S, Harmon ME, **Pineda MJ**, Overbaugh J. Early and intermediate stage variances of simian immunodeficiency virus replicate efficiently in cells lacking CCR5. J. Virol (2003) Sep; 77(17):9723-7.

Dooher JE, **Pineda MJ**, Overbaugh J, Lingappa JR. Characterization of particle infectivity and cell-free capsid assembly of SIVMneCL8. J. Med. Primatology. J. Med Primatol. (2004) Oct;33(5-6):262-71.

Chihara CJ, Song C, LaMonte G, Fetalvero K, Hinchman K, Phan H, **Pineda MJ**, Robinson K, Schneider GP. Identification and partial characterization of the enzyme of omega: one of five putative DPP IV genes in Drosophila melanogaster. J Insect Sci. (2005) Nov 2;5:26.

**Pineda MJ**, Orton BR, Overbaugh J. A TRIM5alpha-independent post-entry restriction to HIV-1 infection of macaque cells that is dependent on the path of entry. Virology. (2007) Jul 5;363(2):310-8. Epub 2007 Mar 9.

Allen RB, **Pineda MJ**, Stanczyk FZ. Human Chorionic Gonadotropic. Goodwin, T. M., Montoro, M. N., Muderspach, L. I., Paulson, R. J. and Roy, S. (eds) (2010) Front Matter, in Management of Common Problems in Obstetrics and Gynecology, Fifth Edition, Wiley-Blackwell, Oxford, UK.

**Pineda MJ**, Roy S. Genital Herpes. Goodwin, T. M., Montoro, M. N., Muderspach, L. I., Paulson, R. J. and Roy, S. (eds) (2010) Front Matter, in Management of Common Problems in Obstetrics and Gynecology, Fifth Edition, Wiley-Blackwell, Oxford, UK.

**Pineda MJ**, Singh DK. What Is Integrative Oncology & Can It Help My Patients? Muller, C (ed) Obstetrics and Gynecology Clinics. (2012) June; 39:285-312.

**Pineda MJ.** Lurain JR. Gestational trophoblastic disease - chemotherapy. In Clinical Decision Support: Obstetrics and Gynecology, edited by D'Alton M, Dodson, W, Grobman WA, Hankins GD, Herzog T, Sood, A, Spong CY, Swift S. 2014. Decision Support in Medicine, LLC. Wilmington, DE.

**Pineda MJ**, Lurain JR. Cancer of uterus. In: Gansler T, Brawley OW, et al, (eds). American Cancer Society Textbook of Cancer. (2017) Hoboken, NJ: Wiley-Blackwell; 2017

**Pineda MJ**, Lu Z, Cao D, Kim JJ. Influence of Cancer-Associated Endometrial Stromal Cells on Hormone-Driven Endometrial Tumor Growth. Hormones and Cancer (2015) August; 6(4):131-141.

Singh D, **Pineda MJ.** Integrative Medicine for Ovarian Cancer. In: Bristow R, Cornelison, TH, Montz FJ. (eds) (2015) A Guide to Survivorship for Women Who Have Ovarian Cancer. Second Edition, John Hopkins University Press, Baltimore, MD.

Morgan RJ Jr, Armstrong DK, Alvarez RD, Bakkum-Gamez JN, Behbakht K, Chen LM, Copeland L, Crispens MA, DeRosa M, Dorigo O, Gershenson DM, Gray HJ, Hakam A, Havrilesky LJ, Johnston C, Lele S, Martin L, Matulonis UA, O'Malley DM, Penson RT, Percac-Lima S, **Pineda M**, Plaxe SC, Powell MA, Ratner E, Remmenga SW, Rose PG, Sabbatini P, Santoso JT, Werner TL, Burns J, Hughes M. Ovarian Cancer, Version 1.2016, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2016 Sep;14(9):1134-63.

PEER REVIEWED ABSTRACTS AND PRESENTATIONS

**Pineda MJ**, Forte S, Gosink J, Overbaugh J. A macaque cell line that does not express CCR5 allows entry of CCR5-using SIV and HIV. *Poster Presentation*, West Coast Retrovirus Meeting, 2001.

**Pineda MJ**, Forte S, Harmon ME, Pineda M, Overbaugh J. Characterization of Coreceptor Usage of Temporal Variants of SIVMne Suggest the Existence of a Novel SIV Coreceptor, *Oral Presentation*, U.S.-Japan Cooperative Medical Science Program, Fourteenth Joint Scientific Meeting of the AIDS Panels, 2002.

**Pineda MJ**, Forte S, Overbaugh J. The rhesus macaque sMAGI cells express an uncharacterized coreceptor that permits fusion and entry by a wide range of SIV variants and some HIV-1 isolates. *Poster Presentation*, Cold Spring Harbor Meeting on Retroviruses, 2003.

**Pineda MJ**, Overbaugh J. Restriction to HIV-1 Infection in Simian Cells are Dependent upon Mechanism of Entry. *Oral Presentation*, 21<sup>st</sup> Annual Symposium on Nonhuman Primate Models for AIDS, 2003.

**Pineda MJ**, Overbaugh J. Restriction to HIV-1 Infection in Non-Human Primate Cells is Dependent upon Mechanism of Entry. *Oral Presentation*, Minority Research Training Forum, Sept. 2004.

**Pineda MJ**, Caraveo M, Kim J. The Effect of Hormones on Endometrial Adenocarcinoma-Associated Stromal Cells. *Oral Presentation*, WAGO Annual Meeting, June 2012.

# **INVITED ORAL PRESENTATIONS**

**Pineda MJ.** "Low-Risk Gestational Trophoblastic Neoplasia Case Presentation." The Society of Gynecologic Oncologists (SGO) State of the Art Conference: Gestational Trophoblastic Disease. 2013.

**Pineda MJ.** "The Biology of Ovarian Cancer: Lessons for Treatment." Ovarian Cancer Survive & Thrive Course. Robert H. Lurie Comprehensive Cancer Center. 2013, 2015.

**Pineda MJ.** "Things You Should Have Asked During Your Clerkship, But Didn't; Examining Opportunities and Compromises in Medicine." Advancing the Front Line: Latino Physicians Across All Specialties. Latino Medical Student Association MidWest Conference. 2014.

**Pineda, MJ.** "Precision Medicine in Gynecologic Oncology." 2016 Gynecologic Cancer Survivors Course. Foundation for Women's Cancer, Society for Gynecologic Oncology. 2016

## **GRANTS/CONTRACTS**

Friends of Prentice Foundation Grant (Peer-reviewed)

"Myeloid Derived Suppressor Cells in Detection and Progression of
Endometrial Adenocarcinoma"

Principle Investigator (1%)

Annual/Total Direct Costs \$50,000

Friends of Prentice Foundation Grant (Peer-reviewed)

"Myeloid Derived Suppressor Cells in Detection and Progression of

Endometrial Adenocarcinoma"

Principle Investigator (1%)

Annual/Total Direct Costs \$50,000

National Comprehensive Cancer Network (NCCN)

01/2014-06/2017

09/2013-08/2014

"The Efficacy and Safety of Tivozanib in Recurrent, Platinum-resistant

Ovarian, Fallopian Tube & Peritoneal Cancer"

Principle Investigator

Annual/Total Direct Costs \$249,365

TESARO, Inc. 02/2014-02/2017

"A Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib

Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer"

Principle Investigator

Annual/Total Direct Costs \$98,097

TESARO, Inc. 05/2015-05/2018

"A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Women with Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received at Least Three Previous Chemotherapy Regimens"

Principal Investigator

Annual/Total Direct Costs \$230,000

AEterna Zentaris, Inc

03/2014-03/2017

"Randomized controlled study comparing AEZS-108 with doxorubicin as second line therapy for locally advanced, recurrent or metastatic endometrial cancer" Principal Investigator

Annual/Total Direct Costs \$81,609

American Cancer Society (Peer-reviewed)

1/2016-06/2017

"Navigating end-of-life care: understanding barriers to palliative care utilization in women with gynecologic cancer"

Principal Investigator

Annual/Total Direct Costs \$30,000

Merck Sharpe & Dohme Corp

5/2017-Current

"Phase II Study of Pembrolizumab in Combination with Carboplatin and Paclitaxel for Advanced or Recurrent Endometrial Adenocarcinoma"

Sponsor Investigator

Annual/Total Costs \$998,262

# Clinical Trials – Sub Investigator

# **Lung Cancer Trials**

- <u>Novocure Protocol EF-24/Lunar:</u> Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields) concurrent with standard of care therapies for treatment of stage 4 non-small cell lung cancer (NSCLC) following platinum failure (LUNAR) (2018-).
- <u>BeyondSpring Pharmaceuticals Inc. Protocol 450-0001/Dublin-3:</u> Assessment of Docetaxel + Plinabulin Compared to Docetaxel + Placebo in Patients With Advanced NSCLC With at Least One Measurable Lung Lesion (DUBLIN-3) (2017- ).
- <u>G1 Therapeutics Protocol G1T28-05</u>: Phase 2 Study of Carboplatin, Etoposide, and Atezolizumab With or Without Trilaciclib (G1T28) in Patients with Untreated Extensive-Stage Small Cell Lung Cancer (2017- )
- <u>Pharma Mar Protocol PM1183-C-003-14</u>: Phase III Randomized Clinical Trial of Lurbinectedin (PM01183)/Doxorubicin (DOX) Versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients With Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line (ATLANTIS Trial) (2016- )
- <u>Eli Lilly and Company Protocol LUN 288/I6A-MC-CBBE</u>: A Phase II Study of the Combination of LY3023414 and Necitumumab After First-Line Chemotherapy for Metastatic Squamous Non-small Cell Carcinoma of the Lung (2016-2018)
- Hoffmann-La Roche Protocol GO29436: A Phase III, Open-Label, Randomized Study of MPDL3280A (Anti-PD-L1 Antibody) In Combination with Carboplatin + Paclitaxel With or Without Bevacizumab Compared With Carboplatin + Paclitaxel + Bevacizumab In Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (2015- )
- <u>AstraZeneca Protocol D4191C00004</u>: A Phase III, Open Label, Randomised, Multi-centre, International Study of MEDI4736, Given as Monotherapy or in Combination With Tremelimumab Determined by PD-L1 Expression Versus Standard of Care in Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (Stage IIIB-IV) Who Have Received at Least Two Prior Systemic Treatment Regimens Including One Platinum Based Chemotherapy Regimen and Do Not Have Known EGFR TK Activating Mutations or ALK Rearrangements (ARCTIC) (2014-2018)
- AstraZeneca Protocol D4191C00001: A Phase III, Randomised, Double-blind, Placebocontrolled, Multi-centre, International Study of MEDI4736 as Sequential Therapy in Patients With Locally Advanced, Unresectable Non-Small Cell Lung Cancer (Stage III) Who Have Not Progressed Following Definitive, Platinum-based, Concurrent Chemoradiation Therapy (PACIFIC) (2014-2017)
- <u>Peregrine Protocol PPHM1202</u>: SUNRISE: A Phase III, Randomized, Double-Blind, Placebo-Controlled Multicenter Trial of Bavituximab Plus Docetaxel Versus Docetaxel Alone in Patients With Previously Treated Stage IIIb/IV Non-Squamous Non Small-Cell Lung Cancer (2014-2017)

#### **Breast Cancer Trials**

• Boehringer Ingelheim BI1280-0022: Xenera-1: A multi-centre, double-blind, placebo-controlled,

- randomised phase II trial to compare efficacy of xentuzumab in combination with everolimus and exemestane versus everolimus and exemestane in post-menopausal women with HR+ / HER2-metastatic breast cancer and non-visceral disease (2019-)
- <u>Daiichi Sankyo Protocol DS8201-A-U303</u>: A Phase-3, multicenter randomized, open-label, active-controlled trial of DS-8201A, an anti-her2-antibody drug conjugate (ADC) versus treatment of physician's choice for HER2low, unresectable and/or metastatic breast cancer subjects.(2019 )
- <u>Daiichi Sankyo Protocol DS8201-A-U301</u>: A Phase 3, multicenter, randomized, open-label, active-controlled of DS-8201A, an anti-HER2-antibody drug conjugate, versus treatment of investigator's choice for HER2-positive, unresectable and/or metastatic breast cancer subjects pretreated with prior standard of care HER2 therapies, including T-DM1(2019-)
- Novartis Pharmaceuticals Protocol CLAG525B2101: A phase II open-label, randomized, three-arm, multicenter study of LAG525 given in combination with spartalizumab (PDR001), or with spartalizumab and carboplatin, or with carboplatin, as first or second line therapy in patients with advanced triple-negative breast cancer (2018-)
- Odonate Therapeutics Protocol ODO-TE-V301: A Multinational, Multicenter, Randomized,
  Phase 3 Study of Tesetaxel plus a Reduced Dose of Capecitabine versus Capecitabine Alone in
  Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic
  Breast Cancer Previously Treated with a Taxane
- Merrimack Pharmaceuticals Protocol MM-121-02-02-10/ Sherboc: Phase 2 Trial of Seribantumab Plus Fulvestrant in Postmenopausal Women With Metastatic Breast Cancer (SHERBOC) (2018- )
- Macrogenics, Inc. Protocol CP-MGAH22-04: A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment (2016-)
- <u>Celgene Corporation Protocol CC-486-BRSTM-001</u>: A Phase 2, Randomized, Open-label, Twoarm Study to Assess the Efficacy and Safety of the Epigenetic Modifying Effects of CC-486 (Oral Azacitidine) in Combination With Fulvestrant in Postmenopausal Women With ER+, HER2- Metastatic Breast Cancer Who Have Progressed on an Aromatase Inhibitor (2015-2017)
- Novartis Pharmaceuticals Protocol CLEE011A2404: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease COMPLEEMENT-1 (2017-)
- Novartis Pharmaceuticals Protocol CLEE011XUS29: A Phase I/II, Single Arm, Open-label Study of Ribociclib in Combination With Everolimus + Exemestane in the Treatment of Men and Postmenopausal Women With HR+, HER2- Locally Advanced or Metastatic Breast Cancer Following Progression on a CDK 4/6 Inhibitor (2017-)
- Novartis Pharmaceuticals Protocol CLEE011XUS29: A Phase I/II, Single Arm, Open-label Study of Ribociclib in Combination With Everolimus + Exemestane in the Treatment of Men and Postmenopausal Women With HR+, HER2- Locally Advanced or Metastatic Breast Cancer

- Following Progression on a CDK 4/6 Inhibitor (2017- )
- Merck Sharp & Dohme Corp. Protocol MK3475-119: A Randomized Open-Label Phase III Study of Single Agent Pembrolizumab Versus Single Agent Chemotherapy Per Physician's Choice for Metastatic Triple Negative Breast Cancer (mTNBC) - (KEYNOTE-119) (2016-2017)
- Novartis Protocol CBYL719C2301A: Phase III Randomized Double-blind, Placebo Controlled Study of Alpelisib in Combination With Fulvestrant for Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor Treatment (2016-)
- Novartis Protocol CLEE011F2301: A Randomized Double-blind, Placebo-controlled Study of Ribociclib in Combination With Fulvestrant for the Treatment of Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer Who Have Received no or Only One Line of Prior Endocrine Treatment (2015-)
- <u>Eli Lilly Protocol I3Y-MC-JPBM</u>: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) Plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women With Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer With No Prior Systemic Therapy in This Disease Setting (2015-)
- Novartis Protocol CLEE011A2301: A Randomized Double-blind, Placebo-controlled Study of LEE011 in Combination With Letrozole for the Treatment of Postmenopausal Women With Hormone Receptor Positive, HER2 Negative, Advanced Breast Cancer Who Received no Prior Therapy for Advanced Disease (2014- )
- <u>Pfizer protocol A5481023: Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3</u> Trial Of Fulvestrant (Faslodex (Registered)). With Or Without PD-0332991 (Palbociclib) +/- Goserelin In Women With Hormone Receptor-Positive, HER2-Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Endocrine Therapy (2013-)
- Puma Biotechnology Protocol PUMA-NER-1301: A Study of Neratinib Plus Capecitabine
  Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer Who
  Have Received Two or More Prior HER2-Directed Regimens in the Metastatic Setting (NALA)
  (2013-)
- <u>Celgene Corporation Protocol ABI-007-MBC-001</u>: A Phase 2/3, Multi-Center, Open-Label, Randomized Study of Weekly Nab®-Paclitaxel in Combination With Gemcitabine or Carboplatin, Compared to Gemcitabine/Carboplatin, as First Line Treatment in Subjects With ER, PgR, and HER2 Negative (Triple Negative) Metastatic Breast Cancer (2013-2017)
- <u>F. Hoffmann-La Roche Ltd / Genentech Inc Protocol MO27775</u>: A Randomized, Two-arm, Open-label, Multicenter Phase II Trial Assessing the Efficacy and Safety of Pertuzumab Given in Combination With Trastuzumab Plus an Aromatase Inhibitor in First Line Patients With HER2-positive and Hormone Receptor-positive Advanced (Metastatic or Locally Advanced) Breast Cancer (2012-)

# **Pancreatic Cancer Trials**

• <u>Incyte Corporation INCB 18424-362</u>: A Randomized, Double-Blind, Phase 3 Study of the Janus Kinase (JAK) 1/2 Inhibitor, Ruxolitinib, or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or

- Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study) (2014-2017)
- <u>Gilead Sciences Protocol GS-US-370-1296</u>: A Phase 3, Randomized, Double-blind, Placebocontrolled Study of Gemcitabine and Nab-paclitaxel Combined With Momelotinib in Subjects With Previously Untreated Metastatic Pancreatic Ductal Adenocarcinoma Preceded by a Dosefinding, Lead-in Phase (2014-2017)

# **Ovarian Cancer Trials**

• <u>Tesaro, INC. Protocol PR-30-5020-C</u>: A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients With Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens (2016-2018)

## **Prostate Cancer Trials**

- Roche Ltd Protocol CO39303 IPATential150: Ipatasertib Plus Abiraterone Plus
  Prednisone/Prednisolone, Relative to Placebo Plus Abiraterone Plus Prednisone/Prednisolone
  in Adult Male Patients With Metastatic Castrate-Resistant Prostate Cancer (IPATential150)
  (2017-)
- <u>Bayer Healthcare Pharmaceuticals Protocol BAY 1841788 / 17777:</u> A randomized, double—blind, placebo—controlled Phase III study of ODM—201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone—sensitive prostate cancer
- Janssen Research & Development, LLC on behalf of Aragon Pharmaceuticals, Inc. Protocol 56021927PCR3003: A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects With High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment With Primary Radiation Therapy (ATLAS) (2016- )
- Sotio a.s. SP005: A Randomized, Double Blind, Multicenter, Parallel-group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men With Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy (2014-)

#### **Colorectal Cancer Trials**

 <u>AbbVie Protocol M14-064</u>: Phase 2 Study Comparing Efficacy and Safety of ABT-165 plus FOLFIRI vs Bevacizumab plus FOLFIRI in Metastatic Colorectal Cancer Previously Treated with Fluoropyrimidine/Oxaliplatin and Bevacizumab.(2018- )

# Lymphoma Trials

- Bayer Healthcare Pharmaceuticals Inc., Protocol BAY 80-6946 / 17833: A Phase III, randomized, double-blind, controlled, multicenter study of intravenous PI3K inhibitor copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma (iNHL) CHRONOS-4 (2018-)
- <u>TG Therapeutics, Inc Protocol UTX-TGR-205</u>: A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 and TGR-1202 Alone in Patients With Previously Treated Diffuse Large B-Cell Lymphoma (2016- )
- Novartis Protocol OFB114612: A Phase II Open-Label Study of Ofatumumab and

- Bendamustine Followed by Maintenance Ofatumumab for Indolent B-cell Non-Hodgkin's Lymphoma (B-NHL) Which Has Relapsed after Rituximab Therapy (2011-2017)
- Novartis Protocol CRAD001N2301: A Randomized, Double-blind, Placebo-controlled, Multi-center Phase III Study of RAD001 Adjuvant Therapy in Poor Risk Patients With Diffuse Large B-Cell Lymphoma (DLBCL of RAD001 Versus Matching Placebo After Patients Have Achieved Complete Response With First-line Rituximab-chemotherapy (2010-2016)

# **Myeloma Trials**

- Merck Sharp & Dohme MK-3475-183-01: A Phase III Study of Pomalidomide and Low Dose Dexamethasone With or Without Pembrolizumab (MK3475) in Refractory or Relapsed and Refractory Multiple Myeloma (rrMM) (KEYNOTE 183) (2016-)
- Millennium Pharmaceuticals Protocol C16014: A Phase 3, Randomized, Double-Blind, Multicenter Study Comparing Oral IXAZOMIB (MLN9708) Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma (2013-)

#### **CLL Trials**

- <u>TG Therapeutics Protocol UTX-TGR-304</u>: A Phase 3, Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with TGR-1202 Compared to Obinutuzumab in Combination with Chlorambucil in Patients with Chronic Lymphocytic Leukemia (CLL) (2016-)
- <u>TG Therapeutics Protocol UTX-IB-301</u>: Ublituximab in Combination With Ibrutinib Versus Ibrutinib Alone in Patients With Previously Treated High-Risk Chronic Lymphocytic Leukemia (CLL) (2015-)
- <u>Genentech Protocol ML29538</u>: A Phase II, Open-Label Study Of Obinutuzumab Plus Bendamustine (BG) In Patients With Previously Untreated Chronic Lymphocytic Leukemia (2015-)

#### **Melanoma Cancer Trials**

- Merck Sharp & Dohme Corp. Protocol 7902-004: A Multicenter, Open-label, Phase 2 Trial to Assess the Efficacy and Safety of Lenvatinib (E7080/MK-7902) in Combination with Pembrolizumab (MK-3475) in Participants with Advanced Melanoma Previously Exposed to an Anti-PD-1/L1 Agent (LEAP-004)
- <u>Polynoma LLC Protocol 103A-301</u>: A Multicenter, Double-blind, Placebo-controlled, Adaptive Phase 3 Trial of POL-103A Polyvalent Melanoma Vaccine in Post-resection Melanoma Patients With a High Risk of Recurrence (2015-)

# Head & Neck Cancer Trials

Merck Sharp & Dohme Protocl MK-3475-040-10: A Phase III Randomized Trial of MK-3475
(Pembrolizumab) Versus Standard Treatment in Subjects With Recurrent or Metastatic Head
and Neck Cancer (2016- )

#### **Urothelial Carcinoma Trials**

 Merck Sharp & Dohme Corp. Protocol MK3475-361: A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab With or Without Platinum-Based Combination Chemotherapy Versus Chemotherapy in Subjects With Advanced or Metastatic Urothelial Carcinoma (2016-)

# **Renal Cell Carcinoma Trials**

 <u>Bristol-Myers Squibb Protocol CA 209-920</u>: Phase 3b/4 Safety Trial of Nivolumab Combined With Ipilimumab in Subjects With Previously Untreated, Advanced or Metastatic RCC (CheckMate 920: CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 920) (2017-)

# **Registry Trials**

• Guardant Health Protocol 01-MX-003: GEODE: Registry of Guardant360® Use and Outcomes In People With Advanced Cancer