

Michael E. Menefee, M.D.

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EDUCATION:

POST-GRADUATE:

2002 - 2006	National Cancer Institute Bethesda, Maryland	Fellowship Hematology/Oncology
1999 - 2002	Mayo Clinic Jacksonville, Florida	Internship/Residency Internal Medicine

GRADUATE:

1995 - 1999	Meharry Medical College Nashville, Tennessee	Magna Cum Laude
1994 - 1995	Boston University Boston, Massachusetts	Post-Baccalaureate

UNDERGRADUATE:

1989 - 1993	North Carolina A&T State University Greensboro, North Carolina	B.S., Biology Cum Laude
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MEDICAL LICENSURES:

District of Columbia:	MD200001298	(active)
Maryland:	D62162	(active)
Florida:	ME81187	(lapsed)
Georgia	71797	(lapsed)

BOARD CERTIFICATIONS:

American Board of Internal Medicine Diplomate #210208	
Internal Medicine	2017
Medical Oncology	2016

PROFESSIONAL EXPERIENCE:

2020 - Present	Veterans Affairs Medical Center Attending Physician, Medical Oncology	Washington, DC
2018 – 2020	United States Food and Drug Administration Medical Officer, Thoracic and Head and Neck Malignancies	Silver Spring, MD
2007 – 2017	Mayo Clinic Assistant Professor, Division of Hematology and Oncology	Jacksonville, FL
2006 – 2007	Mayo Clinic Senior Associate Consultant, Division of Medical Oncology	Rochester, MN

2012 – 2017

U.S. Food and Drug Administration
Consultant, Oncologic Drug Advisory Committee

RESEARCH SUPPORT:

Research Support

U01CA069912-14

Erlichman/Menefee

08/01/2008 - 02/28/2013

NIH

Phase 1 Clinical Trials of Anticancer Agents Grant

This grant evaluates the safety of certain anti-cancer agents.

Role: site-PI

10KG-04

Fields/Menefee

04/15/2011 – 06/30/2015

James and Esther King Research Program

Combined PKC α and mTOR inhibition for treatment of advanced non-small cell lung cancer

The goal of this project is to conduct a phase I clinical trial to assess the safety and possible efficacy of combined PKC α and mTOR inhibition in advanced NSCLC patients. It should be noted that this trial is distinct and non-overlapping with the present application. If this application is awarded, we will assess ATM/mTOR inhibitor therapy for second line therapy for advanced NSCLC patients who have failed initial therapy. In contrast, the present application will assess the efficacy of ATM/mTOR therapy for maintenance therapy to prevent progression/recurrence in NSCLC patients who have responded to initial therapy but who are at high risk for relapse.

Role: Co-Investigator

Completed Research Support

NIH/NCI

Hartmann/Menefee

09/18/2006 – 06/30/2011

Paul Calabresi Award for Clinical Oncology (K12)

Preclinical Investigation of Combinatorial Therapy with Inhibitors of the Mammalian Target of Rapamycin (mTOR) and the Epothilone B Analog, Ixabepilone (BMS-247550)

PUBLICATIONS:

Hubbard JM, Yin J, Schenk EL, Qin R, Reid JM, Strand C, Fiskum J, **Menefee M**, Lin G, Doyle LA, Ivy P, Erlichman C, Adjei A, Haluska P, Costello BA. Phase I study of cediranib, an oral VEGFR inhibitor, in combination with selumetinib, an oral MEK inhibitor, in patients with advanced solid malignancies. Invest New Drugs. 2022 Feb;40(1):115-123. doi: 10.1007/s10637-021-01175-6.

Bible KC, **Menefee ME**, Lin CJ, Millward MJ, Maples WJ, Goh BC, Karlin NJ, Kane MA, Adkins DR, Molina JR, Donehower RC, Lim WT, Flynn PJ, Richardson RL, Traynor AM, Rubin J, LoRusso PM, Smallridge RC, Burton JK, Suman VJ, Kumar A, Voss JS, Rumilla KM, Kipp BR, Chintakuntlawar AV, Harris P, Erlichman C. An International Phase 2 Study of Pazopanib in Progressive and Metastatic Thyroglobulin Antibody Negative Radioactive Iodine Refractory Differentiated Thyroid Cancer. Thyroid. 2020 Jul 29. doi: 10.1089/thy.2019.0269.

Iñiguez-Ariza NM, Jasim S, Ryder MM, Chintakuntlawar AV, Morris JC, Hilger CR, **Menefee ME**, Smallridge RC, Karlin NJ, Alcaino C, Bible KC. Foundation One Genomic Interrogation of Thyroid Cancers in Patients with Metastatic Disease Requiring Systemic Therapy. J Clin Endocrinol Metab. 2020 Jul 1;105(7):e2346-57. doi: 10.1210

Xie H, Yin J, Shah MH, **Menefee ME**, Bible KC, Reidy-Lagunes D, Kane MA, Quinn DI, Gandara DR, Erlichman C, Adjei AA. A phase II study of the orally administered negative enantiomer of gossypol (AT-101), a BH3 mimetic, in patients with advanced adrenal cortical carcinoma. *Invest New Drugs*. 2019 Aug;37(4):755-762. doi: 10.1007/s10637-019-00797-1.

Wahner Hendrickson AE, **Menefee ME**, Hartmann LC, Long HJ, Northfelt DW, Reid JM, Boakye-Agyeman F, Kayode O, Flatten KS, Harrell MI, Swisher EM, Poirer GG, Satele D, Allred J, Lensing JL, Chen A, Ji J, Zang Y, Erlichman C, Haluska P, Kaufmann SH. A Phase I Clinical Trial of the Poly(ADP-ribose) Polymerase Inhibitor Veliparib and Weekly Topotecan in Patients with Solid Tumors. *Clin Cancer Res*. 2018 Feb 15;24(4):744-752. doi: 10.1158/1078-0432.CCR-17-1590.

Cabanillas ME, de Souza JA, Geyer S, Wirth LJ, **Menefee ME**, Liu SV, Shah K, Wright J, Shah MH. Cabozantinib As Salvage Therapy for Patients with Tyrosine Kinase Inhibitor-Refractory Differentiated Thyroid Cancer: Results of a Multicenter Phase II International Thyroid Oncology Group Trial. *J Clin Oncol*. 2017 Oct 10;35(29):3315-3321. doi: 10.1200/JCO.2017.73.0226.

Haluska P, **Menefee M**, Plimack ER, Rosenberg J, Northfelt D, LaVallee T, Shi L, Yu XQ, Burke P, Huang J, Viner J, McDevitt J, LoRusso P. Phase I dose-escalation study of MEDI-573, a bispecific, antiligand monoclonal antibody against IGFI and IGFII, in patients with advanced solid tumors. *Clin Cancer Res*. 2014 Sep 15;20(18):4747-57. doi: 10.1158/1078-0432.CCR-14-0114.

Bible KC, Suman VJ, Molina JR, Smallridge RC, Maples WJ, **Menefee ME**, Rubin J, Karlin N, Sideras K, Morris JC 3rd, McIver B, Hay I, Fatourech V, Burton JK, Webster KP, Bieber C, Traynor AM, Flynn PJ, Cher Goh B, Isham CR, Harris P, Erlichman C; Endocrine Malignancies Disease Oriented Group, Mayo Clinic Cancer Center, and the Mayo Phase 2 Consortium. A multicenter phase 2 trial of pazopanib in metastatic and progressive medullary thyroid carcinoma: MC057H. *J Clin Endocrinol Metab*. 2014 May;99(5):1687-93. doi: 10.1210/jc.2013-3713.

Schenk E, Hendrickson AE, Northfelt D, Toft DO, Ames MM, **Menefee M**, Satele D, Qin R, Erlichman C. Phase I study of tanespimycin in combination with bortezomib in patients with advanced solid malignancies. *Invest New Drugs*. 2013 Oct;31(5):1251-6. doi: 10.1007/s10637-013-9946-7.

von Roemeling CA, Marlow LA, Kennedy WP, Kennedy GT, Copland JA, **Menefee ME**. Preclinical evaluation of the mTOR inhibitor, temsirolimus, in combination with the epothilone B analog, ixabepilone in renal cell carcinoma. *Am J Cancer Res*. 2013 Aug 14;3(4):390-401.

Cooper SJ, Von Roemeling CA, Kang KH, Marlow LA, Grebe SK, **Menefee ME**, Tun HW, Colon-Otero G, Perez EA, Copland JA. Re-expression of tumor suppressor, sFRP1, leads to antitumor synergy of combined HDAC and methyltransferase inhibitors in chemo-resistant cancers. *Mol Cancer Ther*. 2012 Oct. DOI:10.1158/1535-7163.

Bible KC, Suman VJ, **Menefee ME**, Smallridge RC, Molina JR, Maples WJ, Karlin NJ, Traynor AM, Kumar P, Goh BC, Lim WT, Bossou AR, Isham CR, Webster KP, Kukla AK, Bieber C, Burton JK, Harris P, Erlichman C, the Mayo Phase 2 Consortium and Mayo Clinic Endocrine Malignancies Disease Oriented Group. A Multi-institutional Phase 2 Trial of Pazopanib Monotherapy in Advanced Anaplastic Thyroid Cancer. *J Clin Endocrinol Metab.* 2012 Sep; 97(9):3179-84. DOI:10.1210/jc.2012-1520.

Menefee ME, Smallridge RC, Bible KC. Systemic therapeutic approaches to advanced thyroid cancers. *Am Soc Clin Oncol Educ Book.* 2012:389-92. doi: 10.14694

Bible KC, Smallridge RC, Morris JC, Molina JR, Suman VJ, Copland JA, Rubin J, **Menefee ME**, Sideras K, Maples WJ, Mclver B, Fatourechi V, Hay I, Foote RL, Garces YI, Kasperbauer JL, Thompson GB, Grant CS, Richards ML, Sebo T, Lloyd R, Eberhardt NL, Reddi HV, Casler JD, Karlin NJ, Westphal SA, Richardson RL, Buckner JC, Erlichman C. Development of a multidisciplinary, multicampus subspecialty practice in endocrine cancers. *J Oncol Pract.* 2012 May; 8(3 Suppl):e1s-5s. DOI:10.1200/JOP.2011.000496.

Bible KC, Suman VJ, Molina JR, Smallridge RC, Maples WJ, **Menefee ME**, Rubin J, Sideras K, Morris JC 3rd, Mclver B, Burton JK, Webster KP, Bieber C, Traynor AM, Flynn PJ, Goh BC, Tang H, Ivy SP, Erlichman C, Endocrine Malignancies Disease Oriented Group, Mayo Clinic Cancer Center, Mayo Phase 2 Consortium. Efficacy of pazopanib in progressive, radioiodine-refractory, metastatic differentiated thyroid cancers: results of a phase 2 consortium study. *Lancet Oncol.* 2010 Oct; 11(10):962-72. DOI:10.1016/S1470-2045(10)70203-5.

Sideras K, **Menefee ME**, Burton JK, Erlichman C, Bible KC, Ivy SP. Profound hair and skin hypopigmentation in an African American woman treated with the multi-targeted tyrosine kinase inhibitor pazopanib. *J Clin Oncol.* 2010 Jul 1; 28(19):e312-3. DOI:10.1200/JCO.2009.26.4432.

Huang H, **Menefee ME**, Edgerly M, Zhuang S, Kotz H, Poruchynsky M, Huff LM, Bates S, Fojo T. A phase II clinical trial of ixabepilone (Ixempra; BMS-247550; NSC 710428), an epothilone B analog, in patients with metastatic renal cell carcinoma. *Clin Cancer Res.* 2010 Mar 1; 16(5):1634-41. DOI:10.1158/1078-0432.CCR-09-0379.

Stein WD, Huang H, **Menefee ME**, Edgerly M, Kotz H, Dwyer A, Yang J, Bates SE. Other paradigms: growth rate constants and tumor burden determined using computed tomography data correlate strongly with the overall survival of patients with renal cell carcinoma. *Cancer J.* 2009 Sep-Oct; 15(5):441-7. DOI:10.1097/PPO.0b013e3181be1b90.

Fojo T, **Menefee ME**. Mechanisms of multidrug resistance: the potential role of microtubule-stabilizing agents. *Ann Oncol.* 2007 Jul; 18 Suppl 5:v3-8. DOI:10.1093.

Fojo AT, **Menefee ME**. Microtubule targeting agents: basic mechanisms of multidrug resistance (MDR). *Semin Oncol.* 2005 Dec; 32(6 Suppl 7): S3-8. DOI:10.1053.

Book Chapters

Menefee M., Smallridge R., Endocrine and Metabolic Medical Emergencies: A Clinician's Guide. Washington, DC. Endocrine Press. 2014: 158-163

Menefee M., Piekarz R, Fojo A. Bethesda Handbook on Clinical Oncology, 3rd ed; Endocrine Tumors. Philadelphia, PA: Lippincott-Raven, 2009: 415-429

Menefee M., McDewitt, P., Fojo, A. Hematology-Oncology Therapy; Chemotherapy Dose Modifications,. New York, NY: McGraw-Hill, 2007: 569-578

Menefee M., Fojo A. Bethesda Handbook on Clinical Oncology, 2nd ed; Endocrine Tumors. Philadelphia, PA: Lippincott-Raven, 2005: 455-472

Selected Abstracts:

Menefee M., Gong Y, Mishra-Kalyani P, Rajeshwari S, Kanapuru B, Blumenthal G, Pazdur R. Project Switch: Docetaxel as a potential synthetic control in metastatic Nonsmall Cell Lung Cancer Trials. 2019 ASCO Annual Meeting.

Baldeo C, Kaleem T, Paz-Fumagalli, Copland J, **Menefee M.** Mixed response to immunotherapy in lung cancer. 2019 ASCO-SITC (poster presentation)

Menefee M., Paz-Fumagalli, et al. Genomic Heterogeneity in Tumors Demonstrating a Mixed Response to Nivolumab for Stage IV Squamous Cell Carcinoma of the Lung. 2016 World Conference on Lung Cancer (poster presentation).

Menefee M., D'Amico T. Lung adenocarcinoma harboring both a KRAS mutation and an EML4-ALK fusion gene with response to crizotinib: A Case Report. 2013 World Conference on Lung Cancer (poster presentation).

Olumide Kayode, Alice Chen, Scott H. Kaufmann, Charles Erlichman, **Michael E. Menefee.** Investigation of a potential pharmacokinetic interaction between ABT-888 and topotecan in a phase I trial. 2011 AACR Annual Meeting (poster presentation).

Michael E. Menefee, Keith C. Bible, Christina Von Roemeling, John Al Copland Preclinical evaluation of the mTOR inhibitor, temsirolimus, in combination with the epothilone B analog, ixabepilone. 2010 AACR Annual meeting (poster presentation).

C. Erlichman, **M. E. Menefee**, et al. Phase I trial of dasatinib and lapatinib. J Clin Oncol 28:15s, 2010 (suppl; abstr 2610)

Menefee, M., et al. Effects of the P-glycoprotein (Pgp) antagonist tariquidar (XR-9576; TQD) on Pgp function as well as the toxicity and efficacy of combined chemotherapy in patients with metastatic adrenocortical cancer (mACC). 2008 ASCO Annual Meeting Abstract No: 2543

Menefee, M., Fojo, A, et al. The efficacy of combination chemotherapy with cisplatin and gemcitabine in patients with advanced adrenal cortical carcinoma. 2006 ASCO Annual Meeting Abstract No: 12033

Menefee, M., Fojo, A. Tariquidar (XR9576) is a potent and effective P-glycoprotein (Pgp) inhibitor that can be administered safely with chemotherapy. 2005 ASCO Annual Meeting Abstract No: 3093

Fojo, A. **Menefee, M.** A translational study of ixabepilone (BMS-247550) in renal cell cancer (RCC): Assessment of its activity and demonstration of target engagement in tumor cells. 2005 ASCO Annual Meeting Abstract No: 4541

Zhuang, S., **Menefee, M.,** Fojo, A. A phase II clinical trial of BMS-247550 (ixabepilone), a microtubule-stabilizing agent in renal cell cancer. 2004 ASCO Annual Meeting Abstract No: 4550

ORAL PRESENTATIONS AND INVITED LECTURES:

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| 2020 | FDA-AACR-IASLC Workshop to Address the Criticality of Tobacco Use Assessment in Oncology Therapeutic Trials. Co-Chair |
| 2019 | World Conference on Lung Cancer (IASLC). Co-Chair: Strategies for Cancer Patients to Have Optimal Outcomes. |
| 2018 | Translational Cancer Research for Basic Scientists Workshop
Invited Lecture: Regulatory science: What are the issues? |
| 2018 | International Thyroid Oncology Group Annual Meeting. ITOG-FDA Liaison. |
| 2012 | Best of ASCO, Cuenca, Ecuador. Abstract No: 94113- 5508 |
| 2010 | 22 nd EORTC-NCI-AACR symposium on "Molecular targets and Cancer Therapeutics" MEDI-573, a dual IGF-1/2 neutralizing antibody, blocks IGF-1R and IRA signaling and maintains glucose homeostasis in a Phase 1 study for advanced solid tumors. Plenary Session, November 18, 2010, Berlin, Germany. |
| 2008-11, 15-16 | Mayo Clinic Annual Hematology and Oncology Reviews, Amelia Island, FL. Course Director, Thoracic Oncology Section. |
| 2008 | Grand Rounds, Mayo Clinic, Jacksonville, FL
Therapeutic Advances in Renal Cell Carcinoma |
| 2007 | Grand Rounds, Waterford Regional Hospital, Waterford, Ireland
Therapeutic Advances in Renal Cell Carcinoma

Conference of Hematology and Oncology, Panama <ul style="list-style-type: none">▪ Therapeutic Advances in Renal Cell Carcinoma▪ Targeted Therapeutics for Gastrointestinal Stromal Tumors |

- 2006 Peruvian Society of Medical Oncology, Lima, Peru
- Targeted Therapies in Gastrointestinal Malignancies
 - Medical Management of Gastric Cancer

WORKSHOPS and HONORS:

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| 2006 | FDA/NCI/Duke | Accelerating Anticancer Agent Development and Validation workshop
Bethesda, MD |
| 2004 | AACR | Molecular Biology in Clinical Oncology
Aspen, Colorado |
| 2004 | AACR/ASCO | Methods in Clinical Cancer Research
Vail, Colorado |
| 2001 | | Mayo Clinic International Health Program, Nairobi, Kenya |
| 1996 | | NIH-Fogarty International Center Minority Institution Training Program Fellowship, Lima Peru |

PROFESSIONAL ASSOCIATIONS:

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|--|--------|
| International Association for the Study of Lung Cancer | Member |
| American Society of Clinical Oncology | Member |
| International Thyroid Oncology Group | Member |
| Maryland and District of Columbia Society of Clinical Oncology | Member |