

CURRICULUM VITAE

MARY JOSEPHINE SAVAGE

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<u>EDUCATION School</u>	<u>Degree Date</u>	<u>Courses of Study</u>	<u>Degree</u>
Columbia University	1988	Pharmacology	PhD
Columbia University	1985	Pharmacology	MS
College of St. Elizabeth	1982	Biology/Math	BS

MERCK/MRL EMPLOYMENT HISTORY

11/2013-present Director Molecular Biomarkers and Diagnostics; Early/Late Clinical Development

Advancement of Companion Diagnostic biomarker assays supporting Oncology and Alzheimer's Disease clinical drug development programs spanning multiple modalities including ELISA, Next Generation Sequencing, Immunohistochemistry and PCR; working with internal clinical, regulatory teams, regulatory agencies (FDA, PMDA) external diagnostic partners, academia, consortia & clinical laboratory vendors.

PD1 Oncology: Tumor PDL1 IHC CDx with Agilent (US); dMMR IHC CDx; MSI nucleic acid CDx with Foundation Medicine (US); MSI PCR CDx with Falco (Japan)

- Approval of MSI-H Indication, April 2017: **First biomarker specific, tumor agnostic approval by FDA.** Post marketing commitments to develop 2 companion diagnostics (IHC and nucleic acid)
- Approval of 3L+ Gastric/GEJ Indication, Sept 2017: Biomarker positive population using PD-L1 IHC Combined positive score (Agilent co approved CDx Sept 2017))

BACE inhibitor program: CSF CDx and IVD enrollment threshold for prodromal BACEi Phase III trial with Luminex (US) and Roche (US), concordance studies with amyloid PET tracers (CAMD, ADNI, AIBL).

- Supported Mild/moderate and Prodromal Alzheimer's disease clinical trials. Both trials stopped for lack of efficacy.

7/09-11/13 Director Molecular Biomarkers; Neuroscience Group, Pharmacokinetics, Pharmacodynamics & Drug Metabolism

Worked with internal teams, external academic, consortia and clinical lab vendors to manage development of target engagement, pharmacodynamic and surrogate efficacy biomarker assays which supported a number of neurology/psychiatry drug discovery programs including:

BACE inhibitor:

- 13C leucine/SILK methodology applied to NHP for model building of APP processing with Wash U, U. Leiden, Merck modeling and simulation
- Developed world leading A β oligomer assay for application to AD biomarker discovery and drug development with Singulex.
- ADNI and Alz Association collaboration to evaluate novel biomarkers of diagnoses, prognosis, progression and clinical study enrollment

Tau inhibitor: PD assay development

AD symptomatic: Managed development of rat cholinergic lesion model using IgG Saporin.

ADDL Ab/A β vaccine: Developed PK, target-engagement and PD assays for passive and active immunization approaches to A β lowering, patents filed on these approaches.

11/2006-7/2009 **Senior Research Fellow / Co-lead Discovery Alzheimer's Disease;**
Neuroscience Therapeutic Area (activities, see publications)

5/1988-1/1990 **Postdoctoral Fellow -** Department of Genetic and Cellular Toxicology;
Safety Assessment

CEPHALON, INC (NOW TEVA Pharmaceuticals) EMPLOYMENT HISTORY

2002-2006 Senior Scientist II and Biology Lead, Alzheimer's Disease, Tau Kinase Inhibitor program (activities, see publications)

1998-2002 Senior Scientist I; Alzheimer's Disease, amyloid and kinase biology (activities, see publications)

1990-1998 Research Scientist I-III; Alzheimer's Disease animal models and biomarker assay development; Gamma Secretase Inhibitor program (activities, see publications)

TRAINING

Center for Creative Leadership: 2004 Management training; Leadership Development

Merck Sigma: 2010 Six Sigma Green Belt Certification

EXTERNAL MEMBERSHIPS, WORKING GROUPS, JOURNAL REVIEWER

Coalition Against Major Diseases - Alzheimer's disease: CSF biomarker qualification

Society for Neuroscience

Foundation for NIH (FNIH) Biomarkers Consortium: CSF Proteomics Project Team

Global Biomarkers Standardization Committee - Alzheimer's Association

Alzheimer's Disease Neuroimaging Initiative

Annals of Neurology

Alzheimer's Research and Therapy

Journal of Alzheimer's Disease

PROFESSIONAL HONORS

- Special Achievement Award, MRL Rewards and Recognition, December 2007
 - Awarded for performance above and beyond what is expected on the job.
- Merck Award of Excellence MRL Rewards and Recognition, July 2008.
- Special Achievement Award, MRL Rewards and Recognition, November 2009
 - Awarded for leading Novel target efforts for Alzheimer's Disease
- Special Achievement Award, MRL Reward and Recognition, December 2011
 - Awarded for leading Novel assay development for Alzheimer's Disease programs
- Merck Award of Excellence MRL Reward and Recognition, September 2012
 - Awarded for leading efforts to support novel assay development for clinical AD program
- Merck Technology Collaboration Award, May 2013
 - Awarded for development of ultrasensitive Immunoassay on Erenna Platform to Quantify Amyloid Beta oligomers

- Merck Technology Symposium Keynote Speaker, June 2016
 - Alzheimer’s Disease translational biomarkers: Amyloid monomer & oligomer measures to inform Verubecestat BACE inhibitor clinical trials
- MRL Division Pipeline Award, May 2018
 - Outstanding contributions and support of MK3475 MSI-H: KEYTRUDA

PUBLICATIONS AND PATENTS

Patents

1. Savage, MJ, Goure WF, Gaspar RC, McCampbell A, Shughrue, PJ, Wang F, Wang W, Wolfe, AL, Zhang N, Zhao W-Q, Xu M. (2016) Antibodies, kit and method for detecting amyloid beta oligomers. US 9,310,383
2. Savage MJ, Kinney GG, Liang, X, Citron M, Rosen LB, (2011) VACCINE FOR THE TREATMENT OF ALZHEIMER'S DISEASE. US 2011/0002949 A1

Publications

1. Bang Y-J, Kang Y-K, Catenacci DV, Muro K, Fuchs CS, Geva R, Hara H, Golan T, Garrido M, Jalal SI, Borg C, Doi T, Yoon HH, Savage MJ, Wang J, Dalal RP, Kang SP, Wainberg ZA & Chung HC. Pembrolizumab alone or in combination with chemotherapy as first-line therapy for patients with advanced gastric or gastroesophageal junction adenocarcinoma: results from the phase II KEYNOTE-059 study. Submitted 2018 to Annals of Oncology.
2. Kulangara K, Zhang N, Corigliano E, Guerrero L, Waldroup S, Jaiswal D, Jansson M, Shah S, Hanks D, Wang J, Lunceford J, Savage MJ, Juco J, Emancipator K. Clinical Utility of the Combined Positive Score for Programmed Death Ligand-1 Expression and the Approval of Pembrolizumab for Treatment of Gastric Cancer. Accepted 2018 by Archives of Pathology and Laboratory Medicine.
3. Arnerić SP, Batrla-Utermann R, Beckett L, Bittner T, Blennow K, Carter L, Dean R, Engelborghs S, Genius J, Gordon MF, Hitchcock J, Kaplow J, Luthman J, Meibach R, Raunig D, Romero K, Samtani MN, Savage M, Shaw L, Stephenson D, Umek RM, Vanderstichele H, Willis B, Yule S. Cerebrospinal Fluid Biomarkers for Alzheimer's Disease: A View of the Regulatory Science Qualification Landscape from the Coalition Against Major Diseases CSF Biomarker Team. J Alzheimers Dis. 2017; 55:19-35.
4. Balar AV, Castellano D, O'Donnell PH, Grivas P, Vuky J, Powles T, Plimack ER, Hahn NM, de Wit R, Pang L, Savage MJ, Perini RF, Keefe SM, Bajorin D, Bellmunt J. First-line pembrolizumab in cisplatin-ineligible patients with locally advanced and unresectable or

metastatic urothelial cancer (KEYNOTE-052): a multicentre, single-arm, phase 2 study. *Lancet Oncol.* 2017 18:1483-1492.

5. van Maanen EMT, van Steeg TJ, Ahsman MJ, Michener MS, Savage MJ, Kennedy ME, Kleijn HJ, Stone J, Danhof M. Extending a Systems Model of the APP Pathway: Separation of β - and γ -Secretase Sequential Cleavage Steps of APP. *J Pharmacol Exp Ther.* 2018; 365:507-518.
6. Wang X, Smith K, Pearson M, Hughes A, Cosden ML, Marcus J, Hess JF, Savage MJ, Rosahl T, Smith SM, Schachter JB, Uslaner JM. Early intervention of tau pathology prevents behavioral changes in the rTg4510 mouse model of tauopathy. *PLoS One.* 2018 Apr 6; 13:e0195486. doi: 10.1371
7. Mo Y, Stromswold J, Wilson K, Holder DJ, Sur C, Laterza O, Savage MJ, Struyk A, Scheltens P, Teunissen CE, Burke J, Macaulay SL, Bråthen G, Sando SB, White LR, Weiss C, Cowes A, Bush MM, DeSilva G, Darby DG, Rainey-Smith SR, Luthman J, Egan MF. (2016) A study to assess feasibility, sensitivity and specificity to diagnose Alzheimer's disease using a cerebrospinal fluid tau/Amyloid β (42) ratio. *Alzheimers Dement (Amst).* 2017 6:201-209
8. Weiss, C, Cowes A, Bush M, Surls J, DeSilva, G, Sagini E, Tanen M, Laberza O, Savage MJ, Altman A. (2016) Performance characteristics of the Luminex[®] xMAP[®] tau/amyloid β 42 assays in cerebrospinal fluid. Submitted.
9. van Maanen EM, van Steeg TJ, Michener MS, Savage MJ, Kennedy ME, Kleijn HJ, Stone JA, Danhof M. (2016) Systems Pharmacology Analysis of the Amyloid Cascade after β -Secretase Inhibition Enables the Identification of an A β 42 Oligomer Pool. *J Pharmacol Exp Ther.* 357:205-216.
10. Berge G, Lauridsen C, Sando SB, Holder DJ, Møller I, Aasly J, Bråthen G, Savage MJ, White LR. (2015) Effect of Tween-20 on core biomarkers measured in cerebrospinal fluid from patients with Alzheimer's disease, mild cognitive impairment, or healthy control individuals. *J Alzheimers Dis.* 49:493-502.
11. Stivers PJ, Harmonay L, Hicks A, Mehmet H, Morris M, Robinson GM, Strack PR, Savage MJ, Zaller DM, Zwierzynski I, Brandish PE (2015) Pharmacological inhibition of O-GlcNAcase does not increase sensitivity to glucocorticoid receptor-mediated transrepression. *PLoS One.* 10:e0145151.
12. Lucey BP, Gonzales C, Das U, Li J, Siemers ER, Slemmon JR, Bateman R, Huang Y, Fox GB, Claassen JAHR, Slats D, Verbeek MM, Tong G, Soares H, Savage MJ, Kennedy M, Forman M, Sjogren M, Margolin R, Chen X, Farlow MR, Dean RA, Waring JF. (2015) Integrated Multi-study Analysis of Intra-Subject Variability in Cerebrospinal Fluid Amyloid- β Concentrations Collected by Lumbar Puncture and Indwelling Lumbar Catheter. *Alzheimers Res Ther.* 7:53

13. Savage MJ, Holder DJ, Wu G, Kaplow J, Siuciak JA, Potter WZ, ADNI, FNIH Biomarkers Consortium. (2015) Soluble BACE-1 activity and sAPP β levels measured in AD and age-matched healthy control CSF from the ADNI-1 baseline cohort. *J Alzheimers Dis.* 46:431-440.
14. Chu X, Shih SJ, Shaw R, Hentze H, Chan GH, Owens K, Wang S, Cai X, Newton D, Castro-Perez J, Salituro G, Palamanda J, Fernandis A, New LS, Liaw A, Savage MJ, Evers R. (2015) Evaluation of cynomolgus monkeys for the identification of endogenous biomarkers for hepatic transporter inhibition and as a translatable model to predict pharmacokinetic interactions with statins in humans. *Drug Metab Dispos.* 2015 Mar 26.
15. Seeburger JL, Holder DJ, Combrinck M, Joachim C, Laterza O, Tanen M, Dallob A, Chappell D, Snyder K, Flynn M, Simon A, Modur V, Potter W, Wilcock G, Savage MJ, Smith AD. (2015) Cerebrospinal Fluid Biomarkers Distinguish Postmortem-Confirmed Alzheimer's Disease from Other Dementias and Healthy Controls in the OPTIMA Cohort. *J Alzheimers Dis.*, 44:525-539.
16. Converso A, Hartingh T, Fraley ME, Garbaccio RM, Hartman GD, Huang SY, Majercak JM, McCampbell A, Na SJ, Ray WJ, Savage MJ, Wolffe C, Yeh S, Yu Y, White R, Zhang R. (2014) Adenosine analogue inhibitors of S-adenosylhomocysteine hydrolase. *Bioorg Med Chem Lett.*, 24:2737-2740.
17. Dobrowolska JA, Michener MS, Wu G, Patterson BW, Chott R, Ovod V, Pyatkivskyy Y, Wildsmith KR, Kasten T, Mathers P, Dancho M, Lennox C, Smith BE, Gilberto D, McLoughlin D, Holder DJ, Stamford AW, Yarasheski KE, Kennedy ME, Savage MJ, Bateman RJ. (2014) CNS Amyloid- β , Soluble APP-a and - β Kinetics during BACE Inhibition. *J Neurosci.*, 34:8336-8346.
18. Savage MJ, Kalinina J, Wolfe A, Tugusheva K, Korn R, Cash-Mason T, Maxwell JW, Hatcher NG, Haugabook SJ, Wu G, Howell BJ, Renger JJ, Shughrue PJ, McCampbell A. (2014) A sensitive a β oligomer assay discriminates Alzheimer's and aged control cerebrospinal fluid. *J Neurosci.*, 34:2884-2897.
19. Wu G, Miller RA, Connolly B, Marcus J, Renger J, Savage MJ (2014) Pyroglutamate-Modified Amyloid- β Protein Demonstrates Similar Properties in an Alzheimer's Disease Familial Mutant Knock-In Mouse and Alzheimer's Disease Brain. *Neurodegener Dis.*, 14:53-66.
20. Wu G, Sankaranarayanan S, Wong J, Tugusheva K, Michener MS, Shi X, Cook JJ, Simon AJ, Savage MJ (2012) Characterization of plasma β -secretase (BACE1) activity and soluble amyloid precursor proteins as potential biomarkers for Alzheimer's disease. *J Neurosci Res.*, 90:2247-2258.
21. Wu G, Sankaranarayanan S, Montgomery DL, Simon AJ, An Z, Savage MJ (2011) Pharmacological applications of a novel neopeptide antibody to a modified amyloid precursor protein-derived beta-secretase product. *Protein Cell*, 2:573-584.

22. Wu G, Sankaranarayanan S, Hsieh SH, Simon AJ, Savage MJ. (2011) Decrease in brain soluble amyloid precursor protein β (sAPP β) in Alzheimer's disease cortex. *J Neurosci Res.*, 89:822-32.
23. McCampbell A, Wessner K, Marlatt MW, Wolffe C, Toolan D, Podtelezchnikov A, Yeh S, Zhang R, Szczerba P, Tanis KQ, Majercak J, Ray WJ, Savage MJ. (2011) Induction of Alzheimer's-like changes in brain of mice expressing mutant APP fed excess methionine. *J. Neurochem.*, 116:82-92.
24. Veng L, Savage MJ, Barrow JC, Zerbinatti CV (2010) Non-Amyloid Approaches to Alzheimer's Disease. *Burger's Medicinal Chemistry, Drug Discovery and Development*. Editors: Abraham DJ, Rotella DP, vol. 8 – CNS Disorders. 7th edition, Wiley Press.
25. Savage MJ, Gingrich DE (2009) Advances in the Development of Kinase Inhibitor Therapeutics for Alzheimer's Disease. *Drug Dev. Res.* 70:125-144.
26. Flood DG, Lin YG, Lang DM, Trusko SP, Hirsch JD, Savage MJ, Scott RW, Howland DS (2009) A Transgenic Rat Model of Alzheimer's Disease with Extracellular A β Deposition. *Neurobiol. Aging*, 30:1078-1090.
27. Chang EH, Savage MJ, Flood DG, Levy RB, Aoki C, Thomas JT, Huerta PT (2006) AMPA receptors are selectively impaired at the onset of pathology in double knock-in mouse model of Alzheimer's Disease. *Prod. Natl. Acad. Sci USA*, 103:3410-3415.
28. Wu Z-L, Ciallella, JR, Flood, DG, Bozyczko-Coyne D, Savage MJ (2006) Comparative Analysis of Cortical Gene Expression in Mouse Models of Alzheimer's Disease. *Neurobiol Aging*, 27:377-386.
29. Wu Z-L, O'Kane TM, Scott RW, Savage MJ, Bozyczko-Coyne D (2002) Protein tyrosine phosphatases are up regulated and participate in cell death induced by polyglutamine expansion. *J. Biol. Chem.*, 277:44208-44213.
30. Savage MJ, Lin YG, Ciallella JR, Flood DG, Scott RW (2002) Activation of c-Jun N-terminal kinase and p38 in an Alzheimer's disease model is associated with amyloid deposition. *J. Neurosci.*, 22:3376-3385.
31. Flood DG, Reaume AG, Dorfman KS, Lin YG, Lang DM, Trusko SP, Savage MJ, Siman R, Scott RW (2002) Familial Alzheimer's disease mutation in Presenilin-1 gene-targeted mice: enhanced A β 42 production and generation of a model of amyloid deposition without amyloid precursor protein overproduction. *Neurobiol. Aging*, 23:335-348.
32. Maroney AC, Finn JP, Connors TJ, Durkin JT, Angeles T, Gessner G, Xu Z, Meyer SL, Savage MJ, Greene LA, Scott RW, Vaught JL (2001) CEP-1347 (KT7515), A Semi-Synthetic Inhibitor Of The MLK Family. *J Biol Chem*, 276:25302-25308.
33. Yeon SW, Jung MW, Ha MJ, Kim SU, Huh K, Savage MJ, Masliah E, Mook-Jung I (2001) Blockade of PKC ϵ activation attenuates phorbol ester-induced increase of a-secretase-derived secreted form of amyloid precursor protein. *Biochem. Biophys. Res. Com.*, 280:782-787.

34. Siman R, Reaume AG, Savage MJ, Scott RW, Flood DG (2000) Presenilin-1 P264L knock-in mutation: Differential effects on A β production, amyloid deposition, and neuronal vulnerability. *J. Neurosci.*, 20:8717-8720.
35. Horsburgh K, Cole GM, Yang F, Savage MJ, Greenberg BD, Gentleman SM, Graham DI, Nicoll JA (2000) beta-Amyloid (A β)₄₂(43), abeta₄₂, abeta₄₀ and apoE immunostaining of plaques in fatal head injury. *Neuropathol. Appl. Neurobiol.*, 26:124-132.
36. Durkin JT, Murthy S, Husten EJ, Trusko SP, Savage MJ, Rotella DP, Greenberg BD, Siman R (1999) Rank-order of potencies for inhibition of the secretion of A β ₄₀ and A β ₄₂ suggests that both are generated by a single β -secretase. *J. Biol. Chem.*, 274:20499-20504.
37. Howland DS, Trusko SP, Savage MJ, Reaume AG, Lang DM, Hirsch JD, Maeda N, Siman R, Greenberg BD, Scott RW, Flood DG (1998) Modulation of secreted β -amyloid precursor protein and amyloid β -peptide in brain by cholesterol. *J. Biol. Chem.*, 273:16576-16582.
38. Savage MJ, Trusko S., Howland DS, Pinsker LR, Mistretta S, Reaume AG, Greenberg BD, Siman R, Scott RW (1998) Turnover of amyloid β -protein in mouse brain and acute reduction of its levels by phorbol ester. *J. Neurosci.*, 18:1743-1752.
39. Gentleman SM, Greenberg BD, Savage MJ, Friman R, Noori M, Newman SJ, Roberts GW, Griffen WS, Graham DI (1997) A β ₄₂ is the predominant form of amyloid β -protein in the brains of short-term survivors of head injury. *Neuroreport*, 8:1519-1522.
40. Reaume AG, Howland DS, Trusko SP, Savage MJ, Lang DM, Greenberg BD, Siman R, Scott RW (1996) Enhanced amyloidogenic processing of the β -amyloid precursor protein in gene-targeted mice bearing the Swedish familial Alzheimer's disease mutations and a "humanized" A β sequence. *J. Biol. Chem.*, 271:23380-23388.
41. Greenberg BD, Savage MJ, Howland DS, Ali SM, Siedlak SL, Perry G, Siman R, Scott RW (1996) APP transgenesis: Approaches toward the development of animal models for Alzheimer's disease neuropathology. *Neurobiol. Aging*, 17:153-171.
42. Kalaria RN, Cohen D., Savage M J, Greenberg BD, Bogdabivucm NE, Winblad B, Lannfelt L, Adem A (1996) Abundance of the longer A β ₄₂ in neocortical and cerebrovascular amyloid β deposits in Swedish familial Alzheimer's disease and Down's syndrome. *Neuroreport*, 7:1377-1381.
43. Siman R, Bozyczko-Coyne D, Savage MJ, Roberts-Lewis JM (1996) The calcium-activated protease calpain I and ischemia-induced neurodegeneration. *Advances in Neurology*, Siesjo, B.K., Wieloch, T., Eds., Lippencott-Raven, 71:167-175.
44. Cummings BJ, Satou T, Head E, Milgram NW, Cole GM, Savage MJ, Podlisny MB, Selkoe DJ, Siman R, Greenberg BD, Cotman CW (1996) Diffuse plaques contain C-terminal A β ₄₂ and not A β ₄₀: Evidence from cats and dogs. *Neurobiol. Aging*, 17:653-659.

45. Ali SM, Siedlak SL, Gonzalez-DeWhitt PA, Altman RA, Glendening JM, Lowery DE, Savage MJ, Polites HG, Perry G, Greenberg BD (1996) Artfactual strain-specific signs of incipient brain amyloidosis in APP transgenic mice. *Neurobiol. Aging*, 17:223-234.
46. Savage MJ, Kawooya J, Pinsker LR, Emmons TL, Mistretta SM, Siman R, Greenberg BD (1995) Elevated A β levels in Alzheimer's disease brain are associated with selective accumulation of A β 42 in parenchymal amyloid deposits and both A β 40 and A β 42 in cerebrovascular deposits. *Amyloid: Int. J. Exp. Clin. Invest.*, 2:234-240.
47. Siman R, Durkin JT, Husten EJ, Savage MJ, Murthy S, Mistretta S, Chatterjee S, Dembofsky B, Poorman R, Greenberg BD (1995) Genesis and degradation of A β protein by cultured human neuroblastoma cells. *Research advances in Alzheimer's Disease and Related Disorders*, Iqbal, K., Mortimer, J.A., Winblad, B., Wisniewski, H.M., Eds., John Wiley and Sons, 675-684.
48. Howland DS, Savage MJ, Huntress FA, Wallace RE, Schwartz DA, Loh T, Melloni RH, DeGennaro LJ, Greenberg BD, Siman R, Swanson ME, Scott RW (1995) Mutant and native human β -amyloid precursor proteins in transgenic mouse brain. *Neurobiol. Aging*, 16:685-699.
49. Savage MJ, Howland DH, Scott DW, Greenberg BD (1995) APP transgenesis: Approaches towards the development of animal models for Alzheimer's disease neuropathology. *Neurobiology of Alzheimer's Disease*, Dawbarn, D., Allen, S.J., Eds., BIOS Scientific Publishers Limited, 149-192.
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51. Savage MJ, Iqbal M, Loh T, Trusko S, Scott R, Siman R (1994) Cathepsin G: Localization in human cerebral cortex and generation of amyloidogenic fragments from the β -amyloid precursor protein. *Neuroscience*, 60:607-619.
52. Roberts-Lewis JM, Savage MJ, Marcy VR, Pinsker LR, Siman R (1994) Immunolocalization of calpain I-mediated spectrin degradation to vulnerable neurons in the ischemic gerbil brain. *J. Neurosci.*, 14:3934-3944.
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57. Savage MJ, Goldberg DJ, Schacher S (1987) Absolute specificity for retrograde fast axonal transport displayed by lipid droplets originating in the axon of an identified *Aplysia* neuron in vitro. *Brain Res.*, 406:215-223.