# Michelle Baladi, PhD

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## Key Qualifications

- Scientific and therapeutic experience in neuroscience for orphan and prevalent diseases (e.g., psychiatry, epilepsy, sleep, movement disorders)
- Provides clinical development leadership and strategic input to early and late-stage development programs
- Effectively leads cross-functional teams with ability to form strong relationships with internal and external collaborators
- Excellent ability to interpret clinical data and contextualize within the benefit/risk framework
- Direct experience with regulatory interactions (FDA, EMA, and PMDA), preparation of regulatory filings, and successful US/EU regulatory approvals (i.e., Sunosi™)
- Excellent written/verbal communication skills and high emotional intelligence

## Employment

Jazz Pharmaceuticals, Palo Alto, CA

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|---|---|
| *Executive Director, Clinical Development – Neuroscience* | 2022-present |
| *Senior Director, Global Development Lead, Clinical Development – Neuroscience* | 2021-2022 |
| *Director, Global Development Lead, Clinical Development - Neuroscience* | 2019-2021 |
| *Associate Director, Clinical Development - Neuroscience* | 2017-2019 |
| *Senior Manager, Clinical Development - Neuroscience* | 2015-2017 |

- Leads a cross-functional R&D Clinical Development Team (e.g., clinical operations, data management, biostatistics, clinical pharmacology, regulatory) to develop and execute the clinical development strategy and plans in alignment with the overall molecule strategy and Target Product Profile.
- Provides clinical development leadership and represents Clinical Development Team members on the Global Molecule Strategy Team.
- Presents at internal governance and executive committee meetings to facilitate program and go/no-go decisions.
- Provides clinical and scientific expertise on the integrated development plan, including pre-clinical, clinical pharmacology, commercial development (e.g., target product profile), and medical affairs (e.g., evidence generation planning, scientific platforms).
- Integrates clinical and regulatory strategy for development programs and consolidates insights from global and regional teams.
- Leads patient centric initiatives to incorporate the patient perspective and voice into development plans (via patient survey studies, advisory boards, and advocacy groups).
- Pro-actively identifies and interacts with key opinion leaders and academic organizations to incorporate latest clinical thinking and guidelines into clinical development plans.
- Provides leadership to and manages 4 direct reports within clinical development.
- Provides abuse liability expertise for strategy and study design across neuroscience programs
- Provides leadership and oversight of clinical trial protocol design to ensure scientific quality and that studies are delivered on time and on budget.
- Provides clinical content for relevant documents (e.g., CSRs, IBs, DSURs) and regulatory filings (e.g., NDA/MAA, briefing books, PSPs/PIPs).
- Contributes to publication strategy, manuscript/abstract preparation, and presents data at scientific meetings.
- Participates in neuroscience diligence activities for external opportunities as a clinical development subject matter expert.

Huntsman Cancer Institute, Salt Lake City, UT 2/15-8/15
*Research Scientist*

- Designs, executes, and interprets in vivo studies focused on identifying candidate molecules and targets within the area of oncology.
- Investigates novel therapeutic combinations and sets the pharmacology strategy in preclinical models in support of proposed clinical studies.
- Supports multiple projects and serves as an expert resource in pharmacology by team members.
- Interacts with multidisciplinary groups across the Institute including bioinformatics, regulatory, and clinical development groups.

Department of Pharmacology and Toxicology, University of Utah, Salt Lake City, UT 2011-2015
*Research Scientist*

- Developed, designed and implemented pharmacology/toxicology studies to characterize the effects of drugs, drug interactions, and target proteins.
- Provided scientific and team leadership in the conduct and reporting of research studies.
- Independently wrote publications and summarized studies for scientific presentations.
- Maintained knowledge of relevant scientific and DEA regulatory practices.
- Collaborated and recommended strategies with internal research groups to facilitate evaluation of drug mechanism and action.
- Trained research assistants, undergraduate, and graduate students.

Department of Pharmacology, University of Texas Health Science Center, San Antonio, TX 2006-2011
*Research Scientist*

- Designed, analyzed, and interpreted pharmacokinetic/pharmacodynamics studies.
- Worked on complex scientific problems that required an in-depth evaluation and team discussion of various factors.
- Effectively communicated research findings for publications and presentations.
- Managed and trained several research assistants and students.
- Successfully established several collaborations with other internal and external research groups for multidimensional analysis.

Department of Pharmacology, University of Michigan, Ann Arbor, MI 2004-2006
*Research Scientist*

- Conducted non-clinical studies for a novel protein-based therapy in support of proposed clinical studies.
- Engaged in drug discovery studies to assess mechanism of action of drugs.
- Increased productivity and efficiency of laboratory by independently managing several research projects.
- Accountable for critical study reports and complied data for multiple projects.

## Education & Training

- PhD, Pharmacology, University of Texas Health Science Center, San Antonio, TX 2011
- BS, Biopsychology, University of Michigan, Ann Arbor, MI 2004

**Original Publications in Peer-reviewed Journals**

1) Jutkiewicz EM, Baladi MG, Rice KC, Woods JH (2006) The convulsive and electroencephalographic changes produced by nonpeptidic delta-opioid agonists in rats: comparison with pentylenetetrazol. *J Pharmacol Exp Ther* 317: 1337-48.
2) Jutkiewicz EM, Baladi MG, Folk JE, Rice KC, Woods JH (2008) The delta-opioid receptor agonist SNC80 [(+)-4-[alpha(R)-alpha-[(2S,5R)-4-allyl-2,5-dimethyl-1-piperazinyl]-(3-methoxybenzyl)-N,N-diethylbenzamide] synergistically enhances the locomotor-activating effects of some psychomotor stimulants, but not direct dopamine agonists, in rats. *J Pharmacol Exp Ther* 324: 714-24.
3) Jutkiewicz EM, Baladi MG, Cooper ZD, Narasimhan D, Sunahara RK, Woods JH (2009) A bacterial cocaine esterase protects against cocaine-induced epileptogenic activity and lethality. *Ann Emerg Med* 54: 409-420.
4) Baladi MG and France CP (2009) High fat diet and food restriction differentially modify the behavioral effects of quinpirole and raclopride in rats. *Eur J Pharmacol* 610: 55-60.
5) Baladi MG, Newman AH, France CP (2010) Dopamine D3 receptors mediate the discriminative stimulus effects of quinpirole in free-feeding rats. *J Pharmacol Exp Ther* 332: 308-315.
6) Baladi MG and France CP (2010) Eating high-fat chow increases the sensitivity of rats to quinpirole-induced discriminative stimulus effects and yawning. *Behav Pharmacol* 21: 615-620.
7) McGuire BA, Baladi MG, France CP (2011) Eating high-fat chow enhances sensitization to the effects of methamphetamine on locomotion in rats. *Eur J Pharmacol* 658: 156-159.
8) Baladi MG, Newman AH, France CP (2011) Influence of body weight and type of chow on the sensitivity of rats to the behavioral effects of the direct-acting dopamine receptor agonist quinpirole. *Psychopharmacology* 217: 573-585.
9) Baladi MG, Newman AH, Thomas YM, France CP (2011) Drinking sucrose enhances quinpirole-induced yawning in rats. *Behav Pharmacol* 22: 773-780.
10) Li JX, Ju S, Baladi MG, Koek W, France CP (2011) Eating high fat chow increases the sensitivity of rats to 8-OH-DPAT induced lower lip retraction. *Behav Pharmacol* 22: 751-757.
11) Baladi MG, Thomas YM, France CP (2012) Sensitivity to apomorphine-induced yawning and hypothermia in rats eating standard or high-fat chow. *Psychopharmacology* 222: 27-36.
12) Baladi MG, Koek W, Aumann M, Velasco F, France CP (2012) Eating high fat chow enhances the locomotor-stimulating effects of cocaine in adolescent and adult female rats. *Psychopharmacology* 222: 447-457.
13) Baladi MG, Daws LC, France CP (2012) You are what you eat: Influence of type and amount of food consumed on central dopamine systems and the behavioral effects of direct- and indirect-acting dopamine receptor agonists. *Neuropharmacology* 63: 76-86.
14) Baladi MG, Newman AH, France CP (2014) Feeding condition and the relative contribution of different dopamine receptor subtypes to the discriminative stimulus effects of cocaine in rats. *Psychopharmacology* 231: 581-591.
15) Baladi MG, Newman AH, Nielsen SM, Hanson GR, Fleckenstein AE (2014) Dopamine D3 receptors contribute to methamphetamine-induced alterations in dopaminergic neuronal function: role of hyperthermia. *Eur J Pharmacol* 732: 105-110.
16) Baladi MG, Nielsen SM, Umpierre A, Hanson GR, Fleckenstein AE (2014) Prior methylphenidate self-administration alters the subsequent reinforcing effects of methamphetamine in rats. *Behav Pharmacol* 25: 758-765.
17) Baladi MG, Horton RE, Owens WA, Daws LC, France CP (2015) Eating high fat chow decreases dopamine clearance in adolescent and adult male rats, but selectively enhances the locomotor stimulating effects of cocaine in adolescents. *Int J Neuropsychopharmacol* 24: 1-11.
18) German CL, Baladi MG, McFadden LM, Hanson GR, Fleckenstein, AE (2015) Regulation of the dopamine and vesicular monoamine transporters: Pharmacological targets and implications for disease. *Pharmacological Reviews* 67: 1004-1024.
19) Baladi MG, Nielsen SM, Hanson GR, Fleckenstein AE (2015) Prior nicotine self-administration attenuates subsequent dopaminergic deficits of methamphetamine in rats: Role of nicotinic acetylcholine receptors *Behav Pharmacol* 27: 422-430.
20) Baladi MG, Forster MJ, Gatch MB, Mailman RB, Hyman DL, Carter LP, Janowsky (2018) Characterization of the neurochemical and behavioral effects of solriamfetol (JZP-110), a selective dopamine and norepinephrine reuptake inhibitor *J Pharmacol Exp Ther 366: 367-376.*

21) Malhotra A, Shapiro C, Pepin JL, Hedner J, Ahmed M, Foldvary-Schaefer N, Strollo PJ, Mayer G, Sarmiento K, Baladi M, Chandler P, Lee L, Schwab R (2020) Long-term study of the safety and maintenance of efficacy of solriamfetol (JZP-110) in the treatment of excessive sleepiness in participants with narcolepsy or obstructive sleep apnea. *Sleep* 43(2).
22) Schweitzer PK, Strohl KP, Mayer Geert, Rosenberg R, Chandler P, Baladi M, Lee L, Malhotra A (2021) Effects of solriamfetol in a long-term trial of participants with obstructive sleep apnea who are adherent or nonadherent to airway therapy. *Journal of Clinical Sleep Medicine* 17(4).
23) Rosenberg R, Baladi M, Bron M (2020) Clinically relevant effects of solriamfetol on excessive daytime sleepiness: a posthoc analysis of the magnitude of change in clinical trials in adults with narcolepsy or obstructive sleep apnea. *Journal of Clinical Sleep Medicine* 17(4).
24) Schweitzer PK, Mayer G, Rosenberg R, Malhotra A, Zammit GK, Gotfried M, Chandler P, Baladi M, Strohl KP (2021). Randomized Controlled Trial of Solriamfetol for Excessive Daytime Sleepiness in OSA: An Analysis of Subgroups Adherent or Nonadherent to OSA Treatment. *Chest* 160(1).
25) Rosenberg R, Babson K, Menno D, Morris S, Baladi M, Hyman D, Black J (2021). Test-retest reliability of the Epworth Sleepiness Scale in clinical trial settings. *J Sleep Res* 20:e13476.
26) Weaver TE, Pepin JL, Schwab R, Shapiro C, Hedner J, Ahmed M, Foldvary-Schaefer N, Strollo PJ, Mayer G, Sarmiento K, Baladi M, Bron M, Chandler P, Lee L, Malhotra A (2021). Long-term effects of solriamfetol on quality of life and work productivity in participants with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. *J Clin Sleep Med* 17(10).

## Book Chapters

1) Baladi MG and Carter LP (2016) Drug discrimination studies for investigations on the mechanisms of actions of $GABA_B$ receptor ligands, in $GABA_B$ receptor: 157-174. Springer International Publishing.

## Teaching

- University of Texas Health Science Center San Antonio (UTHSCSA), Pharmacy course: Guest lecturer — 2008
- University of Utah, Common Medicines course: Guest lecturer — 2012-2015
- University of Utah, Drugs and Behavior course: Guest lecturer — 2013-2015
- University of Utah, Introduction to Neuroscience: Guest lecturer — 2014

## Invited Presentations

- CPDD, co-chair and speaker at scientific symposium — 2011
- National Institute on Drug Abuse, speaker at scientific symposium — 2014
- CPDD, co-chair and speaker at scientific symposium — 2016
- ANA, speaker at scientific symposium — 2016

## Service

- Peer reviewer for Behavioural Pharmacology — 2014-present
- Peer reviewer for Journal of Pharmacology and Experimental Therapeutics — 2014-present

## Professional Societies

- American Academy of Sleep Medicine
- American Neurological Association
- American Academy of Neurology
- Movement Disorder Society
- American Society for Pharmacological and Experimental Therapeutics
- College on Problems of Drug Dependence