Natalie McClure, Ph.D.

Drug Development and Regulatory Affairs Consultant

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EXPERIENCE:

INDEPENDENT REGULATORY CONSULTANT
2018 - Present, Regulatory affairs and drug development consulting

ADAMAS PHARMACEUTICALS, Inc. Emeryville, CA
2013 - 2017, Sr Vice President, Product Development and Regulatory Affairs
2010 - 2013 Vice President, Regulatory Affairs

DEVRX CONSULTING, Portola Valley, CA
June 2008 - Present, Founder and Principal
Major Clients: Adamas Pharmaceuticals, Nuon Therapeutics, Medicines 360, Curasen, Pliant, Maze, Cytokinetics

CERIMON PHARMACEUTICALS, Inc. South San Francisco, CA
June 2005 - June 2008, Founder and Vice President, Regulatory Affairs

TULARIK Inc./AMGEN SF, South San Francisco, CA
2002 - 2004 Vice President, Regulatory Affairs and Compliance

INTRABIOTICS PHARMACEUTICALS, Inc., Mountain View, CA
1999 - 2002 Senior Vice President, Regulatory Affairs and Product Development

MATRIX PHARMACEUTICAL, Inc., Fremont, CA
1993 - 1999 Vice President, Regulatory Affairs and Quality Assurance

SYNTEX RESEARCH, Palo Alto, CA
1987 - 1993 Program Director, Regulatory Affairs
1979 - 1987 Institute of Organic Chemistry, Process Development Group

EDUCATION:

1979 Ph.D., Organic Chemistry, Stanford University
1974 B.S., Chemistry, University of Michigan

SIGNIFICANT ACCOMPLISHMENTS:

UC Berkeley Extension: I am the instructor for Principles in Regulatory Affairs, NDA/MAA Commercialization Processes and Regulatory Affairs in Drug Development for the UC Berkeley Extension program.

Adamas Pharmaceuticals: While at Adamas, I was the project team leader for the ADS-5102 (amantadine extended release capsules) project, with responsibility for leading the Pharm Dev, Clinical, Regulatory and Nonclinical research groups. This work culminated in the submission, approval and launch of Gocovri™ (amantadine) extended release capsules for the treatment of dyskinesia for people with Parkinson's disease. Gocovri is the first drug product approved for this indication and it was approved at the PDUFA date. I also was responsible for the regulatory strategy for ADS-8704, a fixed dose combination of extended release memantine and donepezil for the treatment of Alzheimer's disease. This product was licensed to Forest Labs (now Allergan) and is currently marketed as Namzaric® (memantine, donepezil) extended release capsules.

Cerimon Pharmaceuticals: I was one of the founders of Cerimon and assisted in the early rounds of funding and establishing the corporation. While at Cerimon, I filed 3 INDs in 3 years, multiple global CTAs, and took two programs into phase 2/3 trials. In addition, I supervised the conduct of the required toxicology studies, and provided the oversight for CMC operations. In addition, I was heavily involved with our business development group in due diligence reviews and assessments of strategic fit for many potential in-licensing product candidates. Finally, I established the necessary controls and SOPs to insure that Cerimon activities were conducted according to all FDA and ICH standards. I also worked closely with a Japanese drug product manufacturer to bring them into compliance with US GMPs.

Tularik Inc./Amgen SF, IntraBiotics, Inc., Matrix Pharmaceuticals: At these companies, I provided strategic regulatory affairs guidance for multiple clinical programs including global phase 3 oncology, dermatology and anti-infective drug products, and phase 1 and 2 programs in diabetes, obesity, inflammatory diseases and oncology. I also supervised QA departments, and oversaw the design and implementation of an electronic document management system. I was a member of the management team, and was responsible for the coordination of the Development Department's overall budget.

Syntex Research: I started my pharmaceutical career in the process development laboratories at Syntex Research where I developed, patented and transferred to production the large-scale process still in use for the manufacture of a decapeptide, nafarelin acetate (marketed as Synarel® for treatment of endometriosis). Also at Syntex, I transferred to regulatory affairs, where I was responsible for eight registration programs. In addition, I had primary responsibility for the chemistry, manufacturing and control sections for over 12 different drug products and prepared numerous drug master files. My responsibilities included US regulatory planning and working with the international affiliates on international regulatory compliance.

OTHER PROFESSIONAL EXPERIENCE:

- Chair Silicon Valley Section, American Chemical Society, 2008-9, 2011-12, 2022-23

- Fellow, American Chemical Society
- Organizer and Chair, Western Regional Meeting, American Chemical Society, Oct 2013
- Program committee member, FDA/DIA conference "Improve Agency/Industry Communication throughout the Drug Development Process", May, 2004
- Author, Book chapter titled "Regulatory Perspectives and Product Approval" published in Sustained Release Injectable Products, Interpharm Press, 1999
- Inventor on 4 patents
- 10+ publications of my research in the chemistry and medical scientific peer reviewed journals

NATALIE MCCLURE PUBLICATION LIST:

Amantadine extended release for levodopa-induced dyskinesia in Parkinson's disease (EASED Study)
Rajesh Pahwa, Caroline M. Tanner, Robert A. Hauser, Kapil Sethi, Stuart Isaacson, Daniel Truong, Lynn Struck, April E. Ruby, Natalie L. McClure, Gregory T. Went, Mary Jean Stempien
Mov Disord. 2015 May; 30(6): 788–795. Published online 2015 Feb 4. doi: 10.1002/mds.26159
PMCID: PMC5024015

Pharmacokinetics of ADS-5102 (Amantadine) Extended Release Capsules Administered Once Daily at Bedtime for the Treatment of Dyskinesia
Robert A. Hauser, Rajesh Pahwa, William A. Wargin, Cindy J. Souza-Prien, Natalie McClure, Reed Johnson, Jack T. Nguyen, Rajiv Patni, Gregory T. Went
Clin Pharmacokinet. 2019; 58(1): 77–88. Published online 2018 May 18. doi: 10.1007/s40262-018-0663-4
PMCID: PMC6325984

A Novel Once-Daily Fixed-Dose Combination of Memantine Extended Release and Donepezil for the Treatment of Moderate to Severe Alzheimer's Disease: Two Phase I Studies in Healthy Volunteers
Ramesh Boinpally, Laishun Chen, Stephen R. Zukin, Natalie McClure, Robert K. Hofbauer, Antonia Periclou
Clin Drug Investig. 2015; 35(7): 427–435. Published online 2015 May 28. doi: 10.1007/s40261-015-0296-4
PMCID: PMC4488451

A Randomized Double-Blind Phase 2 Study of Combination Antivirals for the Treatment of Influenza
John H Beigel, Yajing Bao, Joy Beeler, Weerawat Manosuthi, Alex Slandzicki, Sadia Majid Dar, John Panuto, Richard L. Beasley, Santiago Perez-Patrigeon, Gompol Suwanpimolkul, Marcelo H. Losso, Natalie McClure, Dawn R Bozzolo, Christopher Myers, H. Preston Holley, Jr., Justin Hoopes, H Clifford Lane, Michael D Hughes, Richard T Davey
Lancet Infect Dis. Author manuscript; available in PMC 2018 Dec 1.
Published in final edited form as: Lancet Infect Dis. 2017 Dec; 17(12): 1255–1265. Published online 2017 Sep 22. doi: 10.1016/S1473-3099(17)30476-0
PMCID: PMC5777222

exo,endo-3-[(Dimethylamino)methyl]-d-camphor: d-camphor Mannich products
Natalie L. McClure, Gui Yuan Dai, and Harry S. Mosher
Cite this: J. Org. Chem. 1988, 53, 11, 2617–2620
Publication Date: May 1, 1988
https://doi.org/10.1021/jo00246a042

Synthetic studies in the ajmaline series
Ian S. Cloudsdale, Arthur F. Kluge, and Natalie L. McClure
Cite this: J. Org. Chem. 1982, 47, 6, 919–928
Publication Date:March 1, 1982
https://doi.org/10.1021/jo00345a004

Directive effects in the electrophilic substitution of deltahedral boranes and heteroboranes. Halogenation of 1-thiadecaborane(9). Unusually long boron-11 spin-lattice relaxation timesW. L. Smith, B. J. Meneghelli, N. McClure, R. W. Rudolph, J. Am. Chem. Soc., 98, 624 (1976)

PATENT LIST:

United States Patent	**10,154,971**
Went, et al.	**December 18, 2018**

****Please see images for: (Certificate of Correction) ****

Methods of administering amantadine

Abstract

Methods of nighttime administration of amantadine to reduce sleep disturbances in patient undergoing treatment with amantadine are described, as well as compositions of extended release amantadine that are suitable for nighttime administration.

Inventors: **Went; Gregory T.** (Mill Valley, CA)**, Fultz; Timothy J.** (Jasper, GA)**, *McClure*; Natalie** (Portola Valley, CA)

Applicant:	**Name**	**City**	**State**	**Country**	**Type**
	***Adamas* Pharma, LLC**	Emeryville	CA	US	

Assignee: ***Adamas* Pharma, LLC** (Emeryville, CA)

Family ID: 52105179
Appl. No.: 14/307,195
Filed: June 17, 2014

United States Patent	**5,212,288**

Temporary minimal protection synthesis of serine-containing polypeptides

Abstract

In a process for the solid phase synthesis of a polypeptide containing at least one serine residue, the improvement comprising temporarily protecting the side chain of the serine residue with a protecting group which is removed immediately following the addition of the serine to the peptide chain.

Inventors: **Nestor, Jr.; John J.** (Cupertino, CA)**, *McClure*; Natalie L.** (Portola Valley, CA)**, Arzeno; Humberto** (Cupertino, CA)

Assignee: ***Syntex*** **(U.S.A.) Inc.** (Palo Alto, CA)

Family ID: **27047278**

Appl. No.: **07/654,149**

Filed: **February 8, 1991**

BOOK CHAPTER:

Book chapter titled “Regulatory Perspectives and Product Approval” published in Sustained Release Injectable Products, Interpharm Press, 1999