DAVID Y. MITCHELL, PH.D.

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SUMMARY OF QUALIFICATIONS

Strong leader and scientist with 20 years experience in the pharmaceutical industry. Proven leadership in clinical pharmacology programs at Pfizer and Procter & Gamble Pharmaceuticals, and as Development Team Leader at Array BioPharma, OSI Pharmaceuticals, and Pfizer. Goal oriented with the ability to see the big picture and adjust quickly to changing situations to consistently exceed expectations.

Technical

- Phase 1-4 Clinical Study Design Experience
- Pharmacokinetic / Toxicokinetic Data Analysis / Interpretation / Report Writing
- IND, IB, EOP2 and NDA/MAA Regulatory Experience
- Label Updates and PSUR Experience
- Strong Publication Record

Management / Organizational

- Leadership and Team-Building
- Development / Management of Portfolio Budget / Resources
- Strategic Planning
- Building Co-Development Partnerships
- Project Planning and Management

PROFESSIONAL EXPERIENCE

MITCHELL PHARMACEUTICAL CONSULTING, LLC, Lafayette, CO **2009 - present**

President / Owner

Mitchell Pharmaceutical Consulting provides a full complement of services, including:

- Clinical Pharmacology
  - Phase 1-4 protocol design and development
  - Pharmacokinetic / toxicokinetic data analysis, interpretation, and report writing
  - Completion of clinical study reports
  - Regulatory documents
    - IND, FDA End of Phase 2 and pre-NDA documents, EU Scientific Advice briefing documents
    - Investigator brochures
    - EU renewal for marketing authorization (clinical pharmacology section)
    - Labeling variations (EMA) and supplements (FDA) (i.e., drug interactions, special populations, QTc)
    - Respond to label / product monograph / CCDS questions from health authorities
    - Summary documents for health authority queries (i.e., PK waivers, ethnic and gender differences)
    - Periodic safety update report (PSUR, clinical pharmacology section)
  - Clinical pharmacology representative on project teams
  - Clinical Pharmacology sections of comprehensive clinical development plan
  - Writing of abstracts, posters, and manuscripts (clinical pharmacology focus)
- Project / program management
  - Development of target product profile and development plans
  - Project and program management
  - Generation of product communication plan, or annual corporate communication calendar
  - Development of:
    - Product review process; team and governance structure guidance; risk management plans; clinical pharmacology guidelines; product communication plan; or annual corporate communication calendar
- Due diligence

ARRAY BIOPHARMA INC., Boulder, CO **2007 – 2009**

Director / Department Head / Program Team Leader

Project Planning & Management

Co-leader of three to five program teams in development in the areas of oncology, inflammation, and diabetes.

- Led development teams to establish and execute product strategy in alignment with corporate objectives that resulted in project team goals completed in a timely, cost effective and quality manner.
- Reviewed clinical protocols, study reports, regulatory documents, and publications. Utilized expertise in early drug development (clinical pharmacology/pharmacokinetics) to optimize protocol designs, interpret study data, and plan development program.
- Partnered with commercial to develop target product profile and communication strategy to ensure alignment between the program teams and the Executive Management Team.

Leader of monthly Development Planning Committee and bi-weekly Issue Triage Meeting.

- Led Development Planning Committee to ensure program teams provided management the following information:
  - Review of new and significant clinical and nonclinical data; discussion of API and clinical supply issues;
  - Changes to clinical and regulatory strategy;
  - Identification of goals obtained, delayed, or accelerated; and discussion of timeline and resource issues.
- Led Issue Triage Committee to ensure potential study issues were addressed in timely manner.

Management responsibilities and process development.

- Supervised three project managers that were responsible for co-leading six program teams in development and support of up to three discovery projects. Utilized personal management interviews (PMIs) with managers to identify project issues early and to facilitate personal growth opportunities for the individual.
- Established program team and governance structure that increased meeting effectiveness, and that ensured a process was followed for the approval of new strategy and protocols, and changes in the budget or resourcing.
- Developed portfolio review process to review clinical, non-clinical, and CMC plans for each program.
- Developed 2-year corporate planning calendar to coordinate portfolio review, annual budgeting process, corporate communication plan, and board meetings, and to ensure executive management were informed of when specific milestones would be met by the organization.
- Collaborated with finance and clinical outsourcing to establish, update and review budget on a quarterly basis to accurately determine rate of spending and to identify opportunities to conserve funds.
- Member of Protocol Review Committee responsible for the review and approval of clinical protocols.
- Interim supervisor for Regulatory Affairs Department, including 5 regulatory program managers and 2 regulatory associates, focusing on the filing and maintenance of INDs.

OSI PHARMACEUTICALS, Boulder, CO **2005 – 2007**

Director / Project Team Leader

Project Management

Leader of early and post-approval oncology development teams accountable for establishing project goals and development plan in alignment with corporate objectives. Ensured a seamless project delivery in a timely, cost effective and quality manner.

- Led team consisting of commercial, clinical, biostatistics, preclinical and regulatory sub-team members, and co-development partners, to develop and execute the global product strategy.
- Ensured appropriate expertise (clinical, preclinical, and statistical) was utilized to prepare and respond to regulatory documents related to submissions in Europe and Japan.
- Served as primary point of contact with senior management committees. Accountable for presentation of data, identification of issues and proposed resolutions.
- Reviewed external co-development partners' multi-million dollar budget and identified costs and tasks that were not associated with a program goals resulting in cost savings.

Led or participated as a key member of committees to design and develop guidelines and process improvements:

- Wrote guidelines describing the process for the publication and presentation of clinical trials to ensure consistency across clinical programs.
- Established a new project team structure, agendas, and meeting minutes that increased meeting effectiveness.
- Identified redundancies in monthly and quarterly report process and implemented a process to complete the reports in an efficient and timely manner.

PFIZER GLOBAL RESEARCH & DEVELOPMENT, Ann Arbor, MI **1999 – 2005**

Senior Director / Development Team Leader, **2003-2005**

Oncology and Neuroscience Therapeutic Area Team, Medical and Development Sciences

Leader of neuroscience development team accountable for delivering on project goals as established in the development plan and aligned with corporate goals. Ensured project team core members (8) included appropriate team goals as personal goals, and co-responsible for annual performance evaluation of core team members.

- Single-point of accountability between project team and senior management. Presented data, identified issues and potential resolutions to issues, and team's recommended path forward.
- Collaborated with commercial sub-team leader to develop a target product profile that integrated commercial needs with clinical and outcomes research.
- Proposed and managed multi-million dollar clinical and manufacturing budget to within 4% of forecast.
- Met with key opinion leaders to discuss potential development plans for a novel sleep indication and determine the medical need for treatment.
- Utilized personal management interviews (PMIs) with key team members to identify project issues early, solicited team meeting agenda items, and to facilitate personal growth opportunities for the individual resulting in highest team effectiveness ratings at Pfizer.
- Co-authored 2 peer-reviewed articles and 2 abstracts at meetings describing an insomnia compound.
- Co-inventor of patent describing the use of alpha-2-delta ligands for nonrestorative sleep.

Key member and spokesperson of speed-to-market committee charged with developing process improvements to shorten development timelines and the time to complete clinical trials.

- Prepared and presented current and proposed clinical trial metrics to therapeutic area leadership teams.
- Established clinical trial metrics to be challenging but attainable, and that should place Pfizer in top 5-10% of pharmaceutical companies. New metrics were incorporated into team member's individual goals.

Senior Research Associate & Associate Director **1999-2001 & 2001-2003**

Clinical Pharmacokinetics & Pharmacodynamics Department

Clinical Sciences Team Leader responsible for completion of clinical pharmacology studies for central nervous system (CNS) and oncology drug development candidates.

- Designed, implemented, analyzed, and reported clinical pharmacology studies according to GCP and FDA and EU regulatory guidelines in therapeutic areas of insomnia, anxiety, schizophrenia, and oncology.
- Wrote clinical pharmacokinetics section of development plan, investigators brochure, and as needed, regulatory documents for 4 drug candidates.
- Prepared clinical sciences budget, including identification of personnel needs, for a co-development project with a small biotech company.
- Co-authored 3 peer-reviewed articles for an oncology compound; presented 6 abstracts at international meetings on clinical pharmacokinetics and metabolism of potential anxiety and oncology compounds.

PROCTER & GAMBLE PHARMACEUTICALS, Norwich, NY and Cincinnati, OH **1992 – 1999**

Pharmacokineticist & Senior Pharmacokineticist **1992-1996 & 1996-1999**

Clinical Pharmacology and Pharmacokinetics

Clinical Pharmacology Team Leader of 10-member multi-department team that was responsible for clinical pharmacology and pharmacokinetics studies.

- Designed, implemented, analyzed, and reported numerous clinical pharmacology studies in the therapeutic areas of bone disease (Paget's disease and osteoporosis) and hypertension.
- Completed human pharmacokinetics and bioavailability section for NDA (2), pharmacokinetics section for NDS (2), summary for European filings, and clinical pharmacology section of product label (Actonel®, for Paget's disease and osteoporosis). Defended submissions with the appropriate regulatory agencies.
- Worked with Ajinomoto to assist in the clinical development of Actonel® in Japan.
- Authored 6 peer-reviewed journal articles and presented 13 abstracts at international meetings describing the clinical pharmacokinetic attributes of Actonel®.
- Leader of clinical sub-team to design, implement, analyze and report pediatric studies that resulted in obtaining an additional 6-months exclusivity for a marketed product for hypertension.

PFIZER INC., Groton, CT **1990 – 1992**

Research Scientist

Drug Metabolism Department

Laboratory supervisor responsible for the preclinical and clinical pharmacokinetic and metabolism studies for anti-inflammatory drug candidates.

- Worked on compounds from early discovery through phase 3.
- Supervised up to 4 laboratory technicians.
- Co-authored 2 peer-reviewed journal articles, and 3 abstracts at international meetings describing nonclinical pharmacokinetics of anti-inflammatory compounds.

EDUCATION

Postdoctoral Fellowship, Department of Pharmacology, Toxicology & Therapeutics, University of Kansas, School of Medicine, Kansas City, Kansas

Ph.D., Pharmaceutical Sciences, University of Colorado, Boulder, Colorado

BA, Biological Sciences, University of Northern Colorado, Greeley, Colorado

PROFESSIONAL DEVELOPMENT

Leading the Organization – University of Michigan, School of Business, Ann Arbor, 2004.

Leadership Practices in Action - University of Michigan, School of Business, Ann Arbor, 2002.

Advanced and Population Pharmacokinetics – University of California, San Francisco, 1995 & 1997.

PROFESSIONAL MEMBERSHIPS

American Association of Pharmaceutical Sciences (AAPS), 1992-present.

- President, 2012
  - Member of Executive Council (Board of Directors)
- President-Elect, 2011
  - Member of Executive Council (Board of Directors)
  - Executive Council liaison to Member Groups Coordination Committee, International Affairs Committee, and AAPS Member Awards Task Force
- Member-at-Large, 2008-2010
  - Member of Executive Council (Board of Directors)
  - Executive Council liaison to National Biotechnology Conference Planning Committee, Fellows Committee, Nominations Committee, Annual Meeting Planning Committee, Pharmaceutical Sciences World Congress Committee, and Quantitative Model-based Drug Development Committee (2010 Chair)
  - Provide guidance to scientific sections including: Drug Discovery and Design and Analytical and Pharmaceutical Quality in 2008; Regulatory Sciences and Physical Pharmacy and Biopharmaceutics in 2009; and Formulation Design and Development and Manufacturing Science and Engineering in 2010.
- Organizer of AAPS-ASCPT Joint Symposium at AAPS Annual Meeting, 2010
- Chair of AAPS Program Coordination Committee, 2007
- Chair and co-Chair of AAPS Annual Meeting and Annual Meeting Planning Committee, 2005-2006
- Co-Chair of AAPS-ACCP Joint Symposium at AAPS Annual Meeting, 2004 & 2005
- Member of Publicity Committee for the 2007 Pharmaceutical Sciences World Congress, 2005-2006.
- Vice-chair, Chair-elect, Chair and Past-chair of Pharmacokinetics, Pharmacodynamics and Drug Metabolism Section (PPDM), 2002 – 2005
- Member of numerous AAPS committees and task forces, 2002-2008
  - Committees include Nomination, Fellows, Annual Meeting Planning Committee, National Biotechnology Conference Planning Committee, and Program Coordination Committee
- Secretary/Treasurer of PPDM Section, 2000 & 2001
- PPDM Awards Committee, 2000 – 2004, 2006.
- Clinical Pharmacology and Translational Research (CPTR) Abstract Screening Committee, 2010-2011.
- PPDM Abstract Screening Committee, 1999-2011.
  - Chair of Clinical Pharmacokinetics Subcommittee, 1999.
- Co-Chair of PPDM Open Forum, the primary fundraiser for the PPDM section, 1998 & 1999.
- Chair of Indianapolis/Cincinnati Discussion Group (ICDG) of AAPS, 1996-1997.
  - Member of Executive Committee, 1994-1999.

American Society for Clinical Pharmacology and Therapeutics (ASCPT), 1997-present.

- Oncology Section Abstract Screening Committee, 2011

American Society of Clinical Oncology (ASCO), 2007-present.

Society of Toxicology (SOT), International Society for the Study of Xenobiotics (ISSX) - prior memberships.

PATENTS AND PUBLICATIONS

Patents:

Griffin T, McCarthy B, **Mitchell DY**, Ouellet D, Stern T, Werth JL. Alpha-2-Delta Ligands for Nonrestorative Sleep. U.S. Patent and Trademark Office, Application No. 60/779,636, filed March 6, 2006.

Publications:

Invited Book Chapters:

Petersen DR, Hjelle JJ and **Mitchell DY**. Aldehydic products of lipid peroxidation: Substrates or inhibitors of hepatic aldehyde dehydrogenase? In: Enzymology and Molecular Biology of Carbonyl Metabolism, Vol. 3, H. Weiner Ed., Plenum Press, New York, pp. 67-73 (1990).

Manuscripts in Refereed Journals:

1. **Mitchell DY** and Petersen DR. The oxidation of α-β unsaturated aldehydic products of lipid peroxidation by rat liver aldehyde dehydrogenases. *Toxicol. Appl. Pharmacol.* **87**:403-410 (1987).
2. **Mitchell DY** and Petersen DR Inhibition of rat liver aldehyde dehydrogenases by acrolein. *Drug Metab. Dispos.* **16**:37-42 (1988).
3. **Mitchell DY** and Petersen DR Oxidation of aldehydic products of lipid peroxidation by rat liver microsomal aldehyde dehydrogenase. *Arch. Biochem. Biophys.* **269**:11-17 (1989).
4. **Mitchell DY** and Petersen DR. Metabolism of the glutathione-acrolein adduct, *S*-(2-aldehydo-ethyl)glutathione, by rat liver alcohol and aldehyde dehydrogenase. *J. Pharmacol. Exp. Ther.* **251**:193-198 (1989).
5. **Mitchell DY** and Petersen DR. Competitive inhibition of rat liver mitochondrial aldehyde dehydrogenase by *trans*-4-hydroxy-2-nonenal. *Hepatology*, **13**:728-734 (1991).
6. Avery MJ, **Mitchell DY**, Falkner FC and Fouda HG. Simultaneous determination of tenidap and its stable isotope analog in serum by high-performance liquid chromatography/atmospheric pressure chemical ionization tandem mass spectrometry. *Biol. Mass Spec.* **21**:353-357 (1992).
7. Madhu C, **Mitchell DY** and Klaassen CD. Effect of P-450 inducers on biliary excretion of glutathione and its hydrolysis products: Correlation between hepatic γ-glutamyltranspeptidase activity and the proportion of glutathione hydrolysis products in bile. *Drug Metab. Dispos.*, **21**:342-349 (1993).
8. **Mitchell DY** and Petersen DR. Inhibition of rat liver mitochondrial and cytosolic aldehyde dehydrogenase by crotonaldehyde. *Drug Metab. Dispos.*, **21**:396-399 (1993).
9. Griffiths RJ, Pettipher ER, Koch K, Farrell CA, Breslow R, Conklyn MJ, Smith MA, Hackman BC, Wimberly DJ, Milici AJ, Scampoli DN, Cheng JB, Pillar JS, Pazoles CJ, Doherty NS, Melvin LS, Reiter LA, Biggars MS, Falkner FC, **Mitchell DY**, Liston TE and Showell HJ. Leukotriene B-4 plays a critical role in the progression of collagen-induced arthritis. *PNAS*, **92**: 517-521 (1995).
10. Robinson RP, Reiter LA, Barth WE, Campeta AM, Cooper K. Cronin BJ, Destito R, Donahue KM, Falkner FC, Fiese EF, Johnson DL, Kuperman AV, Liston TE, Malloy D, Martin JJ, **Mitchell DY**, Rusek FW, Shamblin SL and Wright CF. Discovery of the hemifumarate and (alpha-L-alanyloxy)methyl ether as prodrugs of an antirheumatic oxindole: Prodrugs for the enolic OH group. *J. Med. Chem.*, **39**: 10-18 (1996).
11. **Mitchell DY**, Eusebio RA, Dunlap LE, Pallone KA, Nesbitt JD, Russell DA, Clay ME and Bekker PJ. Risedronate gastrointestinal absorption is independent of site and rate of administration. *Pharm. Res.,* **15**: 228-232 (1998).
12. **Mitchell DY**, Heise MA, Pallone KA, Clay ME, Russell DA and Melson CW. The effect of dosing regimen on the pharmacokinetics of risedronate. *Brit. J. Clin. Pharm.*, **48**: 536-542 (1999).
13. **Mitchell DY**, Eusebio RA, Sacco-Gibson NA, Pallone KA, Kelly SC, Nesbitt JD, Brezovic CP, Thompson GA and Powell JH. Dose-proportional pharmacokinetics of risedronate upon single-dose oral administration to healthy volunteers. *J. Clin. Pharm*., **40**: 258-265 (2000).

14. **Mitchell DY**, St Peter JV, Eusebio RA, Pallone KA, Kelly SC, Russell DA, Nesbitt JD, Thompson GA and Powell JH. The effect of renal function on risedronate pharmacokinetics after a single oral dose. *Brit. J. Clin. Pharm*., **49**: 215-222 (2000).

15. **Mitchell DY**, Barr WH, Eusebio RA, Pallone KA, Duke FP, Russell DA, Nesbitt JD, Powell JH and Thompson GA. Risedronate Pharmacokinetics and Intra- and Inter-subject Upon Single-Dose Intravenous and Oral Administration. *Pharm. Res.*, **18**: 166-170 (2001).

16. Klawansky S, Komaroff E, Cavanaugh PF, **Mitchell DY**, Gordon MJ, Connelly JE and Ross SD. The Relationship between Age, Renal Function and Bone Mineral Density in the U.S. Population. *Osteoporosis International*, **14**: 570-576 (2003).

17. Wabnitz PA, **Mitchell D**, and Wabnitz DAM. In Vitro and in Vivo Metabolism of the Anti-Cancer Agent CI-1040, a MEK Inhibitor, in Rat, Monkey, and Human. *Pharm. Res.*, **21**: 1670-1679 (2004).

18. Rinehart J, Adjei AA, LoRusso PM, Waterhouse D, Hecht JR, Natale RB, Hamid O, Varterasian M, Asbury P, Kaldjian EP, Gulyas S, **Mitchell DY**, Herrera R, Sebolt-Leopold JS, Meyer MB. A Multicenter Phase 2 Study of the Oral MEK Inhibitor, CI-1040 in Patients with Advanced Nonsmall-Cell Lung, Breast, Colon and Pancreatic Cancer. *J. Clin. Oncol*., **22**: 4456-4462 (2004).

19. LoRusso PM, Adjei AA, Varterasian M, Wozniak A, Gadgeel S. Reid J, **Mitchell DY**, Hanson L, Bruzek L, Piens J, Asbury P, Van Becealeare K, Herrera R, Sebolt-Leopold J, Erlichman C, Meyer MB. A Phase 1 and Pharmacodynamic Study of the Oral MEK Inhibitor, CI-1040 in Patients with Advanced Malignancies. *J. Clin. Oncol*., **23**: 5281-5293 (2005).

20. Morlock R, Tan M, **Mitchell D**. Prevalence and Correlates of Nonrestorative Sleep Complaints in those 65 years and Older. *Proc World Assn Sleep Med*., Berlin (Germany), Oct. 15-18, 2005, 25-28.

21. Morlock R, Tan M, **Mitchell DY**. Sleep Complaints in the National Ambulatory Medical Survey: National Prevalence and Drug Therapeutic Patterns. *Clin Ther*, **28**: 1044-1053 (2006).

Abstracts:

1. **Mitchell DY**. and Petersen DR. Inhibition of rat liver aldehyde dehydrogenases by acrolein. *The Toxicologist* **5**:169 (1985).

2. **Mitchell DY** and Petersen DR. Detoxification of α-β unsaturated aldehydes by rat liver aldehyde dehydrogenases. *The Toxicologist* **6**:258 (1986).

3. **Mitchell DY** and Petersen DR. The oxidation of α-β unsaturated aldehydes of lipid peroxidation by rat liver aldehyde dehydrogenases. Mountain West Chapter of the Society of Toxicology (1986).

4. **Mitchell DY** and Petersen DR. Oxidation of aldehyde lipid peroxidation products by purified rat hepatic microsomal aldehyde dehydrogenase. *The Toxicologist* **7**:222 (1987).

5. **Mitchell DY**, Piccolotti DA, and Petersen DR. Allyl alcohol oxidation by rat liver microsomal oxidizing system and alcohol dehydrogenase. Mountain West Chapter of the Society of Toxicology (1987).

6. **Mitchell DY** and Petersen DR. Metabolism of the acrolein-glutathione adduct *S*-(2-aldehydo-ethyl)glutathione by Sprague-Dawley rats. *The Toxicologist* **8**:186 (1988).

7. **Mitchell DY** and Petersen DR. Competitive inhibition of rat liver aldehyde dehydrogenase by *trans*-4-hydroxy-2-nonenal. *Alcohol. Clin. Exp. Res.* **12**:317 (1988).

8. **Mitchell DY** and Klaassen CD. *In vivo* bilirubin glucuronidation is regulated by UDP-glucuronosyltransferase and not by UDP-glucuronic acid. *The Toxicologist* **9**:169 (1989).

9. Maziasz T, **Mitchell D**, Madhu C, Gemzik B, Sendelbach L and Klaassen CD. Age- and sex-related changes in hepatic co-substrate concentration and synthesis in geriatric Fischer 344 rats. *The Toxicologist* **9**:234 (1989).

10. Kadiiska M, **Mitchell DY** and Klaassen CD. *In vivo* bilirubin-glucuronide excretion is increased following acute cobalt, cadmium and nickel treatment. Bulgarian Academy of Sciences Symposium on Drug Metabolizing Enzyme Systems (1989).

11. **Mitchell DY**, Madhu C and Klaassen CD. Hepatotoxicants elevate serum bilirubin by increasing formation not decreasing elimination of bilirubin. *The Toxicologist* **10**:61 (1990).

12. Petersen DR, Boyer CS and **Mitchell DY**. Inhibition of rat and mouse hepatic aldehyde dehydrogenase by citral. *The Toxicologist* **10**:188 (1990).

13. Satsangi D, Madhu C, **Mitchell DY** and Klaassen CD. Ratio of glutathione hydrolysis products/total sulfur (thiols plus disulfides) in bile reflects hepatic γ-glutamyltranspeptidase activity in rats. *The Toxicologist* **10**:319 (1990).
14. **Mitchell DY**, Madhu C, Bauman JW and Klaassen CD. Bilirubin-glucuronide excretion remains unchanged despite circadian variation in UDP-glucuronic acid and bile flow in rats. *The Toxicologist* **11**:49 (1991).
15. Avery M, **Mitchell D**, Falkner F and Fouda H. Simultaneous determination of tenidap and its stable isotope analogue in plasma by HPLC/APIMS/MS. Amer. Soc. Mass Spec. Conf. Proc. (1991).
16. **Mitchell DY**, Farrell DL and Falkner FC. Pharmacokinetics of tenidap after oral and intravenous administration to rats. *The Pharmacologist* **34**:181 (1992).
17. Falkner FC, Farrell DL and **Mitchell DY**. Pharmacokinetics of the novel antiinflammatory agent tenidap in the monkey. *ISSX Proceedings* **2**:183 (1992).
18. **Mitchell DY**, Vandenouweland FA, Heise MA, Salyers GC, Russell DA, Brezovic CP. and Thompson GA. Effect of food on risedronate pharmacokinetics in healthy volunteers. *Pharm. Res.* **11**:S-370 (1994).
19. **Mitchell DY**, Eusebio RA, Vandenouweland FA, Dunlap LE, Bekker PJ, Russell DA and Clay ME. Bioavailability of a single dose of risedronate solution when administered to three different gastrointestinal sites in healthy male volunteers. *Bone* **17**:615 (1995).
20. **Mitchell DY**, Eusebio RA, Heise MA, Pallone KA, Clay ME, Russell DA and Melson CW. The effect of dosing regimen on the pharmacokinetics of risedronate administered to healthy subjects. *J Bone Min Res* **11**:S347 (1996).
21. Sacco-Gibson N, **Mitchell DY**, Crusan C, Benesh J, Clay M and Anderson G. Effects of risedronate on markers of bone turnover in healthy (nonosteoporotic) postmenopausal women. *J Bone Min Res* **11**:S346 (1996).
22. Ward C, Sacco-Gibson N, **Mitchell DY** and Kelly S. Single dose risedronate (pyridinyl-bisphosphonate) does not induce acute phase reaction in healthy subjects. *J Bone Min Res* **11**:S346 (1996).
23. **Mitchell DY**, Eusebio RA, Dunlap LE, Russell DA, Clay ME and Bekker PJ. Bioavailability of immediate-release and delayed-release risedronate formulations upon oral administration to healthy male subjects in fasted and fed state. *Pharm Res* **13**:S458 (1996).
24. **Mitchell D**, Eusebio R, Pallone K, Clay M, Russell D and Thompson G. Bisphosphonate pharmacokinetics: Use of simultaneous modeling of urine and serum data to determine parameters. *Clin Pharm Ther* **61**:155 (1997).
25. Sacco-Gibson N, **Mitchell DY**, Eusebio RA, Axelrod DW and Powell JH. Risedronate (a pyridinyl bisphosphonate) does not induce acute phase reaction after single and multiple dose, intravenous administration. *Bone*, **20**:102S (1997).
26. **Mitchell DY**, Eusebio RA, Axelrod DW, Hicks KR, Russell DA, Kamra LC and Powell JH. Risedronate pharmacokinetics following single and multiple dose intravenous administration. *Bone*, **20**:100S (1997).
27. **Mitchell DY**, St. Peter JV, Eusebio RA, Pallone KA, Kelly SC, Nesbitt JD, Russell DA and Powell JH. The effect of renal impairment on risedronate pharmacokinetics. *J Bone Min Res*, **12**:S344 (1997).
28. **Mitchell DY**, Barr WH, Eusebio RA, Pallone KA, Duke FP, Russell DA, Nesbit, JD, Powell JH and Thompson GA. Determination of intravenous pharmacokinetics, absolute and relative bioavailability, and intra- and inter-subject variability of risedronate using a four period replicate study design. *Pharm Res* **14**:S610 (1997).
29. **Mitchell DY**, Eusebio RA, Pallone KA, Kelly SC, Nesbitt JD, Brezovic CP, Thompson GA and Powell JH. Single dose linearity of risedronate following oral administration of 2.5, 5, or 30 mg to healthy volunteers. *Pharm Res* **14**:S609 (1997).
30. **Mitchell DY**, Thompson GA, Eusebio RA, Pallone KA, Clay ME, Russell DA, Nesbitt JD and Powell JH. Risedronate pharmacokinetics upon multiple dose oral administration to postmenopausal women for six months. *Clin Pharm Ther* **65**:189 (1999).
31. McRobie CL, Buch AB, Thompson GA, Dato ME, Kelly SC, Agnew JR, Skuster JR and **Mitchell DY**. Bisoprolol Pharmacokinetics and Pharmacodynamics in Pediatric Subjects, 6 Months to 6 Years of Age. *AAPS Pharmsci* 2000; **2** (4), (www.pharmsci.org).

32. McRobie CL, Thompson GA, Dato ME, Johnson TD, Seeck MJ, Russell DA, Skuster JR and **Mitchell DY**. Pharmacokinetics of Ziac® (bisoprolol fumarate/hydrochlorothiazide) and Zebeta® (bisoprolol fumarate) in Children, 6 Through 15 Years of Age, *AAPS Pharmsci* 2000; **2** (4), (www.pharmsci.org).

33. Haig GM, Giordani B, and **Mitchell DY**. Effect of PD 216948, a Partial $GABA_A$ Agonist, on Neurometric Test Performance. *J. Clin. Pharmacol.*, **41**:1033 (2001).

34. **Mitchell DY**, Reid JM, Parchment RE, Meyer MB, Leopold JS, Herrera R, Piens JR, Bruzek LM, Hanson LJ, Van Becelaere K, Carlson T, Packard C, Adjei AA, LoRusso PM. Pharmacokinetics (PK) and Pharmacodynamics (PD) of the Oral MEK Inhibitor, CI-1040, Following Multiple Dose Administration to Patients with Advanced Cancer. *Proc. Am. Soc. Clin. Oncol.* **21**:81a (2002).

35. Adjei AA, LoRusso PM, Meyer MB, Wozniak A, Gadgeel S, DeLuca P, Hanson LJ, Reid JM, **Mitchell DY**, Bruzak LM, Leopold JS, Herrera R, Van Becelaere K, Carlson T, Packard C, Gulyas SW, Erlichman C. A Phase 1 Clinical And Pharmacokinetic Evaluation of Oral CI-1040 Administered For 21 Consecutive Days, Repeated Every 4 Weeks in Patients with Advanced Cancer. *Proc. Am. Soc. Clin. Oncol.* **21**:81a (2002).

36. Randinitis EJ, Haig GM, Wan H, and **Mitchell DY**. Pagoclone and PD 0302772 Pharmacokinetics Upon Multiple Dose Oral Administration to Healthy Volunteers: Dose Proportionality and Absence of Diurnal Variation. *AAPS Pharmsci* 2002; **4** (4), (www.pharmsci.org).

37. Wabnitz PA, Wabnitz DAM, **Mitchell D**, Loi C, Hurst S, Lapham K, Ramanathan R, and Williams JA. Cross Species Comparison of [14C] CI-1040 Metabolites in Rat, Monkey, and Human Microsomes and Hepatocytes with CI-1040 Metabolites in Human Bile. *Drug Metab. Rev.* **34**:77 (2002).

38. Haig GM, Giordani B, Randinitis EJ and **Mitchell DY**. Evaluation of the Pharmacodynamic and Pharmacokinetic Interaction Between Pagoclone and Ethanol. *Clin Pharm Ther* **73**:P93 (2003).

39. Morlock R, Tan M and **Mitchell DY**. Prevalence and Correlates of Nonrestorative Sleep Complaints in those 65 years and Older. *Sleep Med* (2005).

40. Ouellet D, Patel N, Werth J, Feltner D, McCarthy B, Stone R, **Mitchell DY**, Lalonde RL. The use of a Clinical Utility Index (CUI) in Decision Making to Select an Insomnia Compound. *Clin Pharm Ther.* **79**: P28 (2006).