



Kei-Lai L. Fong PhD

Executive Vice President

Summary. Drug development expert with extensive experience in both small molecules and biopharmaceuticals; a strong record of success in identifying discovery paradigms, drug development strategies and regulatory submissions; areas of experience and expertise include:

- Drug Development through Phase 2
- Regulatory Strategies and IND/NDA Filing
- Project Planning and Execution
- CRO Management
- Bioanalytical
- Biotransformation
- Clinical and Preclinical PK/PD
- Drug-Drug Interactions

Professional Experience

Synchroneuron Inc.

Co-founder & Sr. Vice President: 2012-present

Accellent Partners

Co-founder and Executive Vice President: 2010

Aptuit Consulting Inc.

Sr. Principal: 2006-2010

Private Practice

Consultant: 2004-2006

Calvert Laboratories, Inc.

President and Vice President: 2002-2004

Pennsylvania BioLab, Inc.

CEO and Scientific Director: 1997-2002

SmithKline Beecham Pharmaceuticals, UK and US

WW Drug Metabolism and Pharmacokinetics: 1980 to 1996

Education/Certification

1972; BS, Chemistry, National Taiwan University

1977; PhD, Medicinal Chemistry, University of Minnesota

Drug Development Experience

- 125 INDs and 15 NDA/MAA
- Drug discovery and drug development – CNS, cardiovascular, oncology, respiratory, rheumatology, dermal, Immunomodulation with small molecules, oligos, proteins, peptides and 505(b)2 development
- Clinical Pharmacokinetics, pharmacodynamics, toxicokinetics (experimental and simulation)
- Design/Dev of bioanalytical methods for therapeutic proteins and LC/MS/MS methods for small molecules
- In vitro and in vivo biotransformation, metabolite ID and characterization
- P450 methodologies and drug-drug interaction studies

- Drug Metabolism process in lead optimization, industry pioneer in N in one LC/MS/MS application
- Chronic animal models (rodents, dog and primates) for absorption, first-pass effects and formulation development

Selected Publications

- Fong, KL L and Vince, R. Peptidyl Transferase Substrate Specificity with Non-Aromatic Aminoacyl Analogues of Puromycin. *J Med Chem*, 21: 792-795, 1978.
- Kei-Lai L. Fong and Bruch Y-H Hwang. Dog Liver N-Methyltransferase, A Drug Metabolizing Enzyme. *Biochem Pharmacol*, 32(18): 2781-2786, 1983.
- Kei-Lai L. Fong and Bruce Y-H Hwang. Aromatization of 7,8-Dichloro-1,2,3,4-Tetrahydroisoquinoline By Rat Liver Microsomes. *Drug Metab Dispos* 12(1): 14-20, 1984.
- Fong, K.L., Crysler, C., Mico, B., Boyle, K., Kopia, G., Kopaciewicz, L. and Lynn, R. Dose-Dependent Pharmacokinetics of Recombinant Tissue-Type Plasminogen Activator (tPA) in Anesthetized Dogs Following Intravenous Infusion. *Drug Metab Dispos*, 16(2): 201-206, 1988.
- Marder V.J., Brenner B. Totterman S. Francis C.W., Rubin A, Rao K.Kessler, C.M., Kwaan H.C. Sharma G.V.R.K. and Fong K-L.L. Comparison of dosage schedules of rt-PA in the treatment of proximal deep vein thrombosis. *J. Lab Clin Med*, 119 (5): 485-495, 1992
- Davis, C.B., Boyle, K.E., Urbanski, J.J., Paradysz, R.T., and Fong, K.-L.L. Disposition of metabolically labeled recombinant soluble CD4 (sT4) in male Sprague-Dawley rats following intravenous and subcutaneous administration. *Drug Metab Dispos*, 20(5): 695-705, 1992.
- Davis C.B., Crysler C.C., Boppana V.K., Fong K-L.L., Joseph G.L., Urbanski J.J., Macia R.A. and Rhodes G.R. Disposition of growth hormone-releasing peptide (SK&F 110679) in rats and dogs following intravenous or subcutaneous administration. *Drug Metab Dispos*, 22(1): 90-98, 1994.
- Ohlstein E.H., Nambi P., Lago A., Hay W.P., Beck G., Fong K-L., Eddy E. P., Smith P., Ellens H. and Elliott J.D. Nonpeptide endothelin receptor antagonists. VI: Pharmacological characterization of SB 217242, a potent and highly bioavailable endothelin receptor antagonist. *J Pharmacol Exper Ther*, 276(2): 609-615, 1996.
- Troostenberg A, Clark E, Warrington S, Boyce M, Kerns W, Fishman P, Cohn I, Silverman M and Fong K-L.L. Clinical pharmacology of oral CF101 in healthy young men. *International J Clin Pharmacol Ther*, 42(10): 534-542, 2004
- Kathryn W. Woodburn, PhD, Susan D. Wilson, Kei-Lai Fong, Peter J. Schatz, Thomas Ferrell, and Daniel Norton. Chronic Preclinical Safety Evaluation of Hematide™, a PEGylated Peptidic Erythropoiesis Stimulating Agent (ESA), in Monkeys. *Haematologica*, 93: 1376-1379, 2008.
- Woodburn KW, Wilson SD, Fong K-L, Schatz PJ and Norton D. Chronic pharmacological and safety evaluation of Hematide, a PEGylated peptidic erythropoiesis-stimulating agent, in rodents. *Basic Clin Pharmacol Toxicol*, 104(2): 155-163, 2009.
- Elise M. Lewis, Alan M. Hoberman, Kei-Lai Fong, Peter J. Schatz, Susan D. Wilson and Kathryn W. Woodburn. Peri- and Postnatal Development Evaluation of Hematide™, an Erythropoiesis Stimulating Agent, in Rats. *Biology Repro*. 89(2): 155-163, 2010.
- Matthew Hoffmann, Gondi Kumar, Peter Schafer, Dorota Cedzik, Lori Capone, Kei-Lai Fong, Zheming Gu, Dennis Heller, Hao Feng, Sekhar Surapaneni, Oscar Laskin, and Anfan Wu. Disposition, metabolism and mass balance of [14C]apremilast following oral administration. *Xenobiotica*; 41(12):1063-75, 2011
- Woodburn KW, Holmes CP, Wilson SD, Fong KL, Press RJ, Moriya Y, Tagawa Y. Absorption, distribution, metabolism and excretion of peginesatide, a novel erythropoiesis-stimulating agent, in rats. *Xenobiotica*. Jul; 42(7):660-70, 2012

Professional Affiliations

- American Association for Pharmaceutical Scientists
- American Association for Cancer Research (elected member)
- American Society for Pharmacology and Experimental Therapeutics (elected member)
- American Chemical Society
- American College of Clinical Pharmacology (elected member)
- International Society for the Study of Xenobiotics (Charter member)