



## **William D. Kerns DVM, MS, DACVP** **Chief Executive Officer**

**Summary.** Drug Development Entrepreneur with extensive executive experience in Worldwide R&D, Phase 1/Phase 2 and Regulatory in the Biotechnology, Pharmaceutical and Contract Research Industries. Areas of experience and expertise include:

- Managing Early Stage Companies
- Manufacturing through Phase 2 POC
- Regulatory Strategy and IND Filing
- Business Development
- Project Planning and Implementation
- Drug Safety, ADME, Pharmacology
- Cardiovascular Pharmacology/Toxicology
- FDA Interactions from IND thru EOP2

### **Professional Experience**

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Synchroneuron Inc.

Co-founder & Interim CEO: 2012-present

Accellent Partners

CEO: 2010-present

Aptuit Consulting Inc.

Managing Director/President: 2006-2010

Pharma Consulting Inc.

President: 2000-2006

Eisai Co. Ltd.

Global Drug Safety, Metabolism and Safety Pharmacology: 1997-2000

SmithKline Beecham – UK & US

Preclinical Safety Assessment: 1982-1997

### **Education/Certification**

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**1971; BS**, Wilmington College

**1975; DVM**, Ohio State University

**1976; MS**, Ohio State University

**1980; Diplomate**, American College Veterinary Pathologists

### **Drug Development and Regulatory Experience**

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- Managed Pharmaceutical Drug Safety operations in US, UK and Japan
- 200 INDs/CTAs and 14 MAAs/NDAs
- Extensive experience working with most divisions at FDA
- Managed API through Phase 2 POC clinical studies for many emerging companies
- Published and lectured extensively on drug-induced cardiovascular toxicity in animals

## **Selected Publications**

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- **Kerns, W.D.**, Pavkov, K.L., Donofrio, D.J., Connell, M.M., Mitchell, R.I., Gralla, E.J. and Swenberg, J.A. Carcinogenicity of formaldehyde in rats and mice after long-term inhalation exposure. *Cancer Research*, 43: 4382-4392, 1983.
- **Kerns, W.D.**, Arena, E., Macia, R.A., Bugelski, P.J., Matthews, W.D. and Morgan, D. G. Pathogenesis of arterial lesions induced by dopaminergic compounds in the rat. *Toxicol Pathol*, 17, No.1 (Part 2): 203-213, 1989.
- **Kerns, W.D.**, Arena, E. and Morgan, D.G. Role of dopaminergic and adrenergic receptors in the pathogenesis of arterial lesions induced by fenoldopam mesylate and dopamine in the rat. *Am J Pathol*, 135: 339-349, 1989.
- Kinter, L.B., Gossett, K.A., **Kerns, W.D.** Status of Safety Pharmacology in the Pharmaceutical Industry, 1993. *Drug Devel Res*, 32: 208-216, 1994.
- Hertzky, D.J., Reuggier, E.V., Cunningham, L, Polsky, R., Herold, C., Klinker, A.M., Badger, A., **Kerns, W.D.**, Bugelski, P.J. Single-Organism Model of Host Defense Against Infection—A Novel Immunotoxicologic Approach to Evaluate Immunomodulatory Drugs. *Toxicol Pathol*, 25 (4): 351-362, 1997.
- Berkhout, T.A., Simon, H.M., Jackson, B., Yates, J., Pearce, N., Groot, P.H.E., Bentzen, C., Niesor, E., **Kerns, W.D.**, Suckling, K.E. SR-12813 Lowers Plasma Cholesterol in Beagle Dogs by Decreasing Cholesterol Biosynthesis. *Atherosclerosis*, 133(2): 203-212, 1997.
- Cardiovascular Toxicology, Vol Eds, **Kerns, W.D.** and Bishop, S.P., Vol 6 of Comprehensive Toxicology Series, ~700 pages, Sipes, G and Gandolfi, J. editors-in-chief, Elsevier Press, UK. 1997.
- **Kerns WD**, Roth L, Hosokawa S. Idiopathic Canine Polyarteritis. In: Pathobiology of the Aging Dog, Mohr U, Carlton WW, Dungworth DL, Benjamin SA, Capen CA, Hahn FF (eds.). Vol. 2: 118-126, Iowa State University Press, Ames, 2001.
- Hakura A, Suzuki S, Sawada S, Sugihara T, Hori Y, Uchida K, **Kerns WD**, Sagami F, Motooka S, Satoh T. Use of human liver S9 in the Ames test: assay of three procarcinogens using human S9 derived from multiple donors. *Regul Toxicol Pharmacol*, 37(1): 20-7, 2003.
- van Troostenburg, A. R., Clark, E. V., Carey, W. D. H., Warrington, S. J., **Kerns, W.D.**, Cohn, I., Silverman, M. H., Bar-Yehuda, S., Fong, K.L. L., Fishman, P. Tolerability, pharmacokinetics, and concentration-dependent hemodynamic effects of oral CF101, an A3 adenosine receptor agonist, in healthy young men. *Int J Clin Pharmacol Ther*, 42: 534-42, 2004.
- **Kerns W D**, et al. Drug-Induced Vascular Injury--A Quest for Biomarkers. *Toxicol Appl Pharmacol*, 203/1: 62-87, 2005.
- Dietsch G N, DiPalma C R, Eyre R J, Pham T Q, Poole K M, Pefaur N B, Welch W D, Trueblood E, **Kerns W D** and Kanaly S T. Characterization of the Inflammatory Response to a Highly Selective PDE4 Inhibitor in the Rat and the Identification of Biomarkers that Correlate with Toxicity. *Toxicol Pathol*, 34: 39-51, 2006.
- I. Avni, H. Garzozzi, I. Barequet, F. Segev, D. Varssano, G. Sartani, N. Chetrit, E. Bakshi, D. Zadok, O. Tomkins, G. Litvin, K. Jacobson, S Fishman, Z. Harpaz, M. Farbstein, S. Bar Yehuda, M. Silverman, **W. Kerns**, D. Bristol, I Cohn, P. Fishman. Treatment of Dry Eye Syndrome with Orally Administered CF101. Data from a Phase 2 Clinical Trial. *Ophthalmology*, 117:1287-1293, 2010.

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- Chairman, Vascular Biology Meeting, Society of Toxicologic Pathologists
  - President, Toxicologic and Exploratory Pathology Specialty, SOT
  - Councilor, Toxicologic and Exploratory Pathology Specialty, SOT
  - FDA Co-Chair, Expert Working Group of the Non-Clinical Studies Subcommittee on Drug-Induced Vascular Injury (2001-2003)
  - Co-Organiser: Biomarkers of vascular injury-ARP
  - Advisor, Critical Path Institute
  - Expert Panel Review of Caffeine in Energy Drinks