Larry Ereshefsky, Pharm.D., BCPP, FCCP

Chief Scientific Officer

Apex Innovative Sciences

Dr. Ereshefsky joined Hassman Research Institute as CSO, Early Phase Development in early 2017. One year later he accepted the same role with CNS Research, enhancing the partnership between the two companies with his wide-ranging expertise. He facilitated the strategic merger in 2019 to expand on the partnership's leadership in the field, culminating years of collaboration in the formation of Apex. Dr. Ereshefsky has been instrumental in harmonizing the scientific, technological, and clinical processes across organizations, enabling the seamless execution of trials with the enrollment benefits of bi-coastal operations.

Dr. Ereshefsky is an internationally recognized thought leader in clinical translational CNS research with a proven track record in designing and performing Phase I/IIa and clinical pharmacology studies. He is a leader in the application of translational drug development tools, and in the use of signal detection strategies to minimize placebo response. He is utilized as a global resource within Apex, providing support to ensure consistency and high quality across sites, and spearheading ongoing activities to increase capabilities.

Dr. Ereshefsky is actively involved in strategic planning for compound development. He helps design translational research programs and define the critical path towards regulatory approval. He has extensive experience working with regulatory agencies and developing strategic plans to address compound differentiation and reimbursement challenges.

Work History

Over his 43-year career, Dr. Ereshefsky has applied his experience as a clinician, scientist, and investigator to develop treatments and innovate clinical methodologies to make a difference in the lives of patients with neurodegenerative, psychiatric, and other disorders.

Dr. Ereshefsky is a retired Regents Professor of Pharmacy, Psychiatry, and Pharmacology from The University of Texas at Austin and University of Texas Health Science Center at San Antonio. Subsequently, he was EVP and CSO for California Clinical Trials from 2003 to 2008 when it was acquired by PAREXEL International where his role was VP, Principal Pharmacologist, and Therapeutic Area Leader for CNS Early Phase until his departure in 2016. Currently, he is the owner of Follow the Molecule: CNS Consulting, providing services to pharma, CROs, and technology vendors.

Dr. Ereshefsky has contributed significantly to many drug approvals spanning neurology and psychiatry, including drug development planning, PK/PD evaluation, and methodological innovation. He has

Continued on next page...

Larry Ereshefsky, Pharm.D., BCPP, FCCP
Chief Scientific Officer
Apex Innovative Sciences

introduced strategies to de-risk early phase drug development through the application of neurocircuitry/ biomarker based (RDoC) strategies, e.g., continuous CSF sampling, QEEG, ERP, PSG, fMRI, PET, and cognitive and behavioral paradigms. He serves as a consultant to the NIMH, RDoC team. He has extensive experience leading specialty studies such as DDI, BA/ BE bridging, novel formulation development, and Human Abuse Potential.

Dr. Ereshefsky has been a designer and investigator on over 100 Asian Bridging trials. An innovator in the field, he co-created the ex-Japan, US-based strategy. He is the co-author of Accelerating Global Drug Development: The Science and Practice of Ethnobridging. The book, which has served as the definitive reference for global drug developers dealing with ethnically sensitive clinical programs since 2002, focuses on accelerating development for the Asia/ Pacific market and saving time and cost for early phase programs.

Dr. Ereshefsky has published more than 130 peer-reviewed scholarly articles and abstracts, and delivered many invited presentations at professional and scientific meetings. He has served on the FDA Psychopharmacological Drugs Advisory Committee (twice) and USP Psychiatry Special Panels. He has received numerous honors and awards, including election to the Executive Board of The International Society for CNS Clinical Trials and Methodology (ISCTM), where he currently serves as the Steering Committee Chair for the Behavioral and Psychological Symptoms of Dementia working groups on Apathy and Agitation, and as a member of the Scientific Committee. He serves on pharmaceutical advisory boards, and over the years has been a consultant for almost every major pharma company.

Dr. Ereshefsky's clinical scientist career started as an undergraduate, with an Atomic Energy Commission Grant to study the Kinetics of the Organification of Cobalt complexes.

Education

Dr. Ereshefsky received his Pharm.D. from the University of Southern California. His post Post-Graduate Residency in Psychiatric Pharmacy/ Psychopharmacology was completed at LA County Medical Center.