

TUESDAY, SEPTEMBER 17, 2019 | Symposium 13 | 10:00 – 11:30 AM

Human Pharmacodynamic Models Supporting Decision Making in Neuroscience Drug Development

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-013-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Tong Zhu, PhD, Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

TARGET AUDIENCE:

This Symposium will be useful for academic, industrial and regulatory scientists who are interested in translational medicine, drug discovery and development.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Define the required clinical evaluation to establish a human pharmacology model for decision making;
2. Describe when/how pharmaceutical companies conduct human pharmacology studies during clinical development for early decision making;
3. List different decisions that can be made using human pharmacology results such as go/no-go for a compound, dose selection and personalized treatment.

10:00 – 10:10 AM

Challenges of Neuroscience Drug Development & the Role of Human Pharmacology Models in Early Development

Tong Zhu, PhD, Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

10:10 – 10:30 AM

Laser-evoked Potential Method in Healthy Volunteers: Its Predictive Validity of Therapeutic Efficacy in Neuropathic Pain & Its Value in Early Clinical Development Decision Making

Klaus Schaffler, MD, Managing & Medical Director, Human Pharmacodynamic Research

10:30 – 10:50 AM

A Polysomnography Study in Healthy Volunteers to Evaluate the Central Nervous System Pharmacodynamic Effects of ASP8062, a GABA_B Receptor Positive Allosteric Modulator

Mark Walzer, PhD, Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

10:50 – 11:10 AM

Electroencephalography & Event-related Potentials: Future Clinical Use of Neurophysiological Biomarkers to Predict & Monitor Treatment Response for Schizophrenia

Gregory A. Light, PhD, Professor & Deputy Vice Chair, Univ of California San Diego, Psychiatry Education & Training and Director, Veterans Administration San Diego Healthcare System, Mental Health Research & Mental Illness Research, Education & Clinical Ctr

11:10 – 11:30 AM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations