Applying Quantitative Clinical Pharmacology to Support the Drug Development of T cell-redirecting Bispecific Antibodies

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-027-H04-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Weirong Wang, MD, PhD, Scientific Director, Janssen Research & Development LLC
Xiling Jiang, PhD, Staff Fellow, US Food & Drug Administration

TARGET AUDIENCE:
This Symposium will be useful for drug discovery and development scientists, clinical pharmacologists, pharmacometricians, clinician scientists, systems pharmacology scientists, mathematical biologists and regulatory scientists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Review the challenges and opportunities in T cell-redirecting bispecific antibody drug development from a clinical and clinical pharmacology perspective;
2. Explain the mechanism of action of T cell-redirecting bispecific antibodies and the associated toxicity;
3. Discuss quantitative approaches that characterize T cell-redirecting bispecific antibody-induced cytotoxicity and cytokine release;
4. Evaluate the use of quantitative clinical pharmacology in supporting the drug development of T cell-redirecting bispecific antibodies with regard to both efficacy and safety.

Clinical Perspectives on T cell Redirecting Bispecific Antibodies
Donna Przepiorka, MD, PhD, Medical Officer, US Food & Drug Administration

Mechanism-based Modeling & Simulation to Support Discovery & Development of T cell Redirecting Bispecific Antibodies
Weirong Wang, MD, PhD, Scientific Director, Janssen Research & Development LLC

Leveraging a Quantitative Systems Pharmacology Model to Support Early Clinical Development of CD20/CD3 Bispecific Antibody Mosunetuzumab
Monica Susilo, PhD, Associate Scientist, Genentech Inc

Applying Quantitative Clinical Pharmacology Approaches to Support Clinical Development of T cell Redirecting Bispecific Antibodies
Xiling Jiang, PhD, Staff Fellow, US Food & Drug Administration

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