

TUESDAY, SEPTEMBER 17, 2019 | Symposium 15 | 1:30 – 3:00 PM

Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers both CME & CPE Credit

UAN #0238-0000-19-015-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology

Kevin J. Freise, PhD, Scientific Director, AbbVie Inc, Oncology Early Development

TARGET AUDIENCE:

This Symposium will be useful for attendees from academia, industry and clinicians. It will also benefit an audience which is interested in oncology drug development and developing drugs for rare diseases.

GOALS & OBJECTIVES:

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

1. Define surrogate endpoints and explain why surrogate endpoints are needed in many types of cancer;
2. Explain the regulatory requirements to establish surrogacy of endpoints;
3. List the benefits and risks of the use of surrogate endpoints in place of established clinical endpoints;
4. Describe surrogate endpoints to clinical decision making and acceleration of drug development.

1:30 – 1:40 PM

Introduction: Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints

Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology

1:40 – 2:05 PM

Clinical Relevance of Patient-specific Biomarkers Used to Optimize Cancer Treatment

William Douglas Figg, PharmD, Senior Investigator, National Cancer Inst, Molecular & Clinical Pharmacology Program

2:05 – 2:30 PM

Surrogate Endpoints in Regulatory Decision Making

Vishal Bhatnagar, MD, Medical Officer, US Food & Drug Administration, Hematology Products, CDER

2:30 – 2:50 PM

Optimizing Therapy Based on Surrogate Endpoints: An Integrated Semi-mechanistic Model of Minimal Residual Disease Response to Venetoclax Treatment in Chronic Lymphocytic Leukemia

Kevin J. Freise, PhD, Scientific Director, AbbVie Inc, Oncology Early Development

2:50 – 3:00 PM

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