FDA PUBLIC WORKSHOP: Leveraging Human-Relevant Cardiomyocytes in Nonclinical Studies to Provide Mechanistic Insights into Cardiovascular Safety Liabilities

March 29, 2019 Great Room, FDA Headquarters, White Oak, Silver Spring MD

Time	Tentative Topic and Duration	Speakers
8:30 – 8:35	**Welcome**	**Xi Yang (FDA)**
8:35 – 8:55	**Overview of Gaps and Challenges**	**Gary Gintant (Abbvie)**
8:55 – 9:15	**A Novel Framework for Human-Relevant and Failure Mode-focused Assessment of Cardiovascular Safety in Nonclinical Drug Development**	**Brian Berridge (NIH)**
9:15 – 9:35	**Morphologies, Motions and Markers of *In Vitro* Cardiovascular Screening Assessments**	**Blake Anson (Stemonix)**
9:35 – 9:55	**Engineered Heart Tissue: Analysis of Contractile Force in hiPSC-CM**	**Arne Hansen (Univ. Med. Cntr Hamburg-Eppendorf)**
9:55 – 10:10	**Break (15 min)**	
10:10 – 10:30	**Use of Cardiomyocyte Models for the Detection of Cardiovascular Liabilities: the Opportunity and Future Potential**	**Amy Pointon (AstraZeneca)**
10:30 – 10:50	**Using Electrical Field Stimulation for Maturation of hiPSC Cardiomyocytes, Assessment of Inotropic Compounds and Cardiac Safety Assessment**	**Yama Abassi (ACEA)**
10:50 – 11:10	**Micropatterned Human iPSC-derived Cardiomyocytes**	**Alexandre Ribeiro (FDA)**
11:10 – 11:30	**Using Adult Human Primary Cardiomyocyte Models for Drug-induced Cardiotoxicity Detection**	**Najah Abi Gerges (Anabios)**
11:30 – 11:50	**PANEL DISCUSSION WITH AUDIENCE**	**Key Speakers**
11:50 - 13:00	**Lunch Break (70 min)**	
13:00 – 13:20	**Myocardial Biology of Kinase Inhibitor Cardiotoxicity: Predictable On-target and Surprising Off-target Effects**	**Brian Jensen (UNC Div Cardiology)**
13:20 – 13:40	**Secondary Pharmacology and Off-target Profiling as a Way to Provide Mechanistic Insights into Drug-induced Cardiovascular Safety Liabilities**	**Jean-Pierre Valentin (UCB)**
13:40 – 14:00	**Drug Development Tools (DDTs) – Regulatory Perspective**	**Christopher Leptak (FDA)**
14:00 – 14:20	**Chronic/Delayed Drug-Induced Cardiac Toxicity and Cardiac Biomarkers in hiPSC-CMs**	**Hua Rong Lu (Janssen)**
14:20 – 14:30	**Break (10 min)**	
14:30 – 14:50	**Development of In Vitro Cardiotoxicity Assessment for Oncology Drugs**	**Yasunari Kanda (NIHS)**
14:50 – 15:10	**The Pharmacogenomic Basis of Oncology Drug-Induced Cardiovascular Toxicity**	**Paul Burridge (Northwestern Univ)**
15:10 – 15:30	**Integrated Response Markers**	**William B. Mattes (FDA)**
15:30 – 16:30	**PANEL DISCUSSION WITH AUDIENCE / Meeting Wrap-Up**	**Norman Stockbridge (FDA) & Key Speakers**