Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials

December 1, 2017

Organized by FDA with support from: AACR, ACC, AHA & ASCO

Co-Chairs: Dr. Laleh Amiri-Kordestani and Dr. Javid Moslehi

AGENDA

	Topics	Speakers
8:30-9:00	Registration	
9:00-9:10	Welcome and Introduction	**Laleh Amiri-Kordestani, MD** FDA/CDER **Javid Moslehi, MD** Vanderbilt School of Medicine Cardio-Oncology Program
Session 1: Immuno-Oncology and Combination Immunotherapies Moderator: ***Marc Theoret, MD;*** *FDA/OCE*		
9:10-9:25	Immunology Overview	**Andrew Lichtman, MD, PhD** Harvard Medical School Pathology
9:25-9:40	Introduction to Cancer Immunotherapies	**James Gulley, MD, PhD** National Cancer Institute Center for Cancer Research Immunotherapy
9:40-9:50	Combination Cancer Immunotherapies	**Jeffrey Sosman, MD** Northwestern University Robert H. Lurie Comprehensive Cancer Center; Immuno-Oncology
9:50-10:10	Summary and Panel Discussion Question and Answer	**Douglas Johnson, MD, MSCI** with Panel Vanderbilt-Ingram Cancer Center Hematology/Oncology
Session 2: General Toxicities of Cancer Immunotherapies Moderators: ***Apostolia (Lia) Tsimberidou, MD, PhD;*** *MD Anderson Cancer Center* *and* ***Javid Moslehi, MD;*** *Vanderbilt School of Medicine Cardio-Oncology Program*		
10:10-10:25	Clinical Toxicities with Immunotherapies	**Michael Atkins, MD** Georgetown-Lombardi Cancer Center Medical Oncology; Immunotherapy
10:25-10:35	Eligibility Criteria for Immune-oncology Trials	**Douglas Johnson, MD, MSCI** Vanderbilt-Ingram Cancer Center Hematology/Oncology
10:35-10:50	Autoimmunity Associated with Checkpoint Inhibitors: Rheumatologist's perspective	**Paul "PJ" Utz, MD** Stanford School of Medicine Rheumatology
10:50-11:10	Panel Discussion Question and Answer	**Nicole Gormley, MD** and Panel FDA/CDER
11:10-11:25	Break	

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Session 3: Cardiometabolic Toxicities in Immuno-Oncology Trials Moderator: ***Jeffrey Sosman, MD;*** *Northwestern Univ. Robert H. Lurie Comprehensive Cancer Center*		
11:25-11:35	Immunotherapy-associated Myocarditis: Dilemmas for the Practicing Clinician	**JoAnn Lindenfeld, MD, FHSA** Vanderbilt Heart and Vascular Institute Heart Failure/Cardiac Transplant
11:35-11:45	Cardiovascular Toxicities Associated with Checkpoint-Inhibitors	**Javid Moslehi, MD** Vanderbilt School of Medicine Cardio-Oncology Program
11:45-11:55	Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective	**Kevan Herold, MD** Yale School of Medicine Immunobiology
11:55-12:05	Cancer Immunotherapy-associated Myositis and Myasthenia Gravis	**Andrew Mammen, MD, PhD** National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation
~~**12:05-12:15**~~	~~Cardiovascular Complications associated with Other Cancer Immunotherapies~~	~~**Christian Hinrichs, MD**~~ ~~National Cancer Institute~~ ~~Center for Cancer Research~~ ~~Cellular Therapy~~
12:05-12:35	Panel Discussion Question and Answer	**Chaohong Fan, MD, PhD** FDA/CBER **Javid Moslehi, MD** and Panel Vanderbilt School of Medicine Cardio-Oncology Program
12:35-1:25	Lunch	
Session 4: Myocarditis Overview Moderator: ***Ana Barac, MD, PhD;*** *MedStar Health Research Institute*		
1:25-1:40	General Pathophysiology of Myocarditis	**Kirk Knowlton, MD** Intermountain Medical Center; Salt Lake City; Cardiovascular Research
1:40- 1:55	Clinical Myocarditis: Diagnosis and Management	**Mariell Jessup, MD, FAHA, FESC, FACC** Leducq Foundation Cardiovascular Disease
1:55-2:05	Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology	**Andrew Lichtman, MD, PhD** Harvard Medical School Pathology **Javid Moslehi, MD** Vanderbilt School of Medicine Cardio-Oncology Program
2:05-2:30	Panel Discussion Question and Answer	**Shari Targum, MD** FDA/CDER/Division of Cardiovascular and Renal Products; **Mr. John DeWolf** and Panel Patient Perspective

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Session 5: Screening/Monitoring for Cardiovascular Toxicities associated with Cancer Immunotherapies Moderator: ***Daniel Lenihan, MD;*** *Washington University*		
2:30-2:40	How to Screen for Cardiotoxicity	**Susan Gilchrist, MD** MD Anderson Cancer Center Cardiology
2:40-2:50	Imaging Modalities to Diagnose Cardiovascular Toxicities	**Bonnie Ky, MD, MSCE** University of Pennsylvania, Perelman School of Medicine Translational Cardiovascular Epidemiology
2:50-3:00	Adjudicating Cardiovascular Events in Immuno-Oncology Trials	**Marc Bonaca, MD, MPH** Brigham and Women's Hospital, Harvard Medical School Heart & Vascular Medicine
3:00 to 3:25	Panel Discussion Question and Answer	**Alexander Lyon, MA, BM, BCh, PhD, FRCP, FHFA** and Panel Royal Brompton Hospital, London Cardiology
3:25 to 3:35	Break	
3:35 to 3:50	Modernizing Eligibility Criteria for Oncology Clinical Trials	**Julia Beaver, MD** FDA/CDER
Session 6: From Big data to Smart Data for Identification of Cardiovascular Toxicities Moderators: ***Sean Khozin, MD;*** *FDA/OCE and* ***Elad Sharon, MD, MPH;*** *NCI, Investigational Drugs*		
3:50-4:00	Leveraging Big Data in Drug Development: Toxicity Assessment & Signal Detection	**Sean Khozin, MD, MPH** FDA/OCE
4:00-4:10	ASCO's CancerLinQ: Using real-world evidence for discovery	**Robert Miller, MD, FACP, FASCO** CancerLinQ American Society of Clinical Oncology
4:10-4:20	Patient-Generated Data	**Sally Okun, RN, MMHS** Patients Like Me
4:20-4:40	Post-Marketing Drug Safety Surveillance: Cardiovascular Toxicities	**Connie Cheng, PharmD, BCOP** FDA/CDER/Office of Surveillance and Epidemiology (OSE) **Pritpal Singh, PharmD, BCOP** FDA/CDER/OSE
4:40-5:00	Panel Discussion Question and Answer	FDA/CDER/OSE: **Daniel Woronow, MD; Afrouz Nayernama, PharmD; Pete Waldron, MD;** and Panel
5:00	Adjournment	