Cardio-Oncology Workshop: Session 1

Immuno-Oncology (I-O) and Combination Immunotherapies

December 1, 2017

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Oncology Center of Excellence, FDA
FDA Centers Active in Oncology

• **Center for Drugs Evaluation and Research**
  – Drugs – small molecules
  – Biologics – monoclonal antibodies, cytokines

• **Center for Biologics Evaluation and Research**
  – Cellular and gene therapies, oncolytic viruses, therapeutic vaccines

• **Center for Devices and Radiological Health**
  – Devices, including companion diagnostics, Radiologics
Recent “First-in-class” I-O Approvals

- 2010 - Therapeutic Cellular Vaccine
- 2011 - Immune Checkpoint Inhibitors (ICI)
- 2014 - Bispecific CD3 T-cell Engager
- 2015 - Oncolytic Virus
- 2017 - Chimeric Antigen Receptor (CAR) T Cell Immunotherapy
Example - Timeline of ICI* Approvals

HCC
Gastric /GEJ
MSI-h CRC
MSI-high (h)
Merkel
HNSCC
Urothelial
HL
RCC
NSCLC
Melanoma

*ICI Products

Approval: Accelerated  Regular

Ipilimumab
Pembrolizumab
Nivolumab
Atezolizumab
Avelumab
Durvalumab

Updated: September 22, 2017

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Example - Timeline of ICI* Approvals

ICI Products

*ICI Products

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Agenda – Session 1

• Immunology Overview
  Andrew Lichtman, MD, PhD
  Harvard Medical School

• Introduction to Cancer Immunotherapies
  James Gulley, MD, PhD
  National Cancer Institute

• Combination Cancer Immunotherapies
  Jeffrey Sosman, MD
  Robert H. Lurie Comprehensive Cancer Center of Northwestern University

• Panel Discussion / Question and Answer
  Douglas Johnson, MD, MSCI
  Vanderbilt-Ingram Cancer Center