

Cardio-Oncology Workshop: Session 1

Immuno-Oncology (I-O) and Combination Immunotherapies

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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

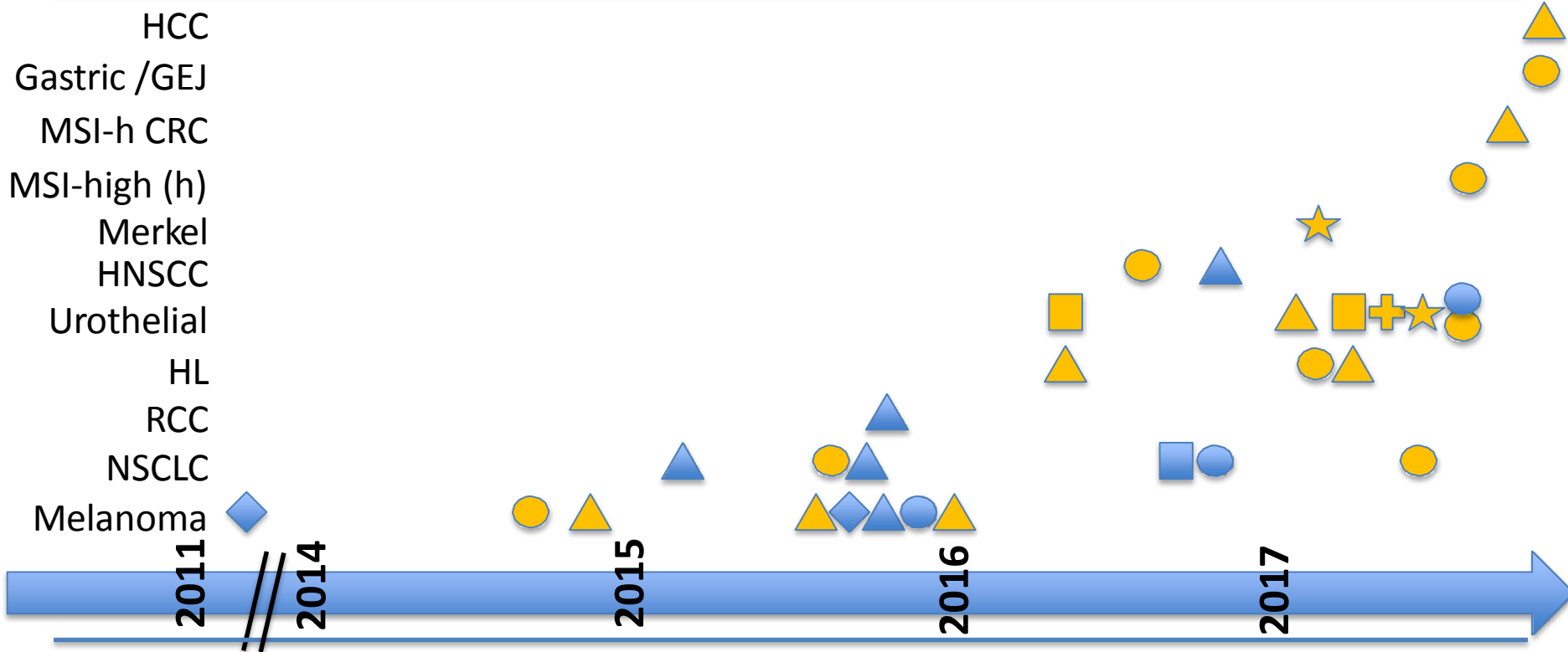
Recent “First-in-class” I-O Approvals



- **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

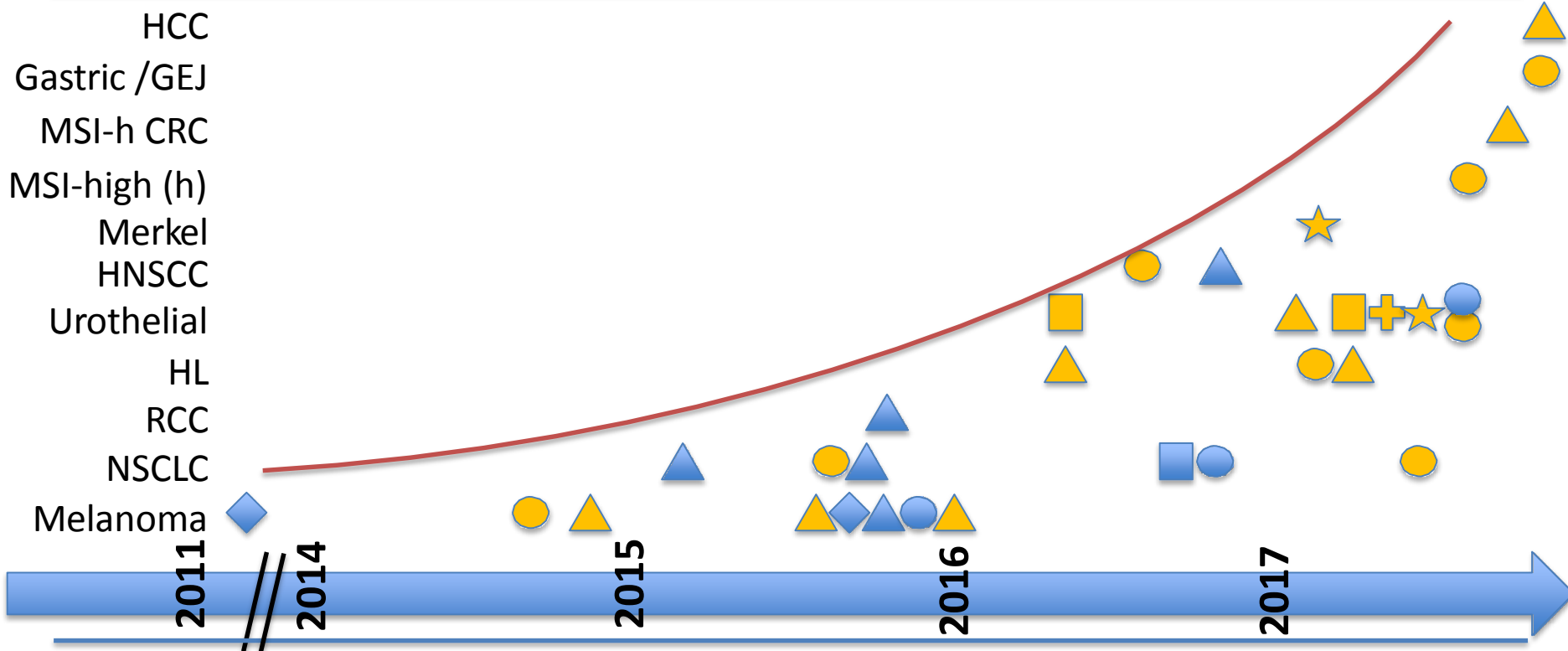


Approval: Accelerated Regular

*ICI Products	Accelerated	Regular
Ipilimumab		◆
Pembrolizumab	●	●
Nivolumab	▲	▲
Atezolizumab	■	■
Avelumab	★	
Durvalumab	+	



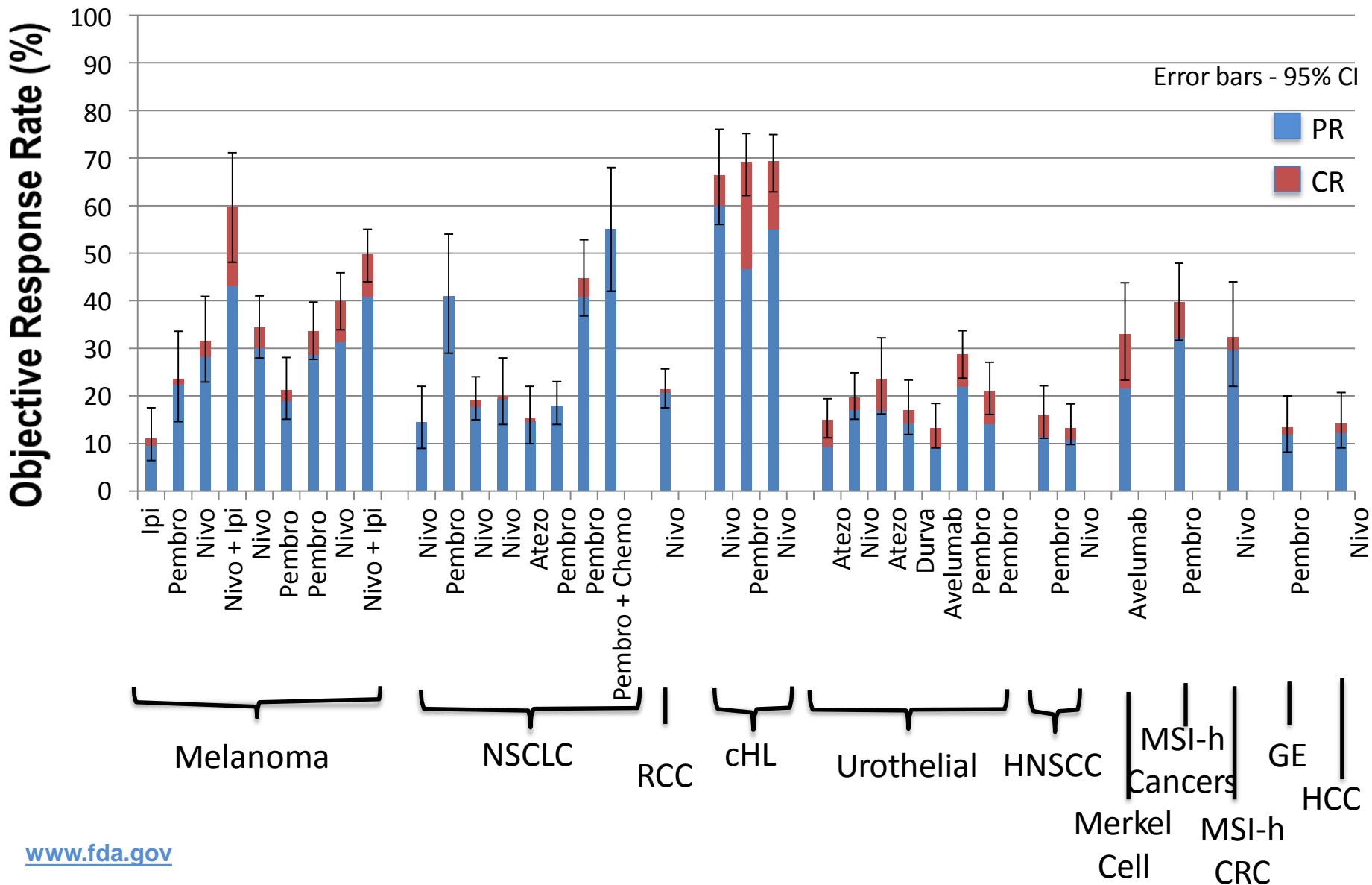
Example - Timeline of ICI* Approvals



Approval: Accelerated Regular

*ICI Products	Accelerated	Regular
Ipilimumab		◆
Pembrolizumab	●	●
Nivolumab	▲	▲
Atezolizumab	■	■
Avelumab	★	
Durvalumab	+	

ICI Approvals - ORR by Tumor Type





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

