NCI Workshop on Cell-based Immunotherapy for Solid Tumors
Dec 10-11, 2018 | 6700B Rockledge Drive, Bethesda, MD

MEETING AGENDA

DECEMBER 10, 2018

9:00 AM Welcome and Opening Remarks
   Ned Sharpless, Director, National Cancer Institute

9:15 AM Goals of the Workshop
   James Doroshow, Director, Division of Cancer Treatment and Diagnosis, NCI

SESSION 1 - CLINICAL PERSPECTIVE

9:25 AM Keynote Presentation - *Bit by Bit: Putting It Together*
   Malcolm Brenner, Baylor College of Medicine

9:45 AM *Targeting Unique Somatic Mutations for the Immunotherapy of Solid Epithelial Cancers*
   Steven Rosenberg, National Cancer Institute

10:05 AM *TCR Gene Therapy for Epithelial Cancers*
   Christian Hinrichs, National Cancer Institute

10:25 AM COFFEE BREAK

10:40 AM *Successes and Challenges with CAR-T Cell Therapy for Hematologic Malignancies*
   Terry Fry, University of Colorado, Denver

11:00 AM *Insights into Toxicities of CD19 CAR-T Cells*
   Cameron Turtle, Fred Hutchinson Cancer Research Center and University of Washington

11:20 AM *Opportunities and Challenges in Developing CAR-T Cells for Solid Tumors*
   Marcela Maus, Massachusetts General Hospital and Harvard University

11:40 AM PANEL DISCUSSION, TERRY FRY

12:10 PM LUNCH

SESSION 2 - STATE OF THE SCIENCE

1:10 PM *CAR-T Cell Therapy for Solid Tumors: A Work in Progress*
   Steven Albelda, University of Pennsylvania

1:30 PM *Target antigen selection for solid tumor CAR T-cell therapy*
   Stephen Gottschalk, St. Jude Children’s Research Hospital

1:50 PM *An NIH Intramural/Extramural Collaboration to Target Renal Cell Carcinoma with TCR Transduced Autologous T Cells*
   Michael Nishimura, Loyola University of Chicago

2:10 PM COFFEE BREAK

2:25 PM *Moving CARs Forward: Next Generation CAR-T Cells*
   Renier Brentjens, Memorial Sloan Kettering Cancer Center

2:55 PM *Switchable CARs: Targeting More Than One Antigen*
   Travis Young, California Institute for Biomedical Research

3:15 PM *Engineered Human Pluripotent Stem Cell-derived NK Cells with Improved Anti-Tumor Activity*
   Dan Kaufman, University of California San Diego

3:35 AM PANEL DISCUSSION, STEVEN ALBELDA
### DECEMBER 11, 2018

**8:45 AM Recap of Day 1 and Goals for Day 2**  
Rose Aurigemma, National Cancer Institute

### SESSION 3 - TECHNOLOGICAL CHALLENGES FOR CELL THERAPY

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<tr>
<td>9:00 AM</td>
<td>Overview of Steps in Manufacturing Genetically Engineered T Cells</td>
<td>David Stroncek, NIH Clinical Center</td>
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<td>9:20 AM</td>
<td>Replicating Virus Testing in Integrating Vectors: So Far So Good</td>
<td>Kenneth Cornetta, Indiana University</td>
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<td>9:40 AM</td>
<td>Genome Editing in the Clinic for Cancer Indications: Status of the Field and General Considerations for IND-enabling Safety and Efficacy Studies</td>
<td>Fyodor Urnov, Altius Institute for Biomedical Sciences</td>
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**10:00 AM COFFEE BREAK**

**10:15 AM** Challenges of Expanding Tumor Infiltrating Lymphocytes (TIL) from Solid Tumors  
Chantale Bernatchez, MD Anderson Cancer Center

**10:35 AM** Challenges in CAR-T Cell Manufacturing  
Isabelle Riviere, Memorial Sloan Kettering Cancer Center

**10:55 AM** Cellular Product Release and Potency Testing  
Lisa Butterfield, Parker Institute and University of California San Francisco

**11:15 AM** CAR-T Cell Therapy: Going Beyond the Test Drive  
Nirali Shah, National Cancer Institute

**11:35 AM** PANEL DISCUSSION, CHANTELE BERNATCHEZ

**12:05 PM LUNCH BREAK**

### SESSION 4 - FDA AND INDUSTRY PERSPECTIVE

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<tr>
<td>1:00 PM</td>
<td>Cell-based Immunotherapy for Solid Tumors: US FDA Regulatory Perspectives</td>
<td>Ke Liu, Food and Drug Administration</td>
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<tr>
<td>1:20 PM</td>
<td>Regulatory Considerations for Cell and Gene Therapy Manufacturing</td>
<td>Thomas Finn, Food and Drug Administration</td>
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<td>1:40 PM</td>
<td>Cell-based Immunotherapy for Solid Tumors: The Role of Small Business</td>
<td>Jake Reder, Celdara Medical and Giesel School of Medicine at Dartmouth</td>
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<td>2:00 PM</td>
<td>Partnering with the NCI: Intellectual Property Issues</td>
<td>Jason Cristofaro, National Cancer Institute</td>
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<td>2:20 PM</td>
<td>PANEL DISCUSSION</td>
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