

# FDA/OCE Public Meeting on Relevant Molecular Targets in Pediatric Cancers: Applicability to Therapeutic Investigation FDARA 2017

FDA White Oak Campus Building 31  
White Oak Great Room A  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
April 20, 2018

## AGENDA

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8:00 am	Introduction and Background	<b>Gregory Reaman, MD</b> Associate Director (Acting) for Pediatric Oncology Oncology Center of Excellence, OC Associate Director, Oncology Sciences Office of Hematology and Oncology Products, CDER, OND U.S. Food and Drug Administration (FDA)
8:15 am	Targeted Therapeutics and the Potential for Precision Medicine in Pediatric Oncology	<b>Donald W. Parsons, MD, PhD</b> Co-Director, Brain Tumor Program Co-Director, Cancer Genetics and Genomics Program Director, Pediatric Center for Personal Cancer Genomics and Therapeutics Texas Children's Hospital
8:45 am	Classification of Molecular Targets and Additional Considerations Related to Relevance to Pediatric Cancers	<b>Malcolm A. Smith, MD, PhD</b> Associate Branch Chief for Pediatrics Clinical Investigations Branch, CTEP, DCTD, NCI
9:00 am	<b>Panel Discussion and Public Comments on Gene Abnormality Targets</b>	
<b>Moderators</b>	<b>Scott A. Armstrong, MD, PhD, Dana-Farber Cancer/Boston Children's</b> <b>Katherine A. Janeway, MD, Dana-Farber Cancer/Boston Children's</b> Rajen Mody, MBBS, Mott Children's Hospital Giles W. Robinson, MD, St. Jude Children's Research Hospital Hubert Caron, MD, PhD, Roche Ralf Herold, MD, PhD, Bayer Mark Kieran, MD, PhD, Dana-Farber/Boston Children's Javed Khan, M.D., National Cancer Institute Danielle Leach- Patient Advocate Leslie Doros, MD, FDA Christy Osgood, MD, FDA	
10:30	<b>Break</b>	

10:45 am **Panel Discussion and Public Comments on Cell Lineage Targets**

**Moderators** **E. Anders Kolb, MD, Dupont Hospital for Children**  
**Brenda Weigel, MD, MSc, University of Minnesota**  
Malcolm A. Smith, MD, PhD, National Cancer Institute  
Darshan Wariabharaj, Janssen Research & Development, LLC  
Donna Ludwinski- Patient Advocate  
Shannon Maude, MD, PhD, Children's Hospital of Philadelphia  
Nicholas Richardson, DO, MPH, FDA  
Lori Ehrlich, MD, PhD, FDA  
Maura O'Leary, MD, FDA  
Najat Bouchkouj, MD, FDA

12:15 pm ***Lunch***

1:15 pm **Panel Discussion and Public Comments on Non-cancer cell Targets**

**Moderators** **Timothy Cripe MD, PhD, Nationwide Children's Hospital**  
**Mark Kieran, MD, PhD, Dana-Farber/Boston Children's**  
Elad Sharon, MD, National Cancer Institute  
David Munn, MD, Medical College of Georgia  
Karen Weiss, MD, Janssen Research & Development, LLC  
Eric Rubin, MD, Merck  
Nancy Goodman- Patient Advocate  
Amy Barone, MD, FDA  
Ashley Ward, MD, FDA

2:00 pm **Panel Discussion and Public Comments on Other Targets and Non-Relevant Targets**

**Moderators** **Brenda Weigel, MD, MSc, University of Minnesota**  
**Elizabeth Fox, MD, Children's Hospital of Philadelphia**  
Gilles Vassal, MD, Institut Gustave Roussy  
Alice Chen, MD, National Cancer Institute  
Nita L. Seibel, MD, National Cancer Institute  
Ralf Herold, MD, Bayer  
Hubert Caron, MD, PhD, Roche  
Lucy Vereshchagina, PhD, PhRMA  
Susan Weiner- Patient Advocate  
Martha Donoghue, MD, FDA  
Diana Bradford, MD, FDA

3:15 pm **Summary** **Greg Reaman, MD**

3:30 pm ***Adjourn***