## Workshop on Product Development for CNS Metastases

Co-Sponsored by the FDA and National Brain Tumor Society  
In Collaboration With  
Accelerate Brain Cancer Cure, American Brain Tumor Association,  
Friends of Cancer Research, Kidney Cancer Research Alliance,  
LUNGevity Foundation, Melanoma Research Alliance  
Metastatic Breast Cancer Alliance,  
Response Assessment in NeuroOncology, and  
Society for NeuroOncology

**March 22, 2019**  
8:00am to 4:00pm  
FDA White Oak Campus Building 31, Great Room  
NBTS Meeting contact – Sarah O’Connor, Tel: 617.393.2851

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### Schedule

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<td>8:00 - 8:30AM</td>
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| 8:30 - 8:35AM | **Opening Remarks:**  
David Arons, National Brain Tumor Society  
Richard Pazdur, US Food and Drug Administration  
Wendy Selig, WSCollaborative |
| 8:35 - 8:45AM | **Presenting the Challenge**  
Joohee Sul, Workshop Co-Chair, US Food and Drug Administration  
Patrick Wen, Workshop Co-Chair, Dana Farber Cancer Institute |
| 8:45 - 9:45AM | **Session I: Defining the Problem of CNS Metastases**  
Laleh Amiri-Kordestani, Co-Chair, US Food and Drug Administration  
Greg Riely, Co-Chair, Memorial Sloan Kettering Cancer Center |

**Discussant Presentation:**
  Mike Davies, MD Anderson Cancer Center

**Panel:** Laleh Amiri-Kordestani & Greg Riely, Moderators  
Manmeet Ahluwalia, Cleveland Clinic  
Mike Davies, MD Anderson Cancer Center  
Victoria Ebiana, Merck  
Derrick Queen, Patient  
Luke Walker, Seattle Genetics
9:45 - 11:00AM  **Session II: Key Issues for Clinical Development for Brain Mets**
*Nancy Lin, Co-Chair, Dana Farber Cancer Institute*
*Chana Weinstock, Co-Chair, US Food and Drug Administration*

**Discussant Presentations:**
- **Identifying Targets for Brain Mets Clinical Studies**  
  Priscilla Brastianos, Massachusetts General Hospital
- **Selecting Drug Candidates for Brain Mets**  
  Nancy Lin, Dana Farber Cancer Institute
- **Issues with Conducting Brain Mets Clinical Trials**  
  Kim Margolin, City of Hope
- **Standardizing Brain Mets Response Assessment**  
  Ben Ellingson, University of California, Los Angeles

Q&A

**Session Recap:** Chana Weinstock, US Food and Drug Administration

11:00 - 11:15AM  **Break**

11:15 - 2:30PM  **Session III: Clinical Benefit in Patients with Brain Mets**
*Carey Anders, Co-Chair, Duke University*
*Tatiana Prowell, Co-Chair, US Food and Drug Administration*

11:15-12:30PM  **Discussant Presentations:**
- **Regulatory Definition of “Clinical Benefit”**  
  Paul Kluetz, US Food and Drug Administration

Designing an Endpoints Framework for CNS Metastases
Panel: Carey Anders, Moderator  
Terri Armstrong, National Cancer Institute  
Shelly Engfer-Triebenbach, Patient  
Chitkala Kalidas, Bayer Pharmaceuticals  
Ben Levy, Sibley Memorial Hospital  
Jeff Wefel, MD Anderson Cancer Center  
Arvin Yang, Bristol-Myers Squibb

Q&A

**Panel Recap:** Carey Anders, Duke University

12:30 - 1:00PM  **Lunch**
1:00 - 2:30PM  **Discussant Presentations:**
- **Regulatory Challenges for CNS Metastases**
  Shanthi Marur, US Food and Drug Administration

**Rethinking Trial Designs for Stimulating Product Development for CNS Metastases**
Panel: Tatiana Prowell, Moderator
  - Michael Atkins, Georgetown University
  - Kim Blackwell, Eli Lilly and Company
  - Vinai Gondi, Northwestern Medicine
  - Pallavi Mishra-Kalyani, US Food and Drug Administration
  - Hussein Tawbi, MD Anderson Cancer Center
  - Lynda Weatherby, Patient

**Q&A**

**Panel Recap:** Tatiana Prowell, US Food and Drug Administration

2:30 - 3:30PM  **Session IV: Therapy Development: Challenges & Opportunities**
*Joohee Sul, Co-Chair, US Food and Drug Administration*  
*Patrick Wen, Co-Chair, Dana Farber Cancer Institute*

**Defining Strategies to Advance Product Development**
Panel: Joohee Sul & Patrick Wen, Moderators
  - Lauren Abrey, Novartis
  - Caroline Chung, MD Anderson Cancer Center
  - Nancy Lin, Dana Farber Cancer Institute
  - Kim Margolin, City of Hope
  - Tatiana Prowell, US Food and Drug Administration
  - Greg Riely, Memorial Sloan Kettering Cancer Center
  - Peggy Zuckerman, Patient

**Q&A**

3:30 - 3:40PM  **Overview of the American Brain Tumor Association’s Metastatic Brain Tumor Initiative**
  Ralph DeVitto, American Brain Tumor Association
  Nicole Willmarth, American Brain Tumor Association

3:40 - 4:00PM  **Summary & Next Steps**
  David Arons, National Brain Tumor Society
  Joohee Sul, US Food and Drug Administration
  Patrick Wen, Dana Farber Cancer Institute

4:00PM  **Adjourn**